IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

FEDERAL TRADE COMMISSION,	)	
Petitioner,	)	**Misc. No. _____**
v.	)	
LEXIUM INTERNATIONAL LLC, and	)	
CELLMARK BIOPHARMA, LLC,	)	
Respondents.	)	

PETITION OF THE FEDERAL TRADE COMMISSION FOR AN ORDER ENFORCING ADMINISTRATIVE INVESTIGATIVE PROCESS AND MEMORANDUM OF LAW

The Federal Trade Commission (FTC) petitions this Court under Section 20 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. § 57b-1, for an order requiring Respondents, Lexium International LLC (Lexium) and CellMark BioPharma, LLC (CellMark), to comply with Civil Investigative Demands (CIDs), a form of administrative compulsory process. The CIDs were issued in the course of a nonpublic investigation to determine whether Lexium and CellMark, related companies that sell health products, engaged in deceptive advertising or other unfair or deceptive acts or practices in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45, 52. The CIDs seek documents and information regarding, *inter alia*, the companies' products, advertising and marketing practices, substantiation for advertising claims, billing issues, and consumer complaints.

Lexium and CellMark filed administrative petitions to limit or quash the respective CIDs, *see* 16 C.F.R. § 2.10(a), asserting that compliance would violate their Fifth Amendment privilege against compelled self-incrimination and the Fifth Amendment privilege of their common principal, Derek Vest. The Commission denied the petitions, explaining that corporate entities may not invoke the Fifth Amendment privilege or withhold their records by relying on the Fifth Amendment rights of an individual officer or employee. Nonetheless, Lexium has refused to respond to 39 interrogatories and 29 document requests and has provided only incomplete responses to several other requests. It has not specified which requests it is refusing to answer on Fifth Amendment grounds, and, by its own admission, has failed to produce responsive information not subject to its Fifth Amendment objection. CellMark, too, continues to withhold documents and information, citing the Fifth Amendment.

This is a summary proceeding that is properly instituted by a petition and order to show cause (rather than a complaint and summons). *See, e.g.*, *United States v. Elmes*, 532 F.3d 1138, 1141-45 (11th Cir. 2008); *United States v. Markwood*, 48 F.3d 969, 981-82 (6th Cir. 1995); *Appeal of FTC Line of Bus. Report Litig.*, 595 F.2d 685, 704-05 (D.C. Cir. 1978). Discovery or evidentiary hearings are granted only in exceptional circumstances in such cases. *See, e.g.*, *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980); *FTC v. MacArthur*, 532 F.2d 1135, 1141-42 (7th Cir. 1976); *Genuine Parts Co. v. FTC*, 445 F.2d 1382, 1388 (5th Cir. 1971).

A declaration under penalty of perjury by FTC attorney Carolyn L. Hann, which verifies the allegations of this Petition, is attached hereto as Petition Exhibit ("Pet. Exh.") 1. The remaining exhibits are described in the accompanying Index of Petitioner's Exhibits.

The Parties

1. The FTC is an administrative agency of the United States, organized and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq*. It is empowered by Section 5(a) of the Act, 15 U.S.C. § 45(a), to prohibit, *inter alia*, "unfair or deceptive acts or practices in or affecting commerce," and by Section 12 of the Act, 15 U.S.C. § 52, to prohibit "false advertisement[s] . . . likely to induce . . . the purchase of food, drugs, services, or cosmetics."

2. Respondent Lexium is a privately held Florida limited liability company with its principal place of business at 1591 Hayley Lane, Ste. 203, Fort Myers, FL 33907. Lexium markets and sells "prescription strength" health products including ADDTabz, which it claims treats, cures, or mitigates symptoms associated with Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder; PhenTabz, which it claims causes significant weight loss comparable to prescription drugs; and REMTabz, which it claims treats, cures, or mitigates sleep disorders and anxiety. Pet. Exh. 1 ¶ 3; Pet. Exh. 2 (April 2016 excerpts from Lexium's website). Lexium markets and sells its products over the internet and also purports to sell them through gyms, doctors' offices, and weight loss clinics. Pet. Exh. 1 ¶ 3.

3. Respondent CellMark is a privately held Delaware limited liability company. It also has its principal place of business at 1591 Hayley Lane, Ste. 201, Fort Myers, FL 33907. CellMark positions itself as a medical nutrition company for cancer patients. It

markets and sells two health products: Cognify, which it claims treats, cures, mitigates, or prevents cognitive decline caused by chemotherapy; and CellAssure, which it claims meets the nutritional needs of cancer patients undergoing therapy. Pet. Exh. 1 ¶ 4; Pet. Exh. 3 (April 2016 excerpts from CellMark's website).

4. Lexium and CellMark are among a network of companies owned by Derek Vest or his family members. Mr. Vest co-founded Lexium with his mother, Mary Lirette, and previously served as its sole member and president. Pet. Exh. 1 ¶ 5; Pet. Exhs. 4 (Articles of Organization) & 5 (January 2015 Annual Report). As of April 2015, Ms. Lirette and Mr. Vest's sister, Tara Vest, have served as Lexium's sole authorized members. Pet. Exh. 1 ¶ 5; Pet. Exh. 6 (April 2015 Amended Annual Report). The company currently identifies Mr. Vest as a "consultant." Pet. Exh. 7 at 2 (Lexium Petition to Quash).[1] Mr. Vest is also the founder, Board Chairman, and sole owner of CellMark (Pet. Exhs. 8-9), but is not presently serving as its Chief Executive Officer (Pet. Exh. 10).

Jurisdiction and Venue

5. Section 3 of the FTC Act, 15 U.S.C. § 43, authorizes the Commission to prosecute any inquiry necessary to its duties in any part of the United States. Section 6 of the Act, 15 U.S.C. § 46, empowers the Commission to gather and compile information concerning, and to investigate from time to time, the business and practices of persons, partnerships, or corporations engaged in or whose business affects commerce, with certain exceptions not relevant here. Section 20 of the Act, 15 U.S.C. § 57b-1, empowers the Commission to issue CIDs to require any person, *inter alia*, to produce documentary

[1] Page references for each exhibit are to the CM/ECF headers at the top of the page.

material, to file written reports or answers, and to give oral testimony relating to any Commission law enforcement investigation.

6. Section 20 also vests this Court with jurisdiction over Lexium and CellMark and authorizes it to enforce the CIDs. Section 20(e) states as follows:

> Whenever any person fails to comply with any civil investigative demand duly served upon him under this section, or whenever satisfactory copying or reproduction of material requested pursuant to the demand cannot be accomplished and such person refuses to surrender such material, the Commission, through such officers or attorneys as it may designate, may file, in the district court of the United States for any judicial district in which such person resides, is found, or transacts business, and serve upon such person, a petition for an order of such court for the enforcement of this section.

15 U.S.C. § 57b-1(e). Section 20(h) authorizes the Court "to hear and determine the matter so presented, and to enter such order or orders as may be required to carry into effect the provisions of this section." 15 U.S.C. § 57b-1(h). This Court also has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

7. Lexium and CellMark reside in and engage in commerce in this district, as the term "commerce" is defined under Section 4 of the FTC Act. 15 U.S.C. § 44. Because the Middle District of Florida is a jurisdiction within which Lexium and CellMark "reside[], [are] found, or transact[] business," venue is proper under Section 20 of the FTC Act. 15 U.S.C. § 57b-1(e).

Authority for and Issuance of the CIDs

8. Commission staff opened this investigation after reviewing advertisements for the Lexium and CellMark products described in ¶¶ 2-3, above. Pet. Exh. 1 ¶ 6. The purpose of the inquiry is to determine whether Lexium and CellMark have engaged in deceptive

advertising or other unfair or deceptive acts or practices in violation of Sections 5 or 12 of the FTC Act, 15 U.S.C. §§ 45, 52. Pet. Exh. 1 ¶ 6.

9. On May 24, 2016, the Commission issued CIDs to Lexium and CellMark under the authority of FTC Resolution No. 002-3191, which authorizes the use of any and all compulsory process

> to investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52.

Pet. Exh. 1 ¶¶ 7-8; Pet. Exh. 11 (Resolution); Pet. Exh. 12-13 (CIDs).

10. The CIDs seek information from Lexium and CellMark about, *inter alia*, (a) their products, including the manufacturing process and product samples; (b) advertising and promotional practices; (c) substantiation for the company's advertising claims; (d) sales and marketing practices and expenditures; (e) billing, customer service, and consumer complaints; (f) lawsuits and communications with government agencies and other organizations; and (g) personnel, corporate relationships, and recordkeeping. Pet. Exh. 1 ¶ 8.

11. The Lexium CID required the company to respond to 42 interrogatories and 36 document requests on or before June 14, 2016. Pet. Exh. 1 ¶ 8; Pet. Exh. 12. The CellMark CID required the company to respond to 43 interrogatories and 34 document requests by the same date. Pet. Exh. 1 ¶ 8; Pet. Exh. 13.

12. The CIDs informed Lexium and Cellmark that they must raise any "factual or legal objections" to the respective CIDs by filing a petition to limit or quash the CIDs with the Commission within 20 days after service. Pet. Exhs. 12 at 9; Pet. Exh. 13 at 9; *see* 16 C.F.R. § 2.10(a). The CIDs further advised that the Commission would only consider objections first raised with Commission staff at a mandatory meet-and-confer session. Pet. Exh. 12 at 9; Pet. Exh. 13 at 9; *see* 16 C.F.R. 2.7(k).

FTC Staff Meet-and-Confer Sessions with Lexium and CellMark

13. FTC staff and CellMark representatives participated in a meet-and-confer session on June 6, 2016. Pet. Exh. 1 ¶ 9. CellMark disclosed that its principal, Mr. Vest, is under federal grand jury investigation by the U.S. Attorney's Office for the Middle District of Florida regarding "introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws." *Id.*; *see* Pet. Exh. 14 (target letter).[2] CellMark advised FTC staff that it planned to file a petition to limit or quash the CID because it sought information protected by Mr. Vest's privilege against self-incrimination. Pet. Exh. 1 ¶ 9.

14. On June 8, 2016, CellMark's outside counsel sent FTC staff an email confirming that "[s]ubject to the petition to quash or limit [the CID] on the Fifth Amendment privilege issue," CellMark agreed to comply with a rolling production schedule proposed by Commission staff at the earlier meet-and-confer session. Pet. Exh. 15; Pet. Exh. 1 ¶ 10.

[2] Lexium and CellMark filed the grand jury target letter as an exhibit to their respective petitions to limit or quash the CIDs—which are part of the public record (*see* 16 C.F.R. 2.10(d))—and did not seek confidential treatment for the letter. *See* Pet. Exhs. 7 & 17.

Under that production schedule, CellMark agreed to produce responsive records in four two-week rounds between June 14 and July 26, 2016. Pet. Exh. 15; Pet. Exh. 1 ¶ 9.

15. Also on June 8, 2016, FTC staff participated in a meet-and-confer session with Lexium representatives. Pet. Exh. 1 ¶ 11. Staff proposed a rolling production schedule allowing Lexium to respond to the CID in four three-week rounds between June 14 and August 16, 2016. *Id.* Lexium's counsel cited the criminal target letter to Mr. Vest and explained that Lexium would seek to limit the scope of the Lexium CID to avoid impinging on Mr. Vest's Fifth Amendment privilege against self-incrimination. *Id.* Nonetheless, on June 13, 2016, Lexium's counsel sent FTC staff an email stating that "Lexium believes it can meet the discovery schedule discussed on June 8." Pet. Exh. 16.

16. On June 14, 2016, Mary K. Engle, Associate Director of the FTC's Division of Advertising Practices, issued letters to counsel for Lexium and CellMark memorializing the rolling production schedules described above. Pet. Exhs. 18-19. Both letters stated that the companies' filing of petitions to limit or quash "does not alter [their] obligation to produce documents and information [in response] to specifications unaffected by the petition. *See* 16 C.F.R. § 2.10(b)." *Id.*

Petitions To Limit or Quash the CIDs

17. Lexium and CellMark timely filed nearly identical petitions to limit or quash the respective CIDs on June 13, 2016. Pet. Exhs. 7 (Lexium) & 17 (CellMark). The companies asserted that they should not be required to produce materials in Mr. Vest's possession because doing so would "admit their existence and authenticity" and thereby impinge on his Fifth Amendment privilege against compelled self-incrimination. Pet. Exh. 7

at 4; Pet. Exh. 17 at 4. CellMark and Lexium further asserted that, as limited liability companies, they, too, possess a privilege against self-incrimination, which should excuse them from fully complying with the CIDs. Pet. Exh. 7 at 7-8; Pet. Exh. 17 at 6-7. Beyond these blanket objections, neither CellMark nor Lexium specified which document requests or interrogatories they were refusing to answer on Fifth Amendment grounds. The petitions did not raise any other factual or legal objections to the CIDs.

18. While the petitions were pending, CellMark produced responses to the CID consistent with the previously agreed rolling production schedule, but cited the Fifth Amendment when refusing to answer Interrogatory 21, which sought all domain names for which Mr. Vest is the registrant. Pet. Exh. 1 ¶ 15; Pet. Exh. 13 at 18. Although Lexium made small document productions while the petitions were pending, as of July 24, 2016, its responses to 39 of 42 interrogatories and at least 31 of 36 document requests were outstanding. Pet. Exh. 1 ¶ 16.

19. On July 25, 2016, the Commission denied the petitions to limit or quash the CIDs. Pet. Exh. 20. Surveying over a century of case law, the Commission concluded that the Fifth Amendment privilege is a "uniquely individual right" that cannot be asserted by business entities like CellMark or Lexium. *Id.* at 5. Nor could the companies invoke Mr. Vest's personal Fifth Amendment rights, the Commission ruled, since the CIDs sought "only corporate documents" and Mr. Vest, as a CellMark officer and Lexium consultant, was holding those documents "in a representative capacity as a corporate agent." *Id.* at 4. The Commission further concluded that CellMark and Lexium must answer each interrogatory by designating an officer or agent other than Mr. Vest to respond "on behalf of the corporations

without impinging on Mr. Vest's personal Fifth Amendment rights." *Id.* at 4-5 (citing *United States v. Kordel*, 397 U.S. 1, 8 (1970)).

20. The Commission's order directed Lexium and CellMark to produce "all documents and information" responsive to the respective CIDs by August 15, 2016. Pet. Exh. 20 at 5. The companies have failed to comply with the Commission's order.

Lexium's Failure To Comply with the CID

21. On August 3, 2016, Lexium's counsel sent a letter to Commission staff stating that Mr. Vest would not provide documents in his possession to Lexium for production to the FTC. Pet. Exh. 1 ¶ 18. Lexium's counsel also objected to the Commission's conclusion that the company may not invoke the Fifth Amendment privilege. *Id.* Finally, he advised that Lexium was gathering documents in its possession that were not subject to its objection to further respond to the CID by August 15, 2016. *Id.*

22. On August 15, 2016, Lexium produced 47 additional pages of documents to the FTC, but did not respond to any of the 39 interrogatories that remained outstanding. Pet. Exh. 1 ¶ 20; *see supra* ¶ 18. When Commission staff asked whether Lexium intended to produce additional material, Lexium's counsel replied, "Lexium will have more to produce but I'm not going to get more today. It is also working on the written discovery [interrogatory responses]. I will update you." Pet. Exh. 22. In response, FTC staff granted Lexium an extension of the compliance deadline to August 18, 2016. *Id.*

23. Lexium has not produced any documents or interrogatory responses since August 15, 2016. Pet. Exh. 1 ¶ 21.

24. To date, Lexium's response to the CID remains deficient. Lexium has completely withheld any responses to Document Requests 2, 4-8, 11-21, 23-25, 27, and 29-36 and Interrogatories 4 through 42. Pet. Exh. 1 ¶ 22. In addition, Lexium's responses to Document Requests 9-10, 22, 26, and 28 are incomplete. Specifically, Lexium has failed to produce the following categories of information.

25. Product Information: Lexium has refused to identify all of its products or provide even basic information about their manufacture, marketing, ingredients, or sales (Interrogatory 5). For the three Lexium products described in ¶ 2, *supra* (the "Tabz products"), the company has failed to produce the required product samples (Document Request 2) and information about the manufacturing process, including product components, product specifications, product testing and analysis, and the persons involved (Interrogatories 6-13 and Document Requests 12-20). *See* Pet. Exh. 1 ¶ 22(a).

26. Advertising and Promotion: Lexium has withheld information regarding its advertising plans (Document Request 4), marketing and consumer research (Document Request 8), schedules for disseminating ads (Interrogatory 15), communications with ad agencies, news media, and educational institutions regarding ads (Document Requests 5-7), websites and keyword placement (Interrogatories 16-17 and 20), ad approval policies (Interrogatory 29), and the identity of persons and entities responsible for creating, reviewing, and approving ads (Interrogatory 24). Lexium has also refused to provide information about its use of consumer testimonials and expert endorsers (Interrogatory 18 and Document Request 21), its policies regarding consumer reviews (Interrogatory 19), or its use of bloggers and affiliate marketers (Interrogatories 22-23). *See* Pet. Exh. 1 ¶ 22(b).

27. Advertising Claims Substantiation: Lexium appears not to have produced all relevant substantiation for its advertising claims. It has not produced studies, or documents related to such studies, substantiating all of the advertising claims enumerated in the CID (Document Requests 9-10), or examining the effectiveness of the Tabz products (Document Request 11). Nor has Lexium identified the ingredients and amounts of each ingredient used in any such studies (Interrogatory 27). The company produced only five journal articles, one of which is a duplicate; none of these articles involves testing of any of the three Tabz products, and only two relate to an ingredient that appears to be in ADDTabz and PhenTabz (*see supra* ¶ 2). In addition, Lexium has not identified persons or entities who participated in testing Tabz products (Interrogatories 25-26) or in evaluating substantiation for those products (Interrogatory 28). Finally, Lexium has failed to identify the experts it used to substantiate advertising claims (Interrogatories 30-31). *See* Pet. Exh. 1 ¶ 22(c).

28. Sales and Marketing Practices and Expenditures: Lexium has not produced any information regarding its sales and marketing practices or expenditures. It has failed to identify its retailers, distributors, or other sellers (Interrogatory 21), produce telemarketing transcripts or call recordings (Document Request 27), or provide information about its consumer accounts (Interrogatory 38). Nor has Lexium has produced information regarding its use of "continuity plans" through which consumers are automatically billed for new product installments (Interrogatories 33-34 and Document Request 23). Finally, Lexium has failed to provide data regarding sales, expenditures (including for marketing purposes), or order fulfillment (Interrogatory 14). *See* Pet. Exh. 1 ¶ 22(d).

29. Billing, Customer Service, and Consumer Complaints: Lexium has not provided any information about customer service, and its responses to the CID's requests for information about billing or consumer complaints are incomplete. It has failed to identify or provide information about the persons or entities responsible for customer service (Interrogatories 35-36), or to produce its customer service and return policies (Document Requests 24-25). With the exception of five chargeback notifications that Lexium received from a third-party payment processor, it has not produced any documents or information regarding contracts, payments, returns, refunds, chargebacks, or other consumer issues (Document Request 26 and Interrogatory 39), consumer complaints (Document Request 28 and Interrogatory 37), or complaints by consumers or medical professionals concerning consumer injury (Document Request 29). *See* Pet. Exh. 1 ¶ 22(e).

30. Lawsuits and Communications with Government and Other Organizations: Lexium has not produced any information about lawsuits concerning the Tabz products or affirmed that there have been no such lawsuits (Interrogatory 40 and Document Request 34). Nor has it produced any communications with government agencies, Better Business Bureaus, self-regulatory organizations, consumer protection groups, health interest groups, or media outlets (Document Requests 30-33, 35-36). *See* Pet. Exh. 1 ¶ 22(f).

31. Personnel, Corporate Relationships, and Recordkeeping: Lexium has failed to describe its business relationships with various entities and individuals (Interrogatory 4). Nor the company provided information about three of its corporate officials (Interrogatory 32) or produced curriculum vitae for two of them (Document Request 22). Finally, Lexium has refused to identify who prepared its responses to the CID (Interrogatory 41) or state

whether any responsive documents may have been destroyed, altered, or deleted (Interrogatory 42). *See* Pet. Exh. 1 ¶ 22(g).

32. Lexium has not specified which of the categories of information described above it is withholding on Fifth Amendment grounds, and which categories it is withholding on some other unspecified basis. Pet. Exh. 1 ¶ 23. Lexium has also failed to produce a privilege log, as required by the FTC's Rules of Practice, 16 C.F.R. § 2.11(a)(1), and Instruction D of the CID. Pet. Exh. 12 at 8-9. *See* Pet. Exh. 1 ¶ 25.

CellMark's Failure To Comply with the CID

33. On August 3, 2016, CellMark's counsel sent a letter to Commission staff objecting to the Commission's order denying its petition to quash. Pet. Exh. 1 ¶ 19; Pet. Exh. 21. The letter advised that Mr. Vest "will continue to invoke his Fifth Amendment right against self-incrimination and will not provide documents in his possession to CellMark for production to the FTC." *Id.* The letter further stated that "[w]ith the exception of Mr. Vest's documents as to which there is a privilege objection, CellMark believes it has produced all responsive documents to the FTC in compliance with the CID." *Id.*

34. In fact, CellMark has not complied with Interrogatory 21, which directs the company to "identify any and all domain names for which Derek Vest is the registrant." Pet. Exh. 1 ¶¶ 15, 24; Pet. Exh. 13 at 18. Although CellMark also has indicated that it is withholding responsive documents under the Fifth Amendment (*see supra* ¶ 33), it has not identified the document requests to which its objection pertains. Pet. Exh. 1 ¶ 24. CellMark has also failed to produce a privilege log, as required by the FTC's Rules of Practice, 16 C.F.R. § 2.11(a)(1), and Instruction D of the CID. Pet. Exh. 13 at 8-9. *See* Pet. Exh. 1 ¶ 25.

35. CellMark's and Lexium's failure to comply with the respective CIDs greatly impedes the Commission's ongoing investigation, and hinders its ability to complete its investigation in a timely manner. Pet. Exh. 1 ¶ 26.

Memorandum of Law

The court's role in a proceeding to enforce an administrative subpoena or CID is "sharply limited." *United States v. Fla. Azalea Specialists*, 19 F.3d 620, 623 (11th Cir. 1994) (quoting *EEOC v. Kloster Cruise Ltd.*, 939 F.2d 920, 922 (11th Cir. 1991)). While "the court's function is neither minor nor ministerial, the scope of issues which may be litigated in [a compulsory process] enforcement proceeding must be narrow, because of the important governmental interest in the expeditious investigation of possible unlawful activity." *FTC v. Texaco, Inc.*, 555 F.2d 862, 872 (D.C. Cir. 1977) (*en banc*) (internal citation omitted). Thus, a district court must enforce agency process so long as (1) the inquiry is within the authority of the agency; (2) the demand is not too indefinite; and (3) the information sought is reasonably relevant. *EEOC v. Tire Kingdom, Inc.*, 80 F.3d 449, 450 (11th Cir. 1996) (per curiam) (citing *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950)); *Fla. Azalea Specialists*, 19 F.3d at 623; *see also United States v. Lockheed Martin Corp.*, 995 F. Supp. 1460, 1462 (M.D. Fla. 1998).

The Commission has satisfied the requirements for judicial enforcement of the CIDs, as shown by the accompanying declaration of Carolyn L. Hann, the FTC's lead attorney in this investigation. *See* Pet. Exh. 1. The CIDs were duly issued in an investigation the Commission is authorized to conduct, and they seek documents and information reasonably relevant to the investigation. The law is clear that business entities such as Lexium and

CellMark lack a Fifth Amendment privilege against self-incrimination and may not withhold corporate records by invoking an individual officer's Fifth Amendment rights. The Commission, accordingly, respectfully asks this Court to direct Lexium and CellMark to appear and show cause why they should not fully comply, and thereafter enter its own order enforcing the CIDs. *See, e.g.*, *Fla. Azalea Specialists*, 19 F.3d at 623-24.

I. The Commission Is Authorized To Conduct the Investigation and Its CIDs Comply with the Applicable Legal Requirements.

The FTC is authorized to issue CIDs in its investigations (*see supra* ¶ 5), and to conduct the investigation at issue. The CIDs request records and information in connection with the companies' advertising and marketing of their respective products and any related customer service issues, consumer complaints, or lawsuits. *See supra* ¶ 10. Deceptive advertising and marketing of health products may violate Section 5 of the FTC Act, 15 U.S.C. § 45(a), which prohibits "unfair or deceptive acts or practices," and Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits the dissemination of any "false advertisement . . . which is likely to induce, directly or indirectly the purchase of food, drugs, devices, services, or cosmetics."

The Commission's May 24, 2016 CIDs fully comport with the applicable procedural requirements of the authorizing statute and its implementing FTC Rules of Practice. *See* Pet. Exhs. 12-13; 15 U.S.C. § 57b-1; 16 C.F.R. § 2.7.

First, the CIDs satisfy the FTC Act's requirements of "definiteness and certainty" because they describe with specificity the kinds of documents and information to be produced. 15 U.S.C. § 57b-1(c)(3)(A), (c)(5)(A); *see also* Pet. Exhs. 12 (Lexium CID) & 13 (CellMark CID). The CIDs also gave Lexium and CellMark a "reasonable period of time"

to assemble the specified documents and prepare their responses to interrogatories, *see* 15 U.S.C. § 57b-1(c)(3)(B), (c)(5)(B), by setting a return date of three weeks after issuance, which Commission staff then extended to allow the companies to make rolling productions over a period of several additional weeks. *See supra* ¶¶ 11, 14-16. The CIDs also "identif[ied] the custodian[s]" (Connor Sands and Lynne Colbert) to whom the documents were to be produced, as required by Section 20(c) of the FTC Act, 15 U.S.C. § 57b-1(c)(3)(C), (c)(5)(C). Moreover, the CIDs were validly "signed by a Commissioner," in this case, Commissioner Terrell McSweeny, "acting pursuant to a Commission resolution." 15 U.S.C. § 57b-1(i).

The CIDs also included a copy of the Commission's compulsory process resolution (*see supra* ¶ 9), which gave Lexium and CellMark adequate notice of "the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation." 15 U.S.C. § 57b-1(c)(2); 16 C.F.R. § 2.6; Pet. Exh. 12 & 13; *see FTC v. O'Connell Assocs., Inc.*, 828 F. Supp. 165, 170-71 (E.D.N.Y. 1993) (notice requirement met by "cit[ing] to a resolution giving the FTC authority to use compulsory process").

II. The Evidence Sought Is Relevant and Material To the Investigation.

The standard for judging relevancy in an investigation is a broad one. The Commission is not limited to seeking information that is necessary to prove specific charges. Rather, the purpose of an investigation is to learn whether there is reason to believe that the law has been, or is being, violated and, if so, whether the issuance of a complaint by the Commission would be in the public interest. *See Texaco*, 555 F.2d at 872; *see also Fla.*

Azalea Specialists, 19 F.3d at 622-23 (an agency "can investigate merely on suspicion that the law is being violated, or even just because it wants assurance that it is not") (quoting *Morton Salt*, 338 U.S. at 642-43). The required documents and information, therefore, need only be relevant to the investigation—the boundary of which may be defined by the agency quite generally. *See Carter*, 636 F.2d at 787-88; *Texaco*, 555 F.2d at 874 & n.26; *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992).

The CIDs seek information at the heart of the current investigation. They require Lexium and CellMark to produce documents and respond to interrogatories concerning the product specifications for their health products, their advertising of those products, any substantiation for those claims, and their marketing and sales practices. Pet. Exh. 1 ¶¶ 8, 22. This information is directly relevant to the subjects identified in the Commission's resolution, namely whether persons or entities engaged in the advertising or marketing of any "product or service intended to provide a health benefit or to affect the structure or function of the body" have committed "unfair or deceptive acts or practices or [ ] the making of false advertisements." Pet. Exh. 11 (Resolution). The CIDs also seek information from Lexium and CellMark about billing, customer service, lawsuits, and communications with government agencies and consumer protection groups, all of which will help Commission staff determine whether the companies have engaged in unfair or deceptive practices. Pet. Exh. 1 ¶¶ 8, 22. Finally, Interrogatory 14 of each CID seeks sales revenue and expenditure data, which will allow Commission staff to ascertain whether monetary relief is feasible or appropriate. The resolution plainly authorizes that inquiry by directing FTC staff to "determine whether Commission action to obtain redress of injury to consumers or others

would be in the public interest." Pet. Exh. 11. Thus, the CIDs seek only information that is "reasonably relevant" to the investigation. *Fla. Azalea Specialists*, 19 F.3d at 624.

III. The Companies' Blanket Fifth Amendment Objections Are Meritless.

Lexium and CellMark have refused to comply with the CIDs on a blanket assertion of the Fifth Amendment privilege against compulsory self-incrimination. *Supra* ¶ 17. On that basis, Lexium has withheld *any* response to dozens of interrogatories and document requests (*see supra* ¶¶ 17, 21-22, 24, 32) and CellMark has refused to answer Interrogatory 21 or produce certain documents that it has failed to identify or describe (*see supra* ¶ 34).[3] As the Commission carefully explained in its order denying the petitions to quash (Pet. Exh. 20), this objection is at odds with over a century of Supreme Court precedent.

The Supreme Court's "plain mandate" is that "a corporate custodian . . . may not resist a subpoena for corporate records on Fifth Amendment grounds." *Braswell v. United States*, 487 U.S. 99, 108-09 (1988); *see also In re Grand Jury Subpoena Dated April 9, 1996*, 87 F.3d 1198, 1200 (11th Cir. 1996). Instead, the "privilege . . . should be 'limited to its historic function of protecting only the natural individual from compulsory incrimination through his own testimony or personal records.'" *Bellis v. United States*, 417 U.S. 85, 89-90 (1974) (quoting *United States v. White*, 322 U.S. 694, 701 (1944)); *see also Hale v. Henkel*,

[3] Courts have repeatedly rejected such blanket assertions of the Fifth Amendment privilege. *See SEC v. Aquacell Batteries, Inc.*, No. 6:07-cv-608-Orl-22DAB, 2007 WL 2274466, at *2 (M.D. Fla. Aug. 6, 2007) (citing *United States v. Vance*, 730 F.2d 736, 738 (11th Cir. 1984)). Someone who invokes the privilege must "identify what documents are sought and, to the greatest extent possible . . . what documents are withheld" and "make a particularized showing as to the grounds" for asserting the privilege "with respect to each document or request." *Id.* at *2-3. *See also United States v. Allee*, 888 F.2d 208, 212 (1st Cir. 1989) ("A *blanket* objection to the issuance of an IRS summons based on the Fifth Amendment privilege against self-incrimination is not a viable defense. The recipient of a summons properly must . . . claim the privilege on a question-by-question and document-by-document basis.") (citations omitted). The companies failed to do so here.

201 U.S. 43, 74-75 (1906). Thus, Lexium and CellMark may not refuse to produce corporate records on the ground that compliance would incriminate either themselves or Mr. Vest. [4] "If the corporation were guilty of misconduct, [its officer] could not withhold its books to save it; and if he were implicated in its violations of law, he could not withhold the books to protect himself from the effect of their disclosures." *Wilson v. United States*, 221 U.S. 361, 384 (1911). Here, the CIDs seek only corporate records and information. Thus, the companies must comply in full.

Lexium and CellMark nonetheless argued in their petitions to quash that two recent *First* Amendment cases have implicitly overturned the Supreme Court's denial of Fifth Amendment protection to corporations. *See* Pet. Exh. 7 at 7 and Pet. Exh. 17 at 6 (citing *Citizens United v. FEC*, 558 U.S. 310 (2010); *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014)). Because these cases do not even *mention* the Fifth Amendment privilege—let alone repudiate over a century of precedent—they simply have no bearing here. The Supreme Court has not "in any way, signaled its readiness" to overturn its "steadfast" position that corporations may not assert the Fifth Amendment privilege. *In re Grand Jury Empaneled on May 9, 2014*, 786 F.3d 255, 261 & n.1 (3d Cir. 2015). The Court's decisions "remain binding precedent" until it "see[s] fit to reconsider them, regardless of whether subsequent cases have raised doubts about their continuing vitality." *Hohn v. United States*, 524 U.S. 236, 252-53 (1998). District courts may not "bas[e] decisions on predictions that

[4] The CIDs instruct Lexium and CellMark to produce documents and information in their "possession" or under their "actual or constructive custody or control," including documents and information possessed by their "attorneys, accountants, directors, officers, employees, and other agents and consultants." Pet. Exh. 12 at 10 (Instruction I); Pet Exh. 13 at 10 (same). As discussed above (*supra* ¶ 4), Mr. Vest has served as an officer of both companies.

the Supreme Court will overturn one of its own decisions." *United States v. Greer*, 440 F.3d 1267, 1275 (11th Cir. 2006).

Equally meritless is the companies' argument that Mr. Vest can rely on the Fifth Amendment to excuse him from an obligation to produce corporate records. This rationale—that in producing those records Mr. Vest would admit their "existence and authenticity" and thereby incriminate himself (Pet. Exh 7 at 4; Pet. Exh. 17 at 4)—was rejected by the Supreme Court in *Braswell*. The Court held that "the custodian of corporate records may not interpose a Fifth Amendment objection to the compelled production of corporate records, even though the act of production may prove personally incriminating." *Braswell*, 487 U.S. at 111-12. Here, Mr. Vest, as a custodian of corporate records, holds those documents in a "representative rather than a personal capacity." *Id.* at 110. His "assumption of his representative capacity leads to certain obligations, including the duty to produce corporate records on proper demand by the government." *Id.* Thus, Mr. Vest's "act of production is not deemed a personal act, but rather an act of the corporation." *Id.* Any claim of privilege for such act "would be tantamount to a claim of privilege by the corporation—which of course possesses no such privilege."[5] *Id.*; *see also United States v. Medlin*, 986 F.2d 463, 467-68 (11th Cir. 1993) (applying *Braswell* to reject corporate custodian's Fifth Amendment claim that the act of production could incriminate him).

[5] The companies did not cite *Braswell* in their petitions to limit or quash the CIDs. Instead, they relied on an observation in *United States v. Hubbell*, 530 U.S. 27 (2000), that an individual's act of producing documents could have a "compelled testimonial aspect" by communicating that "papers existed, were in [the recipient's] possession or control, and were authentic." *Id.* at 36. But *Hubbell* did not address at all the Fifth Amendment status of corporate records. The courts of appeals have consistently recognized that *Braswell* remains binding precedent. *See Grand Jury Empaneled on May 9, 2014*, 786 F.3d at 263 n.2; *Amato v. United States*, 450 F.3d 46, 51 (1st Cir. 2006); *Armstrong v. Guccione*, 470 F.3d 89, 98 (2d Cir. 2006).

Nor may Lexium withhold Mr. Vest's documents by asserting that, as a former employee, he no longer holds the documents in a representative capacity. *See* Pet. Exh. 7 at 6 (Lexium Petition to Quash). Lexium still identifies Mr. Vest as its consultant. *Id.* at 2. Thus the premise of this contention is erroneous. Regardless, the Eleventh Circuit has held that *Braswell* applies equally to current and former corporate representatives. "It is the immutable character of the records as corporate which requires their production and which dictates that they are held in a representative capacity. Thus, the production of such documents is required regardless of whether the custodian is still associated with the corporation." *In re Grand Jury Subpoena Dated Nov. 12, 1991*, 957 F.2d 807, 812 (11th Cir. 1992).

Finally, Lexium and CellMark lack grounds for objecting to the interrogatories. The companies must appoint an officer or representative other than Mr. Vest to "answer the interrogatories without the possibility of compulsory self-incrimination." *United States v. Kordel*, 397 U.S. 1, 9 (1970). *See also* 8 Charles Alan Wright, Arthur R. Miller, et al., Federal Practice & Procedure § 2018 (3d ed. 2010) (corporations have "burden" to answer interrogatories by "designat[ing] someone to answer on [their] behalf who can furnish as much of the requested information as is available to the corporation[s] without fear of self-incrimination"). "It would indeed be incongruous to permit a corporation to select an individual to verify the corporation's answers, who because he fears self-incrimination may thus secure for the corporation the benefits of a privilege it does not have." *Kordel*, 397 U.S. at 9 (quoting *United States v. 3963 Bottles . . . of . . . "Enerjol Double Strength,"* 265 F.2d 332, 336 (7th Cir. 1959)). Having informed FTC staff that Lexium was "working on"

responding to the interrogatories (Pet. Exh. 22 (8/15/16 email); *see supra* ¶ 22), Lexium's counsel appears to understand the company's obligation to appoint another officer to answer the interrogatories. Nonetheless, it still has not produced those responses to date.

IV. The Companies May Not Raise New Objections for the First Time in this Proceeding.

The FTC Act and FTC Rules of Practice require CID recipients to exhaust their administrative remedies by raising all factual and legal objections in a petition to limit or quash the CID with the Commission. *See* 15 U.S.C. § 57b-1(f); 16 C.F.R. § 2.10(a); *see supra* ¶ 12 (describing the CIDs' instructions on this issue). Because Lexium and CellMark raised only Fifth Amendment objections in their respective petitions to limit or quash the CIDs (*supra* ¶ 17), they are precluded from interposing any other objections here.

Section 20(f) of the FTC Act provides that a CID recipient may file with the Commission a petition to "modify[] or set[] aside the demand" within 20 days, and "*shall comply* with *any* portions of the demand not sought to be modified or set aside." 15 U.S.C. § 57b-1(f) (emphasis added). The Commission's Rules of Practice implement this provision by requiring a CID recipient to file with the Commission a "petition to limit or quash any compulsory process," which sets forth "*all* assertions of protected status or other factual and legal objections to the Commission compulsory process, including *all* appropriate arguments, affidavits, and other supporting documentation." 16 C.F.R. § 2.10(a)(1) (emphasis added). The Commission will only consider objections that the petitioner first sought to resolve with FTC staff at a mandatory meet-and-confer session. 16 C.F.R. §§ 2.7(k), 2.10(a)(2).

As Magistrate Judge Thomas G. Wilson of this district recently concluded, a CID recipient's "failure to exhaust administrative remedies" by raising objections in a petition to

limit or quash the CID "precludes [it] from raising objections to the judicial enforcement of the CID." *FTC v. Tracers Info. Specialists, Inc.*, No. 8:16-MC-18TGW, 2016 WL 3896840, at *3 (M.D. Fla. June 10, 2016). *See also Morton Salt*, 338 U.S. at 653; *O'Connell Associates*, 828 F. Supp. at 168; *XYZ Law Firm v. FTC*, 525 F. Supp. 1235, 1237 (N.D. Ga. 1981). By requiring CID recipients to raise all objections through administrative channels, the FTC Act and FTC rules ensure "the expedited and efficient resolution of the investigation." *Tracers*, 2016 WL 3896840, at *6. If CID recipients could raise objections in a "piecemeal manner," this would contravene "the strict statutory and regulatory time limits for the filing of a petition to quash or limit, and the requirement that such petition be limited to those issues raised during the meet and confer." *Id*.

Thus, because Lexium and CellMark exhausted their administrative remedies only with respect to their assertion of the Fifth Amendment privilege, this court should decline to consider any other objections to enforcement that they may raise for the first time here.

Prayer for Relief

WHEREFORE, the Commission invokes the aid of this Court and prays:

a. For the immediate issuance of an order, substantially in the form attached, directing Lexium and CellMark to appear and show cause why they should not comply in full with the CIDs;

b. For a prompt determination of this matter and an order requiring Lexium and CellMark to fully comply with the CIDs within ten (10) days of such order, or at such later date as may be established by the Commission;

c. For such other relief as this Court deems just and proper.

Respectfully submitted,

DAVID C. SHONKA
Acting General Counsel

LESLIE RICE MELMAN
Assistant General Counsel for Litigation

BRADLEY GROSSMAN
Litigation Counsel
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-2994
(202) 326-2477 (fax)
bgrossman@ftc.gov

Of Counsel:

CAROLYN L. HANN
EDWIN RODRIGUEZ
Division of Advertising Practices

Dated: September 15, 2016

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

FEDERAL TRADE COMMISSION,	)	
Petitioner,	)	**Misc. No. _____**
v.	)	
LEXIUM INTERNATIONAL LLC, and	)	
CELLMARK BIOPHARMA, LLC,	)	
Respondents.	)	

INDEX OF PETITIONER'S EXHIBITS

Pet. Exh. 1	Declaration of FTC Attorney Carolyn L. Hann
Pet. Exh. 2	lexiuminternational.com website excerpts (captured April 21, 2016)
Pet. Exh. 3	cellmarkbiopharma.com website excerpts (captured April 26, 2016)
Pet. Exh. 4	Records of Florida Secretary of State, Division of Corporations: Lexium International's Articles of Organization (filed October 1, 2014)
Pet. Exh. 5	Records of Florida Secretary of State, Division of Corporations: Lexium International's 2015 Annual Report (filed January 7, 2015)
Pet. Exh. 6	Records of Florida Secretary of State, Division of Corporations: Lexium International's 2015 Amended Annual Report (filed April 14, 2015)
Pet. Exh. 7	Lexium International's Petition to Limit or Quash Civil Investigative Demand (filed June 13, 2016)
Pet. Exh. 8	Records of Delaware Department of State, Division of Corporations regarding CellMark BioPharma (accessed September 13, 2016)
Pet. Exh. 9	"About Us - Management" page from cellmarkbiopharma.com website (captured April 21, 2016)

Pet. Exh. 10	cellmarkbiopharma.com blog post published July 19, 2016 (captured August 24, 2016)
Pet. Exh. 11	FTC Omnibus Resolution # 0023191 (issued August 13, 2009)
Pet. Exh. 12	FTC Civil Investigative Demand directed to Lexium International LLC (issued May 24, 2016)
Pet. Exh. 13	FTC Civil Investigative Demand directed to CellMark BioPharma, LLC (issued May 24, 2016)
Pet. Exh. 14	Target Letter from the United States Attorney for the Middle District of Florida Directed to Derek Vest (issued March 21, 2016)
Pet. Exh. 15	Email Exchange between Richard J. Oparil and FTC Attorney Carolyn L. Hann (June 6 & 8, 2016)
Pet. Exh. 16	Email Exchange between Oparil and Hann (June 10 & 13, 2016)
Pet. Exh. 17	CellMark BioPharma's Petition to Limit or Quash Civil Investigative Demand (filed June 13, 2016)
Pet. Exh. 18	Letter from Mary K. Engle, Associate Director, FTC Division of Advertising Practices, to Oparil regarding CellMark BioPharma, LLC (dated June 14, 2016)
Pet. Exh. 19	Letter from Engle to Oparil regarding Lexium International LLC (dated June 14, 2016)
Pet. Exh. 20	FTC Order Denying Petitions to Limit or Quash Civil Investigative Demands (issued July 25, 2016)
Pet. Exh. 21	Letter from Oparil to Hann regarding CellMark BioPharma, LLC (dated August 3, 2016)
Pet. Exh. 22	Email Exchange between Hann and Oparil (August 15, 2016)

PRESENTED BY:

DAVID C. SHONKA
Acting General Counsel

LESLIE RICE MELMAN
Assistant General Counsel for Litigation

BRADLEY GROSSMAN
Litigation Counsel
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-2994
(202) 326-2477 (fax)
bgrossman@ftc.gov

Of Counsel:

CAROLYN L. HANN
EDWIN RODRIGUEZ
Division of Advertising Practices

Dated: September 15, 2016

PETITION EXHIBIT 1

Declaration of FTC Attorney
Carolyn L. Hann
(September 15, 2016)

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

FEDERAL TRADE COMMISSION,	)	
Petitioner,	)	**Misc. No. _____**
v.	)	
LEXIUM INTERNATIONAL LLC, and	)	
CELLMARK BIOPHARMA, LLC,	)	
Respondents.	)	

DECLARATION OF CAROLYN L. HANN

Pursuant to 28 U.S.C. § 1746, I declare as follows:

1. I am an attorney employed by the Federal Trade Commission (FTC or Commission), in Washington, D.C, in the Division of Advertising Practices. I am the lead attorney for the FTC's investigation into two related companies, Lexium International LLC (Lexium) (FTC File No. 162-3133) and CellMark BioPharma, LLC (CellMark) (FTC File No. 162-3134). The purpose of the investigation is to determine whether these companies have engaged in deceptive advertising or other unfair or deceptive acts or practices in violation of Sections 5 and 12 of the Federal Trade Commission Act (FTC Act), 15 U.S.C. §§ 45 and 52.

2. I am authorized to execute a declaration verifying the facts that are set forth in the Petition of the Federal Trade Commission for an Order Enforcing Administrative Investigative Process. I have read the petition and exhibits thereto (hereinafter referred to as "Pet. Exh."), and verify that Pet. Exh. 2 through Pet. Exh. 22 are true and correct copies of the original documents. The facts set forth herein are based on my personal knowledge or information made known to me in the course of my official duties.

3. Lexium is a privately held Florida limited liability company with its principal place of business at 1591 Hayley Lane, Ste. 203, Fort Myers, FL 33907. Lexium markets and sells "prescription strength" health products including ADDTabz, purported to treat, cure, or mitigate symptoms associated with Attention Deficit Disorder/Attention Deficit Hyperactivity Disorder; PhenTabz, purported to cause significant weight loss comparable to prescription drugs; and REMTabz, purported to treat, cure, or mitigate sleep disorders and anxiety (collectively, the Tabz products). *See* Pet. Exh. 2, lexiuminternational.com website excerpts (April 21, 2016). Lexium markets and sells these products over the internet and also purports to sell them through gyms, doctors' offices, and weight loss clinics. Lexium is engaged in, and its business affects "commerce," as that term is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. CellMark is a privately held Delaware limited liability company with its principal place of business at 1591 Hayley Lane, Ste. 201, Fort Myers, FL 33907. CellMark positions itself as a medical nutrition company for cancer patients. It markets and sells two health products: Cognify, purported to treat, cure, mitigate, or prevent

cognitive decline caused by chemotherapy; and CellAssure, purported to meet the specific nutritional needs of cancer patients undergoing treatment including surgery, radiation, and chemotherapy. *See* Pet. Exh. 3, cellmarkbiopharma.com website excerpts (April 26, 2016). CellMark markets and sells its products through its website. CellMark is engaged in, and its business affects "commerce," as that term is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. Lexium and CellMark are among a network of companies owned and operated by Derek Vest or his relatives. Mr. Vest co-founded Lexium with Mary Lirette, and previously served as its sole member and president. Pet. Exhs. 4 (Articles of Organization) & 5 (January 2015 Annual Report). As of April 2015, Ms. Lirette and Tara Vest have served as Lexium's sole authorized members. Pet. Exh. 6 (April 2015 Amended Annual Report). During the course of this investigation, we learned that Ms. Lirette is Derek Vest's mother and that Ms. Vest is his sister. Lexium currently identifies Mr. Vest as a consultant to the company. Pet. Exh. 7 at 2 (Lexium Petition to Quash).[1] Mr. Vest is also the founder, Board Chairman, and sole owner of CellMark. Pet. Exhs. 8-9. He recently stepped down as its CEO. Pet. Exh. 10.

6. On April 25, 2016, Commission staff opened its investigation of Lexium and CellMark after reviewing both companies' advertisements for the products described in ¶¶ 3-4, above. Commission staff began this inquiry to determine whether Lexium's and CellMark's marketing and sale of their respective products violate

[1] Page references for each exhibit are to the CM/ECF headers at the top of the page.

Sections 5 and 12 of the FTC Act. Section 5 prohibits "unfair or deceptive acts or practices," 15 U.S.C. § 45, while Section 12 prohibits "false advertisements . . . likely to induce . . . the purchase of food, drugs, services, or cosmetics," 15 U.S.C. § 52.

7. Staff requested the Commission to issue civil investigative demands (CIDs) to Lexium and CellMark pursuant to an FTC Resolution Directing Use of Compulsory Process. Resolution 002-3191 (Pet. Exh. 11) authorizes the use of compulsory process, including CIDs,

> to investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52.

8. On May 24, 2016, the Commission issued CIDs to Lexium and to CellMark. Pet. Exhs. 12 (Lexium CID) and 13 (CellMark CID). The CIDs required Lexium and CellMark to produce all documents and to answer all interrogatories on or before June 14, 2016. The Lexium CID contained 42 interrogatories and 36 document requests and the CellMark CID contained 43 interrogatories and 34 document requests. Each CID sought information relating to, *inter alia*, the following topics:

   a. product information, including product samples and information about the manufacturing process;

b. advertising and promotion, including dissemination schedules, online ads, endorsements and testimonials, and communications with news media;

c. substantiation for the company's specific advertising claims, including relevant studies, use of experts, and research and development efforts;

d. sales and marketing practices and expenditures;

e. billing, customer service, and consumer complaints;

f. lawsuits and communications with government and other organizations; and

g. personnel, corporate relationships, and recordkeeping.

9. As required by the FTC's Rules of Practice, 16 C.F.R. § 2.7(k), on June 6, 2016 Commission staff participated in a meet-and-confer with two CellMark representatives and the company's outside counsel, Richard J. Oparil (who also represents Lexium in this matter). During the meet-and-confer, staff proposed a rolling production schedule requiring CellMark to respond to the CID in four two-week rounds between June 14, 2016 and July 26, 2016. In response, CellMark revealed that its principal, Mr. Vest, is the subject of a federal grand jury investigation by the U.S. Attorney's Office for the Middle District of Florida regarding "introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws." *See* Pet. Exh. 14 (target letter).[2] CellMark advised FTC staff that it would file a

[2] Lexium and CellMark filed the grand jury target letter as an exhibit to their respective petitions to limit or quash the CIDs—which are part of the public record (*see* 16 C.F.R. 2.10(d))—and did not seek confidential treatment for the letter. *See* Pet. Exhs. 7 & 17.

petition with the Commission to limit the scope of the CID to avoid impinging on Mr. Vest's Fifth Amendment privilege against self-incrimination.

10. On June 8, 2016, Mr. Oparil sent Commission staff an email confirming that "[s]ubject to the petition to quash or limit [the CID] on the Fifth Amendment privilege issue," CellMark agreed to comply with the production schedule proposed by Commission staff. Pet. Exh. 15.

11. Also on June 8, 2016, Commission staff participated in a meet-and-confer with two Lexium officials and with Mr. Oparil in his other role as Lexium counsel. Staff proposed a rolling production schedule allowing Lexium to respond to the CID in four three-week rounds between June 14, 2016 and August 16, 2016. Citing the criminal target letter issued to Mr. Vest, Mr. Oparil advised Commission staff that Lexium would seek to limit the scope of the Lexium CID to avoid impinging on Mr. Vest's Fifth Amendment privilege against self-incrimination.

12. On June 13, 2016, Mr. Oparil sent Commission staff an email confirming that "Lexium believes it can meet the discovery schedule discussed on June 8." Pet. Exh. 16.

13. The FTC's Rules of Practice require that a CID recipient set forth any legal or factual objections to the CID in a petition to limit or quash filed with the Commission. 16 C.F.R. § 2.10(a). On June 13, 2016, Lexium and CellMark timely filed nearly identical petitions. Pet. Exhs. 7 (Lexium) and 17 (CellMark). In their respective petitions, Lexium identified Mr. Vest as a "former officer and owner" (Pet. Exh. 7 at 2) and current consultant, and CellMark identified Mr. Vest as "an officer and sole

shareholder." Pet. Exh. 17 at 2. Citing Mr. Vest's and their own Fifth Amendment privilege, both Lexium and CellMark sought to "limit the production of any privileged information" required to be produced pursuant to the CIDs. Neither Lexium nor CellMark raised any other basis to quash or limit the CIDs. Pet. Exh. 7 and 17.

14. On June 14, 2016, Mary K. Engle, Associate Director for the Commission's Bureau of Consumer Protection, Division of Advertising Practices, issued letters to counsel for CellMark and Lexium memorializing the rolling production schedules described in ¶¶ 9-12, above. *See* Pet. Exhs. 18-19. Both letters stated that the filing of the petitions to quash "does not alter [the companies'] obligation to produce documents and information [in response] to specifications unaffected by the petition. *See* 16 C.F.R. § 2.10(b)."

15. From June 13 through July 26, 2016, CellMark produced responses to the CID in accordance with the established rolling production schedule. However, citing Mr. Vest's Fifth Amendment privilege, CellMark expressly refused to respond to Interrogatory 21 of the CID, which requested that CellMark "identify any and all domain names for which Derek Vest is the registrant." Pet. Exh. 13 at 18.

16. For its part, Lexium produced certain responses to the CID on June 14, July 7, and July 12, 2016. However, responses to 39 of 42 interrogatories and at least 31 of 36 document requests remained outstanding.

17. On July 25, 2016, the Commission issued a ruling denying Lexium's and CellMark's petitions to limit or quash the CIDs. Pet. Exh. 20. Specifically, the Commission,

relying on Supreme Court precedent, concluded that corporate entities have no Fifth Amendment privilege against self-incrimination and that Mr. Vest has no constitutional right to withhold Lexium's or CellMark's corporate records. The Commission thus ordered both Lexium and CellMark to produce all remaining responses to their respective CIDs no later than August 15, 2016.

18. On August 3, 2016, Mr. Oparil, in his role as Lexium's counsel, sent Commission staff a letter stating that the company disagreed with the Commission's Order. The letter advised that Mr. Vest would continue to invoke his Fifth Amendment privilege against self-incrimination and would not provide documents in his possession to Lexium for production to the FTC. Mr. Oparil further explained that the company objected to the Commission's conclusion that it could not invoke the Fifth Amendment privilege. Finally, he explained that Lexium was gathering documents in its possession and that were not subject to its objection to further respond to the CID by August 15, 2016.

19. Also on August 3, 2016, Mr. Oparil, in his role as CellMark's counsel, sent a similar letter to Commission staff objecting to the Commission's Order. Pet. Exh. 21. He advised that Mr. Vest "will continue to invoke his Fifth Amendment right against self-incrimination and will not provide documents in his possession to CellMark for production to the FTC." Mr. Oparil further stated that "[w]ith the exception of Mr. Vest's documents as to which there is a privilege objection, CellMark believes it has produced all responsive documents to the FTC in compliance with the CID."

20. On August 15, 2016, Lexium produced 47 pages of documents and no interrogatory responses. When asked by Commission staff whether Lexium planned to produce additional responses, Mr. Oparil replied, "Lexium will have more to produce but I'm not going to get more today. It is also working on the written discovery [interrogatory responses]. I will update you." Pet. Exh. 22. Noting that Lexium "neither has requested an extension nor has provided any explanation for missing the Commission's deadline," Commission staff granted Lexium a short extension to August 18, 2016 but stated that it would grant no further extensions. *Id.*

21. From August 15, 2016 to date, Lexium has produced no additional documents or interrogatory responses in compliance with the CID.

22. Lexium's Continuing Noncompliance: Lexium's response to the CID remains deficient. Lexium has completely withheld responses to Document Requests 2, 4-8, 11-21, 23-25, 27, and 29-36 and Interrogatories 4 through 42. Lexium also made incomplete responses to Document Requests 9-10, 22, 26, and 28. Specifically, Lexium has failed to produce the following information:

    a. Product Information: Lexium has refused to identify all of its products or provide even basic information about their manufacture, marketing, ingredients, or sales (Interrogatory 5). For the three Tabz products (*see* ¶ 3), Lexium has failed to produce the required product samples (Document Request 2) and information about the manufacturing process, including product components, product specifications, product testing and analysis, and the persons involved (Interrogatories 6-13 and Document Requests 12-20).

b. Advertising and Promotion: Lexium has withheld information regarding its advertising practices, including marketing and advertising plans (Document Request 4), marketing and consumer research (Document Request 8), schedules for disseminating ads (Interrogatory 15), communications with ad agencies, news media, and educational institutions regarding ads (Document Requests 5-7), websites and keyword placement (Interrogatories 16-17 and 20), ad approval policies (Interrogatory 29), and the identity of persons and entities responsible for creating, reviewing, and approving ads (Interrogatory 24). Lexium has also refused to identify or provide information about its use of consumer testimonials and expert endorsers (Interrogatory 18 and Document Request 21), its policies regarding consumer reviews (Interrogatory 19), or its use of bloggers and affiliate marketers (Interrogatories 22-23).

c. Advertising Claims Substantiation: Lexium appears not to have produced all relevant substantiation for its advertising claims. It has not produced studies, or documents related to such studies, substantiating all of the advertising claims enumerated in the CID (Document Requests 9-10), or examining the effectiveness of the Tabz products (Document Request 11). Nor has Lexium identified the ingredients and amounts of each ingredient used in any such studies (Interrogatory 27). The company produced only five journal articles, one of which is a duplicate; none of these articles involves testing of any of the three Tabz products, and only two relate to an ingredient that appears to be in ADDTabz and PhenTabz (*see supra* ¶ 3, describing these products). In

addition, Lexium has not identified persons or entities who participated in testing Tabz products (Interrogatories 25-26) or in evaluating substantiation for those products (Interrogatory 28). Finally, Lexium has failed to identify the experts it used to substantiate advertising claims (Interrogatories 30-31).

d. Sales and Marketing Practices and Expenditures: Lexium has not produced any information regarding its sales and marketing practices or expenditures. It has failed to identify its retailers, distributors, or other sellers (Interrogatory 21), produce telemarketing transcripts or call recordings (Document Request 27), or provide information about its consumer accounts (Interrogatory 38). Nor has Lexium produced information regarding its use of "continuity plans" through which consumers are automatically billed for new product installments (Interrogatories 33-34 and Document Request 23). Finally, Lexium has failed to provide data regarding sales, expenditures (including for marketing purposes), or order fulfillment (Interrogatory 14).

e. Billing, Customer Service, and Consumer Complaints: Lexium has not provided any information about customer service, and its responses to the CID's requests for information about billing or consumer complaints are incomplete. It has failed to identify or provide information about the persons or entities responsible for customer service (Interrogatories 35-36), or to produce its customer service and return policies (Document Requests 24-25). With the exception of five chargeback notifications Lexium received from a third-party payment processor, it has not produced any documents or

information regarding contracts, payments, returns, refunds, chargebacks, or other consumer issues (Document Request 26 and Interrogatory 39), consumer complaints (Document Request 28 and Interrogatory 37), or complaints by consumers or medical professionals concerning consumer injury (Document Request 29).

f. Lawsuits and Communications with Government and Other Organizations: Lexium has not produced any information about lawsuits concerning the Tabz products or affirmed that there have been no such lawsuits (Interrogatory 40 and Document Request 34). Nor has it produced any communications with government agencies, the Better Business Bureaus, self-regulatory organizations, consumer protection groups, health interest groups, or media outlets (Document Requests 30-33, 35-36).

g. Personnel, Corporate Relationships, and Recordkeeping: Lexium has declined to describe its business relationships with various entities and individuals (Interrogatory 4). The company also failed to provide information about three of its corporate officials (Interrogatory 32) or produce curriculum vitae for two of them (Document Request 22). Finally, Lexium has refused to provide record-keeping information, such as identifying who prepared the responses to the CID (Interrogatory 41) or describing whether or how any responsive documents may have been destroyed, altered, or deleted (Interrogatory 42).

23. Lexium has not specified which of these categories of information it is withholding on Fifth Amendment grounds, and which categories it is withholding on some other basis.

24. CellMark's Noncompliance on Fifth Amendment Grounds: CellMark's response to its CID also remains deficient. Citing Mr. Vest's Fifth Amendment privilege, CellMark has refused to respond to Interrogatory 21, which asks CellMark to identify from its corporate records any domain name for which Mr. Vest is the registrant. Although CellMark has indicated that it is withholding responsive documents under the Fifth Amendment (*see supra* ¶ 19), it has not identified the document requests to which this objection pertains. *See* Pet. Exh. 17.

25. Failure to Produce Privilege Logs: To date, Lexium and CellMark each have failed to provide Commission staff a privilege log of items withheld, as required by Instruction D of the Lexium CID and the CellMark CID, respectively. Instruction D states:

> D. **Claims of Privilege**: If any material called for by this CID is withheld based on a claim of privilege, work product protection, or statutory exemption, or any similar claim (*see* 16 C.F.R. § 2.7(a)(4)), the claim must be asserted no later than the return date of this CID. In addition, pursuant to 16 C.F.R. § 2.11(a)(1), submit, together with the claim, a detailed log of the items withheld. The information in the log shall be of sufficient detail to enable the Commission staff to assess the validity of the claim for each document, including attachments, without disclosing the protected information . . . . 16 C.F.R. § 2.11(a)(1)(i)-(xi).

Pet. Exhs. 12 at 8-9 (Lexium) and 13 at 8-9 (CellMark).

26. Lexium's and CellMark's non-compliance with their respective CIDs has burdened, delayed, and impeded the Commission's investigation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on September 15, 2016

Carolyn L. Hann, Staff Attorney
Division of Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission

PETITION EXHIBIT 2

lexiuminternational.com website excerpts
(captured April 21, 2016)

Lexium International The Most Trusted Name In Designer Pharmacology

Lexium International™ is the world leader in designer pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products. For over 25 years, we have been using innovative solutions to formulate the finest cutting edge prescription and non-prescription pharmaceuticals. The never ending pursuit of perfection drives Lexium International™ to deliver clinically effective products that are unrivaled in safety and efficacy.

Lexium International™ – The most trusted name in designer pharmacology Lexium International™ is the world leader in designer pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products.

Our Products

FAQS

Store

Contact

CONTACT US

Lexium International US
Address: 1591 Hayley Lane #203 Fort Myers, Fl 33907
Toll Free: 888-666-1714
Los Angeles, CA: 310-622-9805
New York, NY: 646-490-1347

United Kingdom
Office Phone: 0161 971 6681
Direct Phone: 07780006594

OTHER LINKS

Affiliate Program
Affiliate & Wholesale Agreement
Anti-Spam Policy
DMCA Notices
Earnings Disclaimer
External Links Policy
Privacy Policy
Terms & Conditions

CONNECT WITH US

facebook.com/lexiuminternational
@lexiuminternational
youtube.com/lexiuminternational

Have Questions? Click Here!

ADDTabz™ (Ampheta-CDP)

The new smart pill

The absolute need for enhanced mental performance in today's academic and business society is undisputed. Scholastic requirements are as intense as the most competitive corporate environments and the world is simply demanding more and higher levels of performance.

In very much the same way steroids have been used to increase physical performance in both collegiate and professional sports – specific medications such as Adderall have been used to enhance cognitive abilities in a significant manner. The allure of 4.0 vs a 2.5 GPA or a CEO position vs mid-management is too important of a reality to ignore or dismiss. While Adderall is amazing for its intended use – ADD/ADHD – its formulation doesn't provide 100% effectiveness for all of its other "off-label" users. This is not a negative reflection on the aging (16 + years old) Adderall formulation: just the reality that this pharmaceutical was not designed/developed with the sole purpose and function of mental performance and cognitive enhancement (for non ADD/ADHD users) for academic/business strategic purposes.

- Improve Memory and Learning
- Positive Mood
- Enhanced Cognitive Ability
- Improves Brain Function
- Reduces Anxiety

Ampheta-CDP is the active pharmaceutical compound used in Lexium International's non-prescription alternative for Adderall – **ADDTabz™**. Ampheta-CDP is the amplified hybrid of Ampheta-HCL** designed for use in both physician offices as well as OTC versions for enhanced mental performance. The most known of these products are **ADDTabz™** which is most recognized as the alternative for millions for Adderall.

The entire **ADDTabz™** (RX version and the hyper-advanced non-prescription **ADDTabz™**) product line formulation is NOT an herbal supplement but rather a designer non-prescription pharmaceutical analog providing superior results without the side effects of its chemical cousin's amphetamine spectrum.

Compare AddTabz™ to Adderall™:

COMPARISON CATEGORIES	ADDTABZ™	ADDERALL™
Prescription Strength	YES	YES
Prolonged Energy	YES	YES
Crosses Blood Brain Barrier	YES	YES
Designed for non-ADD/ADHD	YES	NO
Memory Support	YES	NO
Side Effects	Minimal	Strong
Requires Prescription	NO	YES
Safe Long-Term Use	YES	Ask Your Physician

ADDTabz™ has been referred to as the new "Smart Drug" or "Study Drug" even though it is available in non-prescription formulation. This new category (Smart Drugs & Study Drugs) is any drug or supplement designed to improve cognitive abilities such as memory, concentration, problem solving and critical thinking. They are sometimes called Nootropics which differ from other "productivity enhancers", such as Adderall, in that they're minimally taxing on the body and aid in the prevention of brain cell damage while providing analogous heightened cognitive function and mental clarity. **ADDTabz™** is the Holy Grail for the students struggling to stay afloat and the ones setting an example alike.

Remember if you have not been diagnosed with ADHD, Adderall may not be the drug for you. It is a very potent drug with serious side effects and requires a legal prescription from a doctor. With **ADDTabz™** there is now an alternative to Adderall for millions without all the side effects, physician visits and expense. Enjoy the peace of mind that comes with upgrading to non-prescription **ADDTabz™** that provides superior results without negative side effects commonly associated with ADHD medications.

** Ampheta HCL is widely regarded as the most advanced and effective Synthetic Amphetamine (non-prescription pharmaceutical) in the world with use in multiple products sold throughout the globe. The most known of these products are the PhenTabz™ weight loss/appetite suppressant line most recognized as the replacement for Phentermine both available through physician's as well as the OTC versions. The PhenTabz™ line includes: PhenTabz™ – PhenTabz RX™.

BUY NOW 80 TABLETS

SAVE $21! 2 BOTTLES ONLY $128 FREE SHIPPING

ADD TO CART

BUY NOW 40 TABLETS

ONLY $69! PLUS SHIPPING

ADD TO CART

CONTACT US

Lexium International US
Address: 1591 Hayley Lane #203 Fort Myers, Fl 33907
Toll Free: 888-666-1714
Los Angeles, CA: 310-622-9808

OTHER LINKS

Affiliate Program
Affiliate & Wholesale Agreement
Anti-Spam Policy
DMCA Notices

CONNECT WITH US

facebook.com/lexuminternational
@lexuminternational

PhenTabz™
(Ampheta-HCL)

PhenTabz is NOW AVAILABLE WITHOUT A PRESCRIPTION!

PhenTabz offers the ultimate in safe, significant weight loss with incredible energy!

Until now, the only way to have the incredible effects of **Phentabz™** was through a physician. Now the world's finest appetite suppressant/weight loss pill is available without a prescription!

Phentabz™ is a true pharmacological diet pill like Phentermine, Xenical or Adipex. **Phentabz™** is NOT an herbal supplement but rather a designer non-prescription pharmaceutical analog providing superior results without the side effects. We have had many health care professionals upgrade their patients to **Phentabz™** as the new Phentermine replacement.

How does PhenTabz work?

The patented ingredients in **Phentabz™** perform two essential functions. It increases the body's mobility of fat while increasing metabolic rate. **Phentabz™** then greatly reduces appetite to ensure patients have control and motivation.

The bottom line is that **Phentabz™** provides consistent significant weight loss and increased energy.

PhenTabz is clinically designed to:

- Suppress Appetite
- Increase Metabolism
- Increase Energy Levels
- Accelerate Fat Mobilization
- Lose Weight Safely Every Single Day
- Lose Body Fat, Not Just Water Retention

PhenTabz works like a prescription drug, but without the prescription.

Lexium International™ has earned a reputation of designing exceptional products with quality, safety and efficacy as the foundation for each formulation. Twenty five years of continuous evolution and innovation have allowed for the development and subsequent worldwide success of **Phentabz™** and now non-prescription **Phentabz™**.

Phentabz™ was clinically designed as the replacement for Phentermine, Xenical, Alli, Adipex and other weight loss pills whose side effects outweigh their benefits.

If you are serious about losing body fat (not just water weight) while achieving an incredible amount of energy needed to get through the day – then look no further than to the #1 selling **Phentabz™**.

Compare PhenTabz™ to Phentermine™

COMPARISON CATEGORIES	PHENTABZ™	PHENTERMINE™
Average Weight Loss	2.5lbs/wk	2-3 lbs/wk
Appetite Suppression	Strong	Strong
Metabolism Boost	Strong	Strong
Energy Boost	Strong	Medium
Prescription Strength	YES	YES
Safe Long-Term Use	YES	NO
Fat Mobilization	YES	YES

TRY PHENTABZ TODAY!

4 MONTH SUPPLY, SAVE $36! BEST VALUE!

ONLY $249 (Free Shipping)

ADD TO CART

TRY PHENTABZ TODAY!

2 MONTH SUPPLY, SAVE $7.00! SPECIAL OFFER!

ONLY $131 (Plus Shipping)

ADD TO CART

TRY PHENTABZ TODAY!

3 MONTH SUPPLY, SAVE $20.00! MOST POPULAR!

ONLY $187 (Plus Shipping)

ADD TO CART

TRY PHENTABZ TODAY!

TRY IT FOR 1 MONTH, YOU WILL LOVE THE RESULTS

ONLY $69 (Plus Shipping)

ADD TO CART

REMTabz™ (Diazaclone)

Some sleep aids are designed to help you fall asleep and others to help you stay asleep. REMTabz is effectively designed to do both!

Lexium International has delivered the world's first non-prescription sleep formulation which directly addresses all the standard medical reasons for poor sleep and is extensively used and recommended by physicians world-wide. REMTabz is now available in OTC without a prescription.

Why Is Sleep Important?

Sleep, especially REM sleep, plays a vital role in good health and well-being throughout your life. Getting enough quality sleep at the right times can help protect your mental health, physical health, quality of life, and safety. REM (Rapid Eye Movement) sleep is a very important part of our sleeping pattern. This stage of sleep is the most important phase of sleep that we experience.

The way you feel while you're awake depends on what happens while you're sleeping. During deep sleep your body is working to support healthy brain function and maintain optimal physical health.

The damage from sleep deficiency may occur in an instant (such as a car crash), or it can harm you over time. Ongoing sleep deficiency can raise your risk for some chronic health problems. It also can affect how well you think, react, work, learn, and get along with others.

SLEEP BETTER – LIVE BETTER

Proper Sleep = Healthy Brain Function and Emotional & Physical Well-Being.

REM sleep helps your brain work properly. While you're sleeping, your brain is preparing for the next day. It's forming new pathways to help you learn and remember information.

If you're sleep deficient, you may have trouble learning, making decisions, solving problems, controlling your emotions and behavior, and coping with change. Sleep deficiency also has been linked to depression, suicide, and risk-taking behavior.

Your immune system relies on sleep to stay healthy. This system defends your body against foreign or harmful substances. Ongoing sleep deficiency can change the way in which your immune system responds. For example, if you're sleep deficient, you may have trouble fighting common infections.

Why do people have trouble sleeping?

33% of all people have trouble falling asleep or staying asleep

- STRESS
- ANXIETY
- DEPRESSION
- CIRCADIAN RYTHUM PROBLEMS
- GABA/NEUROTRANSMITTER INSUFFICEINCY

Why REMTabz?

Doctors use two main types of medications to help their patients improve their sleep:

Anxiety/Stress Reducers such as **Xanax** (BENZODIAZEPINES)

GABA/Neurotransmitter Regulators such as **Ambien & Lunesta**

Unfortunately both types of those medications have massive side effects, and often aren't helpful in both helping you get to sleep AND staying asleep.

REMTabz (Diazaclone) is a true pharmacological sleep pill that safely combines the best attributes of Stress/Anxiety Relief and the most powerful sleep aid formula available. **REMTabz** is designed to safely produce the sleep aid effects of both types of prescription sleep medications without the side effects. In other words, **REMTabz** allows both your body and mind to rest!

The ingredients contained in this powerful sleep aid have been tested in clinical trials and have been proven to decrease the amount of time it takes to fall asleep and allow you to get more quality rest. **REMTabz** proprietary formulation (Diazaclone) directly stimulates the production of Alpha & Delta brain waves creating a state of deep relaxation for all stages of REM sleep (N1, N2 & N3).

REMTabz is your non-prescription solution for your patients' sleepless nights specifically designed for effectiveness without the harmful side effects. Developed through years of research, **REMTabz** is the perfect balance of science & nature that delivers night after night of consistent deep sleep. Formulated with the most powerful patented sleep aiding ingredients, **REMTabz** is designed to help you fall asleep and stay asleep without leaving you feeling drowsy the next day. **REMTabz** is the perfect balance of science & nature brought to you by the global leaders in non-prescription pharmaceuticals.

If you are among the many who suffer from insomnia and other sleep disorders, you owe it to yourself to try REMTabz today!

- Reduce Stress / Anxiety
- Fall Asleep Quickly
- Stay Asleep Longer
- No Side Effects
- Non-Addictive
- Wake Up Refreshed – Not Drowsy
- No Prescription Needed

FAQS

Frequently Asked Questions

PhenTabz – ADDTabz FAQs

PhenTabz FAQs

What are the ingredients in PhenTabz RX and new PhenTabz?

PhenTabz and **PhenTabz RX** are the most advanced proprietary formulations currently available for weight loss and appetite suppression. The formulation consists of FDA Approved ingredients proven safe and effective when taken as directed. Our internationally recognized formulations contain only the finest pharmacological actives to provide maximum safe weight loss.

How does PhenTabz RX and PhenTabz work?

The patented ingredients in **PhenTabz** perform two essential functions. It increases the body's mobility of fat while increasing metabolic rate. **PhenTabz** then greatly reduces appetite to ensure patients have control and motivation. The bottom line is that **PhenTabz** provides consistent significant weight loss and increased energy.

I thought PhenTabz were only available with a prescription?

Our original formula, **PhenTabz RX** is still available by prescription only. But now, for the first time, we have a non-prescription version available. **PhenTabz** contains the exact same powerful ingredients as **PhenTabz RX**, but is a slightly different strength.

How Do I Take PhenTabz™?

PhenTabz™ is best taken on an empty stomach approximately a half-hour before breakfast and again a half-hour before lunch. Because this product could cause sleeplessness, avoid taking a dose late in the day. It is best to take PhenTabz on an empty stomach with a full 8 oz. of water. Doses should never exceed two pills per day.

What are the precautions for PhenTabz RX and PhenTabz?

Keep out of reach of children. Not intended for people under 18 years of age. Do not use if pregnant, nursing, or have a known medical condition such as high blood pressure, heart disease, diabetes, or cardiovascular disorder. This product should not be used by individuals taking antidepressants, amphetamines, other weight loss products or medications. This product contains caffeine and should not be used by individuals wishing to eliminate caffeine from their diet. Consult your physician before starting any diet, exercise regimen, if you are on prescription medications or have questions about taking this product.

What are the side effects of PhenTabs RX and PhenTabz?

The main effects are increased energy and rapid weight loss. Generally you should not experience any adverse side effects. However, on occasion, people may experience side effects such as dry mouth or sleeplessness. If this should occur, please increase the amount of water you consume daily and take the product earlier in the afternoon. It is always recommended to consult your physician before starting any weight loss program – ask your physician if PhenTabz is right for you.

ADDTabz™ FAQs

Does ADDTabz™ feel like Adderall when you take it – what should I expect?

If you are used to taking Adderall then you will be very happy to know that most users describe **ADDTabz™** as "a very clean Adderall type feeling". In other words you can expect a very smooth onset that delivers a very heightened sense of energy and focus without (for most) the jittery feelings (jumpy/speedy) or anxiety like feelings that many have experienced with other types of medications. Some people do experience a "euphoric sense" for awhile. Ampheta-CDP (active compound in **ADDTabz™**) was specifically designed for enhanced mental performace with the cleanest and calmest delivery to the users. So in basic terms you get the focus and concentration without negative side-effects.

Adderall really helps my ADHD, my friends told me to try ADDTabz™ instead – what dose should I try?

None. If you have a professional/medical diagnosis of ADHD then you should NOT switch medications without first speaking to your medical professional. Adderall is the leading medication for your diagnosed disorder and needs to be taken seriously.

What is the difference between Adderall and ADDTabz™?

Adderall is the world's leading formulation specifically designed/formulated for the treatment of ADD/ADHD. **ADDTabz™** is the world's leading formulation specifically designed/formulated for enhancing mental performance and cognitive ability. While **ADDTabzRX™** is available only though physicians globally; **ADDTabz** is now available without a script and is perfectly legal in all countries we sell it in (some countries even the non-prescription **ADDTabz** is considered a controlled substance/drug and thus requires a prescription).

Adderall is banned by the World Anti-Doping Agency – is ADDTabz™?

Yes, our formulation puts us in the same category as Adderall in their view. Even though **ADDTabz™** doesn't require a prescription it's active compound (Ampheta-CDP) is considered to give an unfair advantage in physical energy, focus and concentration to it's users.

Will ADDTabz™ show up on a drug screen like Adderall would (looking for amphetamine type substances)?

No, **ADDTabz™** ingredients are legal in most countries such as the US, Europe, South and Central America etc. So random drug tests are not an issue. Professional athletes or Olympic competitors would need to discuss with their organizations if the use of Ampheta-CDP (active compound in **ADDTabz™**) is prohibited.

Can I get in trouble or kicked out of school for having ADDTabz™ on me?

No, having **ADDTabz™** is not like having a prescription drug such as Adderall without a prescription. You could march into class 30 minutes prior to a major exam and put the bottle on our desk and enjoy the exam like never before.

Can I sell some of my ADDTabz™ out of my bottle to friends?

No. Purchasing a non-prescription pharmaceutical like **ADDTabz™** requires that you take possession of the product but you are not allowed to sell any part of the bottle to anyone else. Mass distribution of a product in not legal and any user of **ADDTabz** should have the opportunity to do their own due diligence and understand if **ADDTabz** is right for them. Ampheta-CDP is a considered the most complex and powerful synthetic/legal amphetamine analog available anywhere in the world.

I heard ADDTabz™ is really helpful for losing weight just like Adderall – what is the best way to take ADDTabz™ for weight loss?

Neither Adderall or **ADDTabz** were specifically designed for weight loss and that would be considered an "off-label" use of either product and thus not recommended unless prescribed by your physician. **ADDTabz™** uses Ampheta-CDP as it's active compound. Ampheta-CDP is the amplified hybrid of Ampheta-HCL. Amphete-HCL is widely regarded as the most advanced and effective Synthetic Amphetamine (non-prescription pharmaceutical) in the world with use in multiple products sold throughout the globe. The most widely known of these products are the PhenTabz weight loss/appetite suppressant line most recognized as the replacement for Phentermine both available through physician's as well as the OTC versions. The **PhenTabz™** line includes: **Phentabz** – **PhenTabz Rx**. So for weight loss we recommend the use of **PhenTabz™**.

Miscellaneous FAQs

Is Lexium International the same company as the United Kingdom Lexium International?

Yes – Lexium International has headquarters in both the United Kingdom as well as the United States. They both are centers of operation, training and management. The majority of actual production is completed in the United States.

I have been receiving PhenTabz RX™ from my doctor, but I am moving to another city – can I send in his prescription and have the RX shipped directly from Lexium International to me?

No – all of Lexium International's RX versions (**PhenTabz RX™**, **PhenTabz Teen RX™**, **ADDTabz RX™**, **InsulTabz RX™**) are only available directly through physicians. Direct shipping is not allowed to patients under any circumstances.

Lexium International™ – The most trusted name in designer pharmacology Lexium International™ is the world leader in designer pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products.

CONTACT US

Lexium International US
Address: 1591 Hayley Lane #203 Fort Myers, Fl 33907
Toll Free: 888-666-1714
Los Angeles, CA: 310-622-9808
New York, NY: 646-490-1347

United Kingdom
Office Phone: 0161 971 6681
Direct Phone: 07780 006594

OTHER LINKS

Affiliate Program
Affiliate & Wholesale Agreement
Anti-Spam Policy
DMCA Notices
Earnings Disclaimer
External Links Policy
Privacy Policy
Terms & Conditions

CONNECT WITH US

facebook.com/lexuminternational
@lexuminternational
youtube.com/lexuminternational

Have Questions? Click Here!

Physicians Only

As physicians, it is our responsibility to find the best treatment regimen for our patients. When it comes to pharmacological therapy, we often have a myriad of drug options that typically all have the same issues which we must carefully consider:

- Side Effects
- Drug Interactions
- Patient Contraindications
- Safety Profiles
- Downregulation Issues
- Addictive / Abuse Potential

Lexium International Solutions

The Leader in Non-Prescription Pharmaceuticals

Lexium International has earned a global reputation as the leader in non-prescription pharmaceuticals through its' unparalleled ability to formulate safe and efficacious alternatives to the most popular prescribed medications in use.

Generate Strong Income

Nuviva® Medical Weight Loss

As president and CEO of Nuviva Medical Weight Loss, we are always looking for the next best product and ultimately something that set us apart for the rest. I heard about PhenTabz from a physician friend of mine who was using this product with great results. Since we introduced this product to our patients, I noticed our patient basis grow and our client attrition rate reduce. With the BMI regulations limiting our ability to prescribe appetite suppressants, PhenTabz was just what we were looking for to those clients who needed something to hold off the hunger and give them the extra support to continue in our program.

- Alex Joseph, President & CEO, Nuviva Medical Weight Loss Centers

Lexium International's advanced RX product line provides direct cash generation for your practice. Your patients can only get our products via physician's offices – but our products are not a prescription medication or drug. Lexium International products are not billed through insurance – it is provided on a cash pay basis.

With the tremendous amount of cutbacks that have occurred and future ones that are planned; Lexium International provides incredible income generation while providing incredible benefits for your patients.

Weight Loss

PhenTabz RX™ For Your Practice

PhenTabzRX (Ampheta-HCL)

Offer your patients a safer product that protects both them and your practice. Prescription drugs have too many side effects and contraindications that put you and your practice at increased risk. **PhenTabz RX** is not a drug – it is a designer pharmacological supplement comprised of safe and effective ingredients.

Overweight / Obesity effects large % of your practice

Statistics continue to show the ever increasing % of both adults and children who are overweight or obese. The health risks of your patients being overweight are well documented and their current medical conditions tend to be exacerbated by excess weight and obesity.

Providing an effective solution will not only help your patients increase their health, but also will increase their loyalty towards your practice and increase referrals.

Without the right tools losing weight safely and keeping it off are nearly impossible. Fighting genetics, hunger, lack of energy and motivation is enough to make the strongest willed patient quit or not even bother attempting to lose weight! PhenTabz™ was specifically designed with all these real world and important factors in mind.

PhenTabz™ seriously reduces your patients hunger levels allowing then to make the right choices when it comes to food and portion size. PhenTabz™ provides your patients with the energy levels required to make it through the day including plenty of energy for exercising.

Lose up to 36lbs in 3 months

Patients lose between 6-12 pounds per month by taking **PhenTabz RX** and following a healthy nutritional plan and incorporating moderate exercise.

Experience More Energy

PhenTabz RX provides its users with a significant boost in their natural energy levels. Getting into a regular exercise routine is highly recommended and lack of energy will no longer be an excuse that can be used for procrastinating.

Eat Less Often

PhenTabz RX suppresses the appetite, making your patients eat less often while being able to make more sensible choices. The extra weight loss and positive results will provide much needed motivation during the journey to weight loss success.

Get The Healthy Lifestyle You Need

PhenTabz RX provides your patients with a healthy balance and also encourages them to eat healthily and exercise regularly. By mitigating your patients hunger levels and providing them with a fat-burning boost you will enable them to make permanent behavior modification and find a healthy lifestyle.

If you wish to receive more information on providing **PhenTabz RX** to your patients please fill out the Physicians Info Request Form and we will send you information and set up as a **PhenTabz RX** provider.

Mental Performance – Adderall Alternative

ADDTabz Rx™ (Ampheta-CDP)

ADDTabz RX™ is a true pharmacological pill like Adderall, Ritalin & Vyvanse. ADDTabz RX™ is NOT an herbal supplement but rather a designer non-prescription pharmacological analog providing superior results without the side effects. We have had many health care professionals upgrade their patients to ADDTabz RX™ as the new Adderall alternative.

ADDTabz RX™ is an exceptional non-prescription pharmaceutical that has received enormous acceptance within the medical community as a first stage alternative to patients seeking an

Adderall type medication without having full-fledged AUU/ADHD as a true diagnosis or having gone through necessary evidence substantiating testing via physicians.

ADDTabz RX™ is particularly popular among elite college and university students around the globe. The abuse of Adderall and subsequent shortage has paved the way for the acceptance of designed alternatives and their massive growth.

Compare AddTabz™ to Adderall™:

COMPARISON CATEGORIES	ADDTABZ™	ADDERALL™
Prescription Strength	YES	YES
Prolonged Energy	YES	YES
Crosses Blood Brain Barrier	YES	YES
Designed for non-ADD/ADHD	YES	NO
Memory Support	YES	NO
Side Effects	Minimal	Strong
Requires Prescription	NO	YES
Safe Long-Term Use	YES	Ask Your Physician

ADDTabz RX offers physicians an effective alternative for their patients asking for Adderall or other stimulatory ADD medications when ADD has not been fully diagnosed or for those patients seeking "off label" use for academic/professional purposes.

Contact Form

Your Name (required)

Send

Lexium International™ – The most trusted name in designer pharmacology Lexium International™ is the world leader in designer pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products.

CONTACT US

Lexium International US
Address: 1591 Hayley Lane #203 Fort Myers, Fl 33907
Toll Free: 888-666-1714
Los Angeles, CA: 310-622-9808
New York, NY: 646-490-1347

United Kingdom
Office Phone: 0161 971 6681
Direct Phone: 07780 006594

OTHER LINKS

Affiliate Program
Affiliate & Wholesale Agreement
Anti-Spam Policy
DMCA Notices
Earnings Disclaimer
External Links Policy
Privacy Policy
Terms & Conditions

CONNECT WITH US

facebook.com/lexuminternational
@lexuminternational
youtube.com/lexuminternational

Have Questions? Click Here!

English | Español | Français

Lexium International

Home | About us | Addtabz | Phentabz | Remtabz | FAQS | Physicians only | News | Contact us

Lexium International – PhenTabz & ADDTabz Affiliate Program

* For Immediate Signup Information, Click Here.

Lexium International™ is the world leader in designer non-prescription pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products. Our flagship product, PhenTabz™, is a Phentermine alternative which is both safe and effective for weight loss with no side effects and subsequent release of ADDTabz, a non-prescription Adderall alternative, have catapulted the Lexium International affiliate program into the top tier of health and wellness programs online today. Other products include diabetes, anxiety/stress relief, and anti-aging pharmacological alternatives.

- Average order size of over $100
- 33% commission entry level commission
- 60 day cookies
- Performance based commission increases available (through in-house program)
- Dedicated affiliate managers
- Vast array of creatives
- Custom creatives available upon request
- Perks and bonuses for top selling affiliates

Are you looking for the perfect product to promote – one that *actually works*? Our products are sold at several **Planet Fitness**, **LA Fitness**, **Zoom Tan** and **Planet Beach** locations, in addition to being recommended and prescribed by several ***REAL*** physicians and doctor-assisted weight loss clinics across the country. You can finally feel comfortable promoting a product that actually works!

planet fitness | LA FITNESS | Planet Beach. a contempo spa. | ZOOM TAN

Join Our Featured Program

CLICK HERE TO REGISTER AS AN AFFILIATE

Already A Member Of The Commission Junction Affiliate Network?

affiliate by CONVERSANT

CLICK HERE TO APPLY TO OUR PROGRAM ON COMMISSION JUNCTION

AFFILIATES LOVE THE PERKS!

As an incentive for our affiliates who are true top performers, we'd love to have you use our corporate condo retreat in sunny Orlando, Florida! Take the family and have fun! This fabulous property is located within 5 minutes of Disney's Magic Kingdom, Epcot, Downtown Disney, and MORE! You work hard – take a vacation on US! Yes, bring your laptop – we have complimentary high speed internet access. The property has a spectacular view of the nightly fireworks show at Epcot, family oriented activities, multiple pools, a lazy river, outdoor grilling areas, a fitness center, and multiple restaurants for your enjoyment. Ask your affiliate manager for more details!

Lexium International™ – The most trusted name in designer pharmacology and the world leader in designer pharmacological alternatives dedicated to applying state of the art technologies to provide safe and effective products.

If you would like to apply for our affiliate program, click here.

CONTACT US

Lexium International US
Address: 1591 Hayley Lane #203 Fort Myers, Fl 33907
Toll Free: 888-666-1714
Los Angeles, CA: 310-622-9808
New York, NY: 646-490-1347

United Kingdom
Office Phone: 0161 971 6681
Direct Phone: 07780 006594

OTHER LINKS

Affiliate Program
Affiliate & Wholesale Agreement
Anti-Spam Policy
DMCA Notices
Earnings Disclaimer
External Links Policy
Privacy Policy
Terms & Conditions

CONNECT WITH US

facebook.com/lexiuminternational
@lexiuminternational
youtube.com/lexiuminternational

Have Questions? Click Here!

PETITION EXHIBIT 3

cellmarkbiopharma.com website excerpts
(captured April 26, 2016)

File Edit View History Bookmarks Tools Help

cognify cellmark - - Yahoo... | Advanced Medical Nutritio...

www.cellmarkbiopharma.com

CellMark Biopharma

HOME MEDICAL NUTRITION PRODUCTS MEDICAL PROFESSIONALS PURCHASE ABOUT

CellAssure™

ADVANCED MEDICAL NUTRITION
FOR ALL CANCER PATIENTS

Leave a message

Our Solutions

CellMark answers the 'Day of Diagnosis' question "What do I do now?"

CellAssure™

Fact: 20-40% of cancer deaths are from malnutrition (cachexia) not cancer and the medical community agrees that nutritional intervention is imperative. **CellAssure™** is an innovative medical nutrition drink designed for the needs of all cancer patients battling the detrimental effects of cancer and cancer treatments (surgery, radiation, chemotherapy and emotional turmoil).

Cognify™ (Ampheta-GPC)

Cognify™ is the world's first product designed specifically to alleviate chemo brain (chemo fog) signs and symptoms. Our patent pending formulation enhances neurocognitive functioning while providing enhanced neuroprotection.

About Us

Know more about our company

Serving the medical community and their patients at the highest level is at the core of our DNA. Our passion for delivering products that profoundly impact patients total health drive our founders, formulators and scientists to push the boundaries of medical nutrition to new heights every single day.

Fueling The Fight Against Cancer

While most people think that their 'Day of Diagnosis' is when their battle with cancer begins – we know better. We know that on the 'Day of Diagnosis' that patients are already compromised and their nutritional challenges have already started and their need for medical nutrition is now! We know it is far better to be proactive than reactive and that is why our products are designed to help you bring the figh to cancer from day one!

Problem worth solving

- Over 14 Million diagnosed with cancer in 2014.
- 'Day of Diagnosis': "What do I do now?".
- 20% – 40% of cancer patients die from malnutrition (cachexia) not cancer itself.
- Up to 82% of chemo patients have 'chemo brain'.
- 'Chemo brain' may last up to 10 years.

Leave a messaa message

CONTACT INFORMATION

CellMark Biopharma LLC
Address: 1591 Hayley Ln Ste 201
Fort Myers, FL 33907
Telephone: 888-444-7992

OTHER LINKS

PRIVACY POLICY

TERMS AND CONDITIONS

SITE MAP

CONTACT US

A Focused Fight Against Chemo Brain

Cognify™ (Ampheta-GPC)

Chemo brain is a common term used by cancer patients use to describe thinking, memory and concentration problems that can occur during, and after, cancer treatment. Chemo brain can also be called chemo fog, Mild Cognitive Impairment (MCI), or chemotherapy-related cognitive dysfunction.

Cognify™ is the world's first product designed specifically to alleviate chemo brain (chemo fog) signs and symptoms. Our patent pending formulation enhances neurocognitive functioning while providing enhanced neuroprotection.

Some recent neuroimaging studies have shown visible changes in the brains of patients treated with chemotherapy. Areas of the brain that have to do with learning and memory seem to be the most affected.

Statistics show that up to 75% of cancer patients may experience chemo brain making it one of the most common side effects reported by cancer patients. For many (up to 35%), this condition persists for months or years following treatment. Click here to visit our online store.

Symptoms can include:

- Memory loss – forgetting things like names, places, dates or appointments
- Difficulty finding the right word for common objects
- Difficulty following the flow of a conversation
- Trouble concentrating or focusing
- Difficulty in multi-tasking
- General confusion

Chemo brain generally describes the alterations in cognitive functioning reflecting the CNS toxic effects of systemic chemotherapy. It's been found that 56 of the 132 FDA approved chemo agents are known to be strong sources of oxidative stress (inflammation). Research has shown that these drugs can damage neural progenitor cells.

Cognify™: The Natural Solution to Chemo Brain

- **Neuroprotection** – protect brain cells/neuro-transmitters against toxins
- **Cognitive Enhancement** – increase cognitive processing and work efficiency

- **Increase Blood Flow** – increase blood flow, nutrients and oxygen to the brain
- **Repair Brain Tissue** – maintain brain cell membranes, repair brain cells & neurons
- **Reduce Inflammation** – decrease inflammation, oxidative stress and inflammatory cytokines
- **Increase Neurotransmitters** – improve cognitive functioning, memory, and processing
- **Promote Neurogenesis** – stimulate the growth of new brain cells

File Edit View History Bookmarks Tools Help

cognify cellmark - - Yahoo... | CellAssure - Cancer Ca...

www.cellmarkbiopharma.com/products/cellassure/patients/

CellMark Biopharma

HOME MEDICAL NUTRITION PRODUCTS MEDICAL PROFESSIONALS PURCHASE ABOUT

CellAssure – Medical Nutrition Drink for Cancer Patients

What is CellAssure?

CellAssure Brochure

CellAssure™

The most common question for cancer patients on their 'Day of Diagnosis' is *"what do I do now?"* or even more important *"what can I do now?"* The answer is simple and complex at the same time – prepare for the fight of your life and plan on winning! Keeping yourself as healthy as possible to be able to withstand the rigors of chemotherapy, radiation, surgery and the emotional stress is absolutely essential.

CellMark Biopharma™ developed a revolutionary new medical nutrition drink, CellAssure, designed for the needs of all cancer patients battling the detrimental effects of cancer and even the side effects from cancer treatments. CellAssure's clinically proven ingredients were scientifically formulated to deliver an unheard of level of health, protection and quality of life for our patients.

Fact: 20-40% of cancer deaths are from malnutrition (cachexia) not cancer and the medical community agrees that nutritional intervention is imperative.

CellAssure is a simple once a day drink created from direct requests by physicians, dietitians and patients battling cancer.

CellAssure includes ingredients clinically proven to:

- Exhibit anti-cancer and anti-tumor properties
- Improve immune system response
- Maintain or increase appetite
- Increase LBM (lean body mass)
- Reduce stress / anxiety and lower cortisol levels
- Provide relief with nausea/vomiting and diarrhea
- Mitigate anemia and improve liver function
- Help reduce inflammation and possibly even pain

Keeping in mind the fact that up to 40% of cancer deaths are from malnutrition (cachexia – the skin and bones look we have all seen) and not cancer itself – it is absolutely critical to put the power of medical nutrition to work immediately. Keeping yourself healthy to be able to fight cancer is absolutely essential and avoiding cachexia can be every bit as important as your chemotherapy and radiation regimens. Many cancer survivors will tell you that chemo and radiation were more difficult for their body to handle than the cancer.

With CellAssure we have literally taken almost every single cancer fighting nutraceutical and nutritional supplement (proven clinically) and put them together in one simple and

Leave a message

Leave a message

Leave a message

convenient medical nutrition product. You would literally have to buy 74 bottles of various products to come close (not equal) to the therapeutic value of CellAssure. The cost of those competing products alone is over $800.00 (nearly $600.00/month more than CellAssure). For about the simple cost of a drive-thru meal ($8/day) you will provide your body with the most advanced medical nutrition designed specifically to fuel the fight against cancer!

Click here to visit our online store.

CellAssure provides 26 grams of pharmaceutical quality ultra-micro filtered pure whey protein isolates for optimal absorption and retention of lean body mass, unique complex carbohydrates for consistent sustainable energy and ZERO sugar (cancer cells thrive on sugar). There is no other product on the market that comes even close to that, but those necessary and critical components are only scratching the surface of why CellAssure delivers more to the cancer patient than all others combined!

"Weight loss occurs in up to 87% of people with cancer. Cancer patients are at risk for malnutrition resulting from the disease itself, from anticancer treatments such as surgery, radiation, and chemotherapy; and/or from anorexia and cachexia due to emotional stress and anxiety."

Cancer is a multi-faceted disease that attacks the body in many ways causing multiple serious side effects, each which needs to be addressed strongly in order for the patient to maintain their health. CellAssure's mission is simple – keeping cancer patients as healthy as possible so their oncologist can kill their cancer with the least amount of side effects/health issues/problems.

Why is CellAssure essential from your Day of Diagnosis?

With figures showing as much as 40% of cancer deaths are from malnutrition (cancer cachexia), the medical community agrees that nutritional intervention is imperative. Cachexia is a series of metabolic changes in the cancer patient's body. Cachexia is initiated when proinflammatory cytokines and other catabolic factors, such as proteolysis-inducing factor and lipid-mobilizing factor are released in tissues and in circulation. Increases in stress, anxiety, cortisol levels, inflammation and decreases in appetite, nutrient absorption, and liver function add to this hypermetabolic scenario.

"Cancer weight loss is associated with poor outcomes for cancer patients—reduced response to therapy, reduced ability to deliver full doses of chemotherapy, stoppages of cancer therapies, increased toxicity, more complications and infections, lower quality of life, and reduced survival."

Cancer cachexia is far more complex and different than other types of weight loss (malnutrition or starvation) and it cannot be reversed by the simple addition of extra calories. CellAssure™ is targeted medical nutrition for these specific inflammatory triggers and all their resultant metabolic abnormalities!

Proper identification of nutrition problems and treatment of nutrition-related symptoms have been shown to stabilize or reverse weight loss in 50% to 88% of oncology patients.

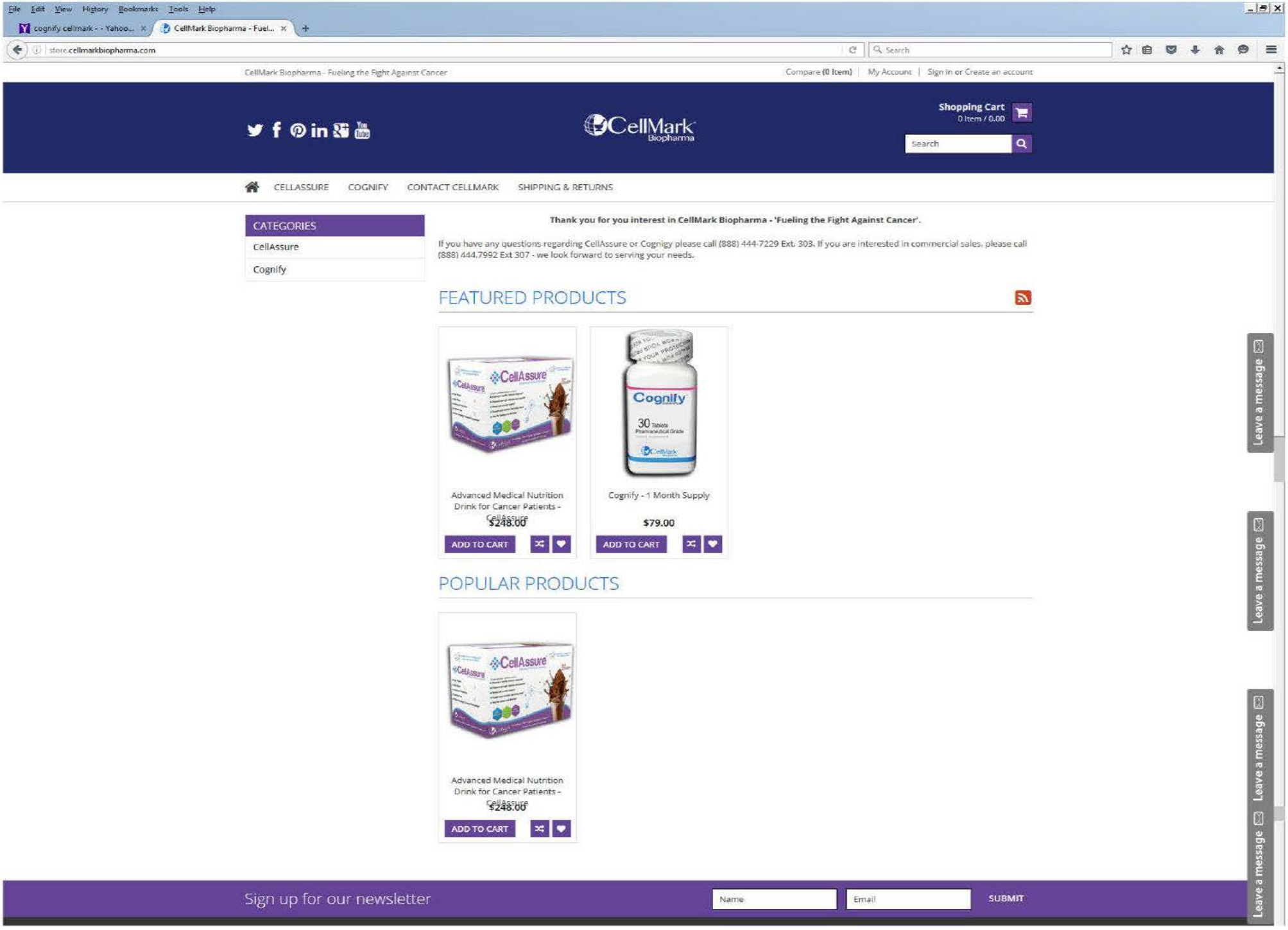
How did we create CellAssure?

CellMark Biopharma™ had to create a medical nutritional product the likes of which the world has never seen. CellAssure had to go far beyond the simple meal replacements and nutritional drinks that are currently on the market. How did we accomplish what was previously impossible?

We had to do something that most companies forget to do: look at the patient as a whole being – a human being – with very specific needs. Our global team of experts had to come up with a specific and complete set of questions that no-one has asked before. Questions from the perspective of physicians, dietitians, scientists and most importantly the cancer patient themselves, questions you **NEED** answered such as:

- What can CellAssure do to massively impact a cancer patient on 'Day of Diagnosis'?
- What specific caloric and nutritional needs do I have as someone diagnosed with cancer?
- What kind of nutritional support can help my immune system in an appropriate manner as someone who is diagnosed with cancer?
- Are there specific active non-drug ingredients that have been clinically proven effective in the fight against cancer?
- How can I keep my appetite up so as not to lose too much weight or get cachexia?
- Can CellAssure help with my patients stress and anxiety or even their cortisol levels?
- Can our formulation help patients with nausea/vomiting and diarrhea?
- Can our formulation help reduce inflammation and possibly even pain?
- Can we densely pack calories into a revolutionary drink without adding massive sugar like the competitors (which of course is the main nutritional source of cancer cells)?
- Can CellAssure help mitigate anemia and improve my liver function?

CellMark Biopharma's team answered all those questions and more to give patients more than just a fighting chance – we gave them a teammate to fight for them and win with them!


File Edit View History Bookmarks Tools Help
cognify cellmark - - Yahoo...
CellMark Biopharma - Fuel...
store.cellmarkbiopharma.com
Search
CellMark Biopharma - Fueling the Fight Against Cancer
Compare (0 Item) | My Account | Sign in or Create an account
CellMark Biopharma
Shopping Cart
0 Item / 0.00
Search
CELLASSURE
COGNIFY
CONTACT CELLMARK
SHIPPING & RETURNS
CATEGORIES
CellAssure
Cognify
Thank you for you interest in CellMark Biopharma - 'Fueling the Fight Against Cancer'.
If you have any questions regarding CellAssure or Cognigy please call (888) 444-7229 Ext. 303. If you are interested in commercial sales, please call (888) 444.7992 Ext 307 - we look forward to serving your needs.
FEATURED PRODUCTS
CellAssure
Advanced Medical Nutrition Drink for Cancer Patients - CellAssure
$248.00
ADD TO CART
Cognify
30 Tablets
Cognify - 1 Month Supply
$79.00
ADD TO CART
POPULAR PRODUCTS
CellAssure
Advanced Medical Nutrition Drink for Cancer Patients - CellAssure
$248.00
ADD TO CART
Sign up for our newsletter
Name
Email
SUBMIT
Leave a message
Leave a message
Leave a message
Leave a message

PETITION EXHIBIT 4

Records of Florida Secretary of State, Division of Corporations: Lexium International's Articles of Organization (filed October 1, 2014)

OCT 1-2014 1[illegible] 608 827-5501 [illegible] P.0[illegible]

L14000153766

Florida Department of State
Division of Corporations
Electronic Filing Cover Sheet

Note: Please print this page and use it as a cover sheet. Type the fax audit number (shown below) on the top and bottom of all pages of the document.

(((H14000230048 3)))

H14000230048 3ABCVV

Note: DO NOT hit the REFRESH/RELOAD button on your browser from this page. Doing so will generate another cover sheet.

FILED
2014 OCT -1 AM 9:19
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

To:
Division of Corporations
Fax Number : (850)617-6383

From:
Account Name : BUSINESS FILINGS
Account Number : 105256001620
Phone : (608)827-5300
Fax Number : (608)827-5501

Enter the email address for this business entity to be used for future annual report mailings. Enter only one email address please.

Email Address: agent@bizfilings.com

RECEIVED
14 OCT -1 PM 12:00
DIVISION OF CORPORATIONS
BUREAU OF COMMERCIAL
INFORMATION SERVICES

FLORIDA LIMITED LIABILITY CO.
Lexium International LLC

OCT - 2 2014
T CLINE

Certificate of Status	0
Certified Copy	1
Page Count	03
Estimated Charge	$155.00

Electronic Filing Menu Corporate Filing Menu Help

FAX AUDIT # **H14000230048 3**

ARTICLES OF ORGANIZATION
OF
Lexium International LLC

ARTICLE I NAME

The name of the limited liability company is: Lexium International LLC

ARTICLE II ADDRESS

The principal place of business and mailing address of this Limited Liability Company shall be 1591 Hayley Lane Ste 203, Fort Myers, Florida 33907.

FILED
2014 OCT -1 AM 9:48
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

ARTICLE III INITIAL REGISTERED AGENT & STREET ADDRESS

The name and address of the registered agent are: Business Filings Incorporated, 515 E. Park Avenue, Tallahassee, Florida 32301. Located in the County of Leon.

Having been named as registered agent and to accept service of process for the above stated limited liability company at the place designated in this certificate, I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relating to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent as provided for in Chapter 605, F.S..

Signature: _____ Date: *October 1, 2014*
Mark Williams, A.V.P. *Business Filings Incorporated*

ARTICLE IV MANAGERS/MEMBERS

The management of the limited liability company is reserved for the members and the names and addresses of the members of the Limited Liability Company are:
Derek Vest, 11561 Isle of Palms Dr, Fort Myers, Florida 33931
Mary Lirette, 18167 Phlox Dr, Fort Myers, Florida 33967

FAX AUDIT # H14000230048 3

FAX AUDIT # H14000230048 3

ARTICLE V DURATION

The duration for the limited liability company shall be: Perpetual.

Date: October 1, 2014

(In accordance with section 605.0203 (1) (b), Florida Statutes, the execution of this document constitutes an affirmation under the penalties of perjury that the facts stated herein are true. I am aware that any false information submitted in a document to the Department of State constitutes a third degree felony as provided for in s.817.155, F.S.)

FILED
2014 OCT -1 AM 9:48
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

Business Filings Incorporated, Organizer
Mark Williams, A.V.P.
Authorized Representative
Prepared by Mark Williams, Business Filings Incorporated, 8020 Excelsior Dr., Suite 200, Madison, WI 53717
608-827-5300

FAX AUDIT # *H14000230048 3*

PETITION EXHIBIT 5

Records of Florida Secretary of State, Division of Corporations: Lexium International's 2015 Annual Report (filed January 7, 2015)

2015 FLORIDA LIMITED LIABILITY COMPANY ANNUAL REPORT

FILED
Jan 07, 2015
Secretary of State
CC4660366890

DOCUMENT# L14000153766

Entity Name: LEXIUM INTERNATIONAL LLC

Current Principal Place of Business:

1591 HAYLEY LANE STE 203
FORT MYERS, FL 33907

Current Mailing Address:

1591 HAYLEY LANE STE 203
FORT MYERS, FL 33907

FEI Number: APPLIED FOR

Certificate of Status Desired: Yes

Name and Address of Current Registered Agent:

BUSINESS FILINGS INCORPORATED
515 E PARK AVE
TALLAHASSEE, FL 32301 US

The above named entity submits this statement for the purpose of changing its registered office or registered agent, or both, in the State of Florida.

SIGNATURE:

Electronic Signature of Registered Agent — Date

Authorized Person(s) Detail :

Title	MGRM
Name	VEST, DEREK
Address	11561 ISLE OF PALMS DR
City-State-Zip:	FORT MYERS FL 33931

I hereby certify that the information indicated on this report or supplemental report is true and accurate and that my electronic signature shall have the same legal effect as if made under oath; that I am a managing member or manager of the limited liability company or the receiver or trustee empowered to execute this report as required by Chapter 605, Florida Statutes; and that my name appears above, or on an attachment with all other like empowered.

SIGNATURE: DEREK VEST PRESIDENT 01/07/2015

Electronic Signature of Signing Authorized Person(s) Detail — Date

PETITION EXHIBIT 6

Records of Florida Secretary of State,
Division of Corporations:
Lexium International's 2015 Amended
Annual Report
(filed April 14, 2015)

2015 FLORIDA LIMITED LIABILITY COMPANY AMENDED ANNUAL REPORT

FILED
Apr 14, 2015
Secretary of State
CC5575060293

DOCUMENT# L14000153766

Entity Name: LEXIUM INTERNATIONAL LLC

Current Principal Place of Business:

1591 HAYLEY LANE STE 203
FORT MYERS, FL 33907

Current Mailing Address:

1591 HAYLEY LANE STE 203
FORT MYERS, FL 33907

FEI Number: 36-4797187

Certificate of Status Desired: Yes

Name and Address of Current Registered Agent:

BUSINESS FILINGS INCORPORATED
515 E PARK AVE
TALLAHASSEE, FL 32301 US

The above named entity submits this statement for the purpose of changing its registered office or registered agent, or both, in the State of Florida.

SIGNATURE:

Electronic Signature of Registered Agent — Date

Authorized Person(s) Detail :

Title	AUTHORIZED MEMBER	Title	AUTHORIZED MEMBER
Name	LIRETTE, MARY E	Name	VEST, TARA E
Address	18167 PHLOX DR	Address	1591 HAYLEY LANE STE 203
City-State-Zip:	FORT MYERS FL 33967	City-State-Zip:	FORT MYERS FL 33907

I hereby certify that the information indicated on this report or supplemental report is true and accurate and that my electronic signature shall have the same legal effect as if made under oath; that I am a managing member or manager of the limited liability company or the receiver or trustee empowered to execute this report as required by Chapter 605, Florida Statutes; and that my name appears above, or on an attachment with all other like empowered.

SIGNATURE: TARA VEST MBR 04/14/2015

Electronic Signature of Signing Authorized Person(s) Detail — Date

PETITION EXHIBIT 7

Lexium International's Petition to Limit or Quash Civil Investigative Demand (filed June 13, 2016)

BEFORE THE FEDERAL TRADE COMMISSION

IN THE MATTER OF LEXIUM INTERNATIONAL, LLC.

PETITION TO LIMIT OR QUASH CIVIL INVESTIGATIVE DEMAND BY LEXIUM INTERNATIONAL, LLC

Petitioner, Lexium International, LLC ("Lexium"), hereby petitions the Federal Trade Commission ("FTC" or "Commission"), pursuant to 16 C.F.R. § 2.7(d), to limit or quash the Civil Investigative Demand ("CID") that it served on May 26, 2016. The FTC issued the CID pursuant to its alleged authority under § 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1. A former officer and owner of Lexium's predecessor, Derek Vest ("Vest"), has received a target letter from the U.S. Attorney for the Middle District of Florida. In order to ensure that his Fifth Amendment right against self-incrimination is not waived by the production of information to the FTC, Lexium files this Petition to limit the production of any privileged information pursuant to the CID.

BACKGROUND

Gentech Pharmaceutical, LLC ("Gentech") was a Delaware limited liability company formed in 2010. It was owned and managed by Vest. The company later changed its name to Lexium. Gentech developed and sold supplement products for cognitive function, weight loss and sleep aid. Lexium continues to sell those products. Vest sold his interest in Lexium in 2015. His only remaining connection to Lexium is as a consultant.

On May 26, 2016, the Commission served a Civil Investigative Demand ("CID") on Lexium with 42 interrogatories (not counting subparts) and 36 document specifications. Ex. 1.

The CID seeks information on broad topics, including corporate information, product development and formulation, manufacturing, labels and advertising, claim substantiation, sales, and return/refund policies. The CID defines "Company", "Company's", "You" and "Your" to mean:

> Lexium International, LLC, sometimes d/b/a Lexium Laboratories, its wholly or partially owned subsidiaries including Gentech Pharmaceutical, LLC, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Tara Vest, Mary Lirette, and Dr. Stan Headley.

Ex. 1 § I.G. The scope of search provision is similarly broad:

> This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

Id. § II.I. The return date on the CID is June 14, 2016.

The Commission staff and Lexium had a meet and confer teleconference on June 8. During that conference, the parties discussed a schedule for producing information to the Commission, and the scope of the definitions and requests. Lexium informed the staff that Vest had received a criminal target letter from the U.S. Attorney for the Middle District of Florida. Ex. 2. The letter to Vest states that "you are now a target of a Federal Grand Jury investigation in this District into introducing and delivering for introduction into interstate commerce misbranded drugs and other matters and possible violations of federal criminal laws. The United States is prepared to proceed before a Federal Grand Jury to seek charges against you." On June 8, the FTC staff received a copy of that letter.

ARGUMENT

The act of compelling the production of interrogatory responses and documents implicates Vest's Fifth Amendment rights and the CID should be limited. The CID, while served on Lexium, requires Vest to produce information to the FTC. *See* Ex. 1 § I.G ("'Company' shall mean Lexium ... and all directors, officers, members , employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest"); *id.* § II.I (CID requires a search for documents and information in the possession of Lexium and its "attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity."). Vest's turning over of the extensive information and documents specified in the CID would admit their existence and authenticity. Accordingly, Lexium seeks to limit the CID to ensure that its officer and sole shareholder, Vest, can protect and assert his Fifth Amendment privilege.

The Fifth Amendment protects a person from being compelled to produce information that would incriminate that person. *See, e.g.*, *Fisher v. United States*, 425 U.S. 391, 397 (1976). The U.S. Supreme Court has long held that a government subpoena cannot compel the holder of documents and information to perform an act that may have testimonial aspects and an incriminating effect. See, e.g., *United States v. Doe*, 465 U.S. 605, 612 (1984). The act of production is privileged under the Fifth Amendment and cannot be compelled without a statutory grant of use immunity pursuant to 18 U. S. C. §§ 6002 and 6003. *Id.* at 617.

In *United States v. Hubbell*, 530 U.S. 27 (2000), the Court found that the act of producing documents in response to a subpoena may have a compelled testimonial aspect. The act of production itself may implicitly communicate statements of fact. By producing documents in

compliance with a subpoena, the witness would admit that the papers existed, were in his possession or control, and were authentic. *Id.* at 36.

Hubbell also found that the Fifth Amendment protects a person who would be compelled to identify information and them produce it:

> It is apparent from the text of the subpoena itself that the prosecutor needed respondent's assistance both to identify potential sources of information and to produce those sources. See Appendix, infra. Given the breadth of the description of the 11 categories of documents called for by the subpoena, the collection and production of the materials demanded was tantamount to answering a series of interrogatories asking a witness to disclose the existence and location of particular documents fitting certain broad descriptions. The assembly of literally hundreds of pages of material in response to a request for "any and all documents reflecting, referring, or relating to any direct or indirect sources of money or other things of value received by or provided to" an individual or members of his family during a 3-year period, ... is the functional equivalent of the preparation of an answer to either a detailed written interrogatory or a series of oral questions at a discovery deposition. Entirely apart from the contents of the 13,120 pages of materials that respondent produced in this case, it is undeniable that providing a catalog of existing documents fitting within any of the 11 broadly worded subpoena categories could provide a prosecutor with a "lead to incriminating evidence," or "a link in the chain of evidence needed to prosecute."

Id. at 41-42. The Court concluded that:

> In sum, we have no doubt that the constitutional privilege against self-incrimination protects the target of a grand jury investigation from being compelled to answer questions designed to elicit information about the existence of sources of potentially incriminating evidence. That constitutional privilege has the same application to the testimonial aspect of a response to a subpoena seeking discovery of those sources. Before the District Court, the Government arguably conceded that respondent's act of production in this case had a testimonial aspect that entitled him to respond to the subpoena by asserting his privilege against self-incrimination.

Id. at 43-44.

On its face, the CID seeks the production of information and documents in Vest's possession by defining "Company" to include Lexium and "its directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing,

including Derek Vest...." Ex. 1 § I.G; *see also id.* § II.I (requiring the search for and production of material by CellMark and its "attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity."). Compelling Vest – who was an owner and officer of Gentech and is now a consultant to Lexium – to produce such information implicates his Fifth Amendment right against self-incrimination. Lexium understands that Vest does not intend to waive his constitutional rights. As such, the CID should be limited or quashed to the extent its requires the production of such protected material.

In addition, the Fifth Amendment is implicated when a witness is "compelled to take the witness stand and answer questions designed to determine whether he has produced everything demanded by the subpoena." *Hubbell*, 530 U.S. at 37. Here, the CID's instructions require a sworn certificate that "all of the documents, information and tangible things required" by the CID have been produced. Ex. 1 at 1-2. Thus, the CID should be limited to exclude the requirement that Lexium certify that all documents and information of Vest have been provided to the FTC.

Further, Lexium brings this Petition because Vest is a former officer of Lexium. The Second Circuit has held that:

> This case presents the question of whether an ex-employee of a corporation may assert a Fifth Amendment privilege to refuse to respond to a grand jury subpoena demanding that he produce documents belonging to his former employer on the ground that the act of producing the documents would be both testimonial and incriminating. Because we conclude that a Fifth Amendment privilege is available to the ex-employee in such circumstances, we affirm the order of the district court denying the government's motion to compel production pursuant to the subpoenas in this case.

In re Three Grand Jury Subpoenas Duces Tecum, 191 F.3d 173, 174 (2d Cir. 1999). Thus, the CID should be limited or quashed to make clear that Vest, a former officer, may invoke his right against self-incrimination.

Finally, Lexium, as a limited liability company and on behalf of its directors, officers, members, employees, agents, consultants and representatives, object to the CID based on the Fifth Amendment privilege against self-incrimination. Cases holding that the Fifth Amendment does not apply to corporate entities are no longer good law in light of *Citizens United v. FEC*, 558 U.S. 310 (2010) and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). In *Citizens United*, the Supreme Court ruled that the government cannot prohibit political expenditures by corporations based on the speaker's corporate identity. The *Hobby Lobby* decision recognized that a closely-held corporation had religious liberties.

Citizens United rejected the premise that a corporate entity's status, advantages of using the corporate form, or the potentially corrupting influence of corporations could justify denial of First Amendment rights. *Citizens United* requires a reexamination of the outdated rationales used to deny a corporation's right against self-incrimination. First, because *Citizens United* treats corporate entities as persons capable of exercising their constitutional rights, the government can hardly still claim that the Fifth Amendment is a "purely personal" privilege belonging only to natural persons – especially because criminal statutes, as well as all the other prongs of the Fifth Amendment, treat a corporation as a "person." Second, because *Citizens United* explicitly rejects discrimination against corporations based upon the "special advantages" of the corporate form, that rationale can no longer serve as a basis to deny corporations a right against self-incrimination. Finally, the government's asserted interest in enforcing criminal laws against corporations can no longer stand as a reason for differential treatment, because there is no for applying that interest solely to corporate crime and not to crimes committed by individuals.

Corporations can invoke rights under other prongs of the Fifth Amendment. *See, e.g., United States v. Martin Linen Supply Co.*, 430 U.S. 564, 569 (1977) (applying Fifth Amendment double

jeopardy clause to corporation); *Mackin v. United States*, 117 U.S. 348 (1886) (applying grand jury clause to corporation); *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 412 (1922) (applying Fifth Amendment takings clause to corporation); *Noble v. Union River Logging R.R. Co.*, 147 U.S. 165, 171, 177 (1893) (applying Fifth Amendment due process clause to corporation). For four of the five prongs of the single-sentence Amendment, its subject – the word "person" – includes corporations. Only as to self-incrimination has the same word been given a different meaning.

Thus, the Commission should quash or limit the CID to allow "the Company" (as broadly defined in the CID) to withhold information and documents pursuant to the Fifth Amendment's right against self-incrimination.

CONCLUSION

For the foregoing reasons, to the extent that the CID compels the production of interrogatory responses and documents protected by the Fifth Amendment, Lexium's Petition to Limit or Quash the CID should be granted.

Dated: June 13, 2016

Respectfully submitted,

Richard J. Oparil
PORZIO, BROMBERG & NEWMAN P.C.
1200 New Hampshire Ave. NW, Suite 710
Washington, DC 20036
(202) 517-1888
(202) 517-6322 (fax)
rjoparil@pbnlaw.com

Counsel for Petitioner
Lexium International, LLC

CERTIFICATION

Pursuant to 16 C.F.R. § 2.7(d)(2), counsel for Lexium hereby certifies that counsel met and conferred with FTC counsel in a good faith attempt to resolve by agreement the issues set forth in this Petition, but the parties were unable to reach agreement.

Richard J. Oparil

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2016, I caused the original and 12 copies to the foregoing Petition to Limit or Quash with attached exhibits to be filed by hand delivery to the Secretary of the Federal Trade Commission, 601 New Jersey Ave., NW, Washington, DC 20580, and one copy to be served by email and hand delivery to Carolyn L. Hann, Esq., Federal Trade Commission, 600 Pennsylvania Ave., NW, Mail Drop CC-10528, Washington, DC 20580.

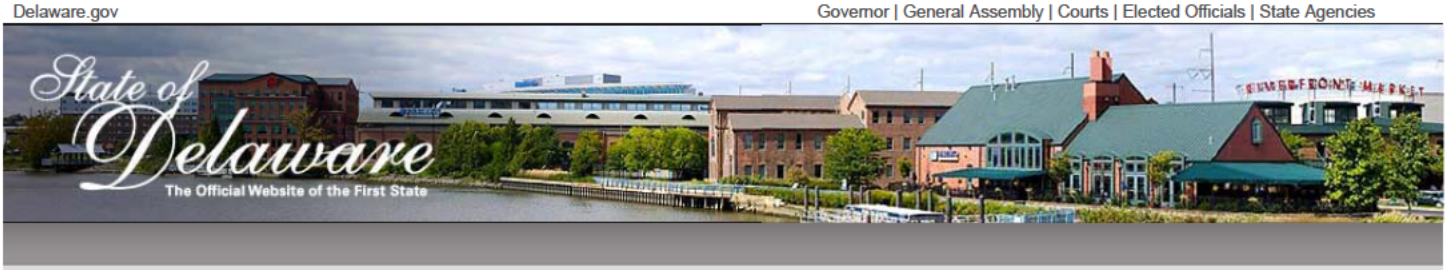
Richard J. Oparil

Lexium’s exhibits in support of its administrative Petition to Limit or Quash the CID have been omitted.

These documents already appear in the record as the FTC's Petition Exhibit 12 (Lexium CID) and Petition Exhibit 14 (target letter from the U.S. Attorney’s Office).

PETITION EXHIBIT 8

Records of Delaware Department of State,
Division of Corporations regarding
CellMark BioPharma
(accessed September 13, 2016)



Department of State Division of Corporations

Allowable Characters

HOME
About Agency
Secretary's Letter
Newsroom
Frequent Questions
Related Links
Contact Us
Office Location

SERVICES
Pay Taxes
File UCC's
Delaware Laws Online
Name Reservation
Entity Search
Status
Validate Certificate
Customer Service Survey

INFORMATION
Corporate Forms
Corporate Fees
UCC Forms and Fees
Taxes
Expedited Services
Service of Process
Registered Agents
GetCorporate Status
Submitting a Request
How to Form a New Business Entity
Certifications, Apostilles & Authentication of Documents

Frequently Asked Questions View Search Results

Entity Details

THIS IS NOT A STATEMENT OF GOOD STANDING

File Number:	5736792	Incorporation Date / Formation Date:	4/28/2015 (mm/dd/yyyy)
Entity Name:	CELLMARK BIOPHARMA, LLC		
Entity Kind:	Limited Liability Company	Entity Type:	General
Residency:	Domestic	State:	DELAWARE

REGISTERED AGENT INFORMATION

Name:	BUSINESS FILINGS INCORPORATED		
Address:	108 WEST 13TH ST		
City:	WILMINGTON	County:	New Castle
State:	DE	Postal Code:	19801
Phone:	800-981-7183		

Addi ional Information is available for a fee. You can retrieve Status for a fee of $10.00 or more detailed information including current franchise tax assessment, current filing history and more for a fee of $20.00.

Would you like ○ Status ○ Status,Tax & History Information Submit

Back to Entity Search

For help on a particular field click on the Field Tag to take you to the help area.

PETITION EXHIBIT 9

"About Us - Management" page from cellmarkbiopharma.com website (captured April 21, 2016)

File Edit View History Bookmarks Tools Help

cognify cellmark - - Yahoo... | Management

www.cellmarkbiopharma.com/about-us/management/

Search

CellMark Biopharma

HOME MEDICAL NUTRITION PRODUCTS MEDICAL PROFESSIONALS PURCHASE ABOUT

Management

Derek Vest

Founder / CEO / Chairman

As CEO, Mr. Vest leads day-to-day operations with an emphasis on product development, global sales, and team development. Prior to CellMark, Mr. Vest was the Founder / CEO of Gentech Pharmaceuticals, one of the world's largest providers of non-prescription pharmaceuticals for doctors, hospitals, pharmacies and other non-prescription outlets. Gentech's products were manufactured in the US and UK and distributed and sold in 47 countries globally. Gentech was acquired by Lexium International in 2015.

Prior to Gentech, Mr. Vest was the Founder / CEO of Superior Respiratory, a leading medical sales and service company for respiratory patients. In developing Superior, Mr. Vest also opened a full scale national pharmaceutical manufacturing facility creating unique respiratory medications for Medicare/Private Insurance patients throughout US. Superior was acquired by Lincare Inc in 2009.

Currently Mr. Vest holds passive equity and Board positions in several other companies including Kalos Therapeutics, an emerging biomedical company in San Diego with the exclusive patent to develop the ANP (atrial natriuretic peptide) family of peptides as a new mechanism for the treatment of cancer as well as a novel drug therapy for AMD, Med Office Direct, 1st in-class virtual distributor of medical supplies, and Mojo Beverage International, a 'designer functional beverages' company with distribution in the US and Asia.

Dr. Anthony Spotora – Pharm. D., MBA

Pharmacy Director

Dr. Spotora has degrees in Pharmacy, Education as well as a MBA. As a Pharm. D., he has worked from owning his own pharmacies to being the Vice President of Managed Care Sales and Marketing for Eckerd Drugs (4th largest drug chain in US with 2,800 stores and later acquired by CVS). His career also included being the COO and partner in a 40+ physician outpatient medical/surgical center outside Chicago which was acquired by Mercy Hospital. He was also brought in to be the Director of Development, Planning and Analysis for Cigna Healthcare of Florida

Dr. Spotora has consulted on a global scale to a variety of companies using his prodigious skills in both pharmacy and business development.

Dr. Spotora has intricate knowledge of oncology drugs and treatments and shares a tremendous passion for changing the lives of cancer patients through advanced medical nutrition.

Craig A. Pisaris-Henderson

Leave a message

Leave a message

Leave a message

COO / Board Member

As COO, Mr. Pisaris-Henderson oversees day-to-day non-medical operations including marketing and corporate finances. Through the past 25 years Mr. Pisaris-Henderson has been immersed in the digital and data analytic sector with an emphasis on leveraging 'big data' in the development of predictive business processes and marketing strategies for private and public entities. Prior to CellMark Mr. Pisaris-Henderson founded Lexos Media, a pioneering digital ad serving technology maintaining the largest patent portfolio related to cursor, touch, and eye-gaze integration (analytics) with online digital advertising.

Prior to Lexos, Mr. Pisaris-Henderson was the Founder / CEO / Chairman of MIVA, Inc. (NASDAQ: MIVA f/k/a FindWhat.com NASDAQ: FWHT). Mr. Pisaris-Henderson lead MIVA, a global leader in analytically driven performance-based marketing and commerce enabling services, to global sales in excess of $225M, a NASDAQ market valuation approaching $1B, and over 500 team members with office in the US, Japan, UK, and throughout the EU.

Mr. Pisaris-Henderson has been a featured speaker at numerous investment banking and industry conferences, is the recipient of the Ernst & Young's Entrepreneur of the Year Award, awarded a DBAh in Business Administration, and been awarded many other national and regional distinctions. Currently Mr. Pisaris-Henderson serves as a board member of Florida Gulf Coast University's College of Business, Lexos Media and several other private firms.

Erica Boliek, M.M.S., PA-C, ATC, CPCC

Chief of Research and Development

Ms. Erica Boliek, M.M.S., PA-C, is a clinician-scientist who has spent her time cultivating a broad experience in research, globally. Among her other credentials are Board Certified Athletic Trainer, Certified Cancer Coach and manuscript reviewer for the Journal of Athletic Training and the American College of Sports Medicine. She is also published works in the Journal of American Academy of Physician Assistants.

Her work has been focused on brain trauma and she has been invited multiple times to work/speak at the Consensus Conference on Concussion in Sport in Zurich, Switzerland and played an integral part in the working group for the module changes in SCAT 3 testing (a standardized tool for evaluating concussions). Further, Ms. Boliek has both lectured and led workshops at several conferences on Pediatric Concussions & Injurie Prevention, including the 2012 and 2013 International Pediatric Orthopedic Society. She was the Key Note Speaker for the 2014 ATAF Annual Symposium for Concussion Evaluation and Management as well. Her personal favorite lecture she gave was at Oxford University delivered entirely in Latin.

She has lead the design, development and implementation of the Concussion and Sports Medicine Program for the Lee Memorial Health System and Lee County Schools. She was involved early on in her career with the Children's Hospital of Pennsylvania in the Pediatric and Adolescent Research Department for Concussion Management and Intervention. She helped facilitate the implementation of ImPACT® Concussion Testing.

Her extensive background in clinical research, solutions development based on mass data analysis, and true pathophysiology solutions enable her to lead an international group of scientists and formulators to generate clinically significant products.

She serves on multiple boards of both hospitals and private institutions.

Dr. Stan Headley, M.D.

Medical Director

Dr. Headley is nationally recognized as a visionary thought leader in integrative wellness. With nearly 24 years of clinical, research and medical teaching experience, Dr. Headley's career is a model for effective partnership between the best of conventional and complementary medicines.

Throughout his career Dr. Headley has held positions in pharmaceutical sales and research with MERCK, clinical Family Medicine and operations consulting for Integrative Medical Clinics, and he has served as Medical Director for multiple international companies.

Dr. Headley has been a key note speaker at medical symposiums, teaching hospitals, expos and events, a guest on numerous U.S and International health talk live radio and television programs, and the author of "A Pocket Guide to ADHD".

- Doctorate of Medicine
- Traditional Naturopath via American Naturopathic Medical Association

- American Academy of Anti-Aging Medicine
- Fellow – American College of Clinical Thermography

Leave

CONTACT INFORMATION

CellMark Biopharma LLC
Address: 1591 Hayley Ln Ste 201
Fort Myers, FL 33907
Telephone: 888-444-7992

OTHER LINKS

PRIVACY POLICY

TERMS AND CONDITIONS

SITE MAP

CONTACT US

PETITION EXHIBIT 10

cellmarkbiopharma.com blog post
published July 19, 2016
(captured August 24, 2016)

CellMark Biopharma Announces Craig Pisaris-Henderson as New CEO

By CellMark

Craig Pisaris-Henderson – CEO

Fort Myers, FL – (July 19, 2016) – CellMark Biopharma, a leader in Nutritional Science For Cellular Health, announces the appointment of Craig Pisaris-Henderson as new chief executive officer. Pisaris-Henderson previously served as the company's founding chief operating officer, and will succeed Derek Vest, the company's founder and former CEO.

"After years of research and development, going through countless variations of our formulas, leading to our commercial launch earlier this year, we are now structuring CellMark for hyper-growth globally. Craig Pisaris-Henderson has done just that with several corporations," said Vest. "He has a consistent track record of strong leadership with both public and private companies. This combined with his deep operational knowledge and relationships with financial institutions, makes Craig uniquely qualified to lead CellMark into its next phase of global growth."

The appointment of Pisaris-Henderson comes as the company transitions from its early commercial launch in January of 2016 to an 'early-revenue' company seeking to organize itself and its operations for the next stage of growth.

"I'm honored and grateful for the opportunity to continue working with Derek on fulfilling his vision of developing unmet dietary and medical nutritional needs for consumers around the world," said Pisaris-Henderson. "This opportunity reminds me of previous companies such as FindWhat.com and MIVA that, like CellMark, provided a much-needed solution to a consumer group that prior to, had no real source or solution. I believe we are potentially looking at a similar growth story – except this time instead of helping advertisers, we have the potential of helping

CellMark Biopharma is a leading global developer of dietary supplements specifically used as medical nutrition providing consumers with supplements developed to help with specific dietary issues not previously met by other known dietary supplements. CellMark Biopharma is headquartered in Fort Myers, Florida. For more information visit www.cellmarkbiopharma.com or call (888) 444-7992.

Leave a Reply

You must be logged in to post a comment.

CONTACT INFORMATION

CellMark Biopharma LLC
Address: 1591 Hayley Ln Ste 201
Fort Myers, FL 33907
Telephone: 888-444-7992

PETITION EXHIBIT 11

FTC Omnibus Resolution # 0023191
(issued August 13, 2009)

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or continuation of actions to enforce any such compulsory process after expiration of the ten year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq. and supplements thereto.

By direction of the Commission. Donald S. Clark

Donald S. Clark
Secretary

Issued: August 13, 2009

PETITION EXHIBIT 12

FTC Civil Investigative Demand directed to
Lexium International LLC
(issued May 24, 2016)

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

Lexium International, LLC
1591 Hayley Lane
Suite 203
Fort Myers, FL 33907

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

☒ You are required to produce the tangible things described on the attached schedule. Produce such things to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS, ANSWERS TO INTERROGATORIES, REPORTS, AND/OR TANGIBLE THINGS MUST BE AVAILABLE

JUN 14 2016

3. SUBJECT OF INVESTIGATION

See attached resolution

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Connor Sands/Lynne Colbert Federal Trade Commission 600 Pennsylvania Ave., NW Mail Drop CC-10528 Washington, DC 20580	Carolyn L. Hann Federal Trade Commission 600 Pennsylvania Ave., NW Mail Drop CC-10528 Washington, DC 20580 202-326-2745

DATE ISSUED	COMMISSIONER'S SIGNATURE
May 24, 2016	Terrell McSweeny

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

A copy of the Commission's Rules of Practice is available online at http://bit.ly/FTCRulesofPractice. Paper copies are available upon request.

Form of Certificate of Compliance*

I/We do certify that all of the documents, information and tangible things required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document or tangible thing responsive to this Civil Investigative Demand has not been submitted, the objections to its submission and the reasons for the objection have been stated.

If an interrogatory or a portion of the request has not been fully answered or a portion of the report has not been completed, the objections to its submission and the reasons for the objections have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or continuation of actions to enforce any such compulsory process after expiration of the ten year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq. and supplements thereto.

By direction of the Commission. Donald S. Clark

Donald S. Clark
Secretary

Issued: August 13, 2009

CIVIL INVESTIGATIVE DEMAND
SCHEDULE FOR PRODUCTION OF DOCUMENTS AND ANSWERS
TO WRITTEN INTERROGATORIES

I. DEFINITIONS

As used in this Civil Investigative Demand, the following definitions shall apply:

A. "**Advertisement**" or "**advertising**" or "**ad**" means any written or verbal statement, illustration, or depiction that promotes the sale of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media include, but are not limited to, packaging and labeling; promotional materials; print; television; radio; and internet, social media, and other digital content.

B. "**And**," as well as "**or**," shall be construed both conjunctively and disjunctively, as necessary, in order to bring within the scope of any specification in this Schedule all information that otherwise might be construed to be outside the scope of the specification.

C. "**Any**" shall be construed to include "**all**," and "**all**" shall be construed to include the word "**any**."

D. **"Chargeback"** shall mean a transaction that is returned as a financial liability to an acquirer by a card issuer, usually because of a disputed transaction. The acquirer may then return or "charge back" the transaction to the merchant.

E. "**CID**" means the Civil Investigative Demand, including the attached Resolution and this Schedule, and including the Definitions, Instructions, and Specifications.

F. "**Communication**" means any transmission or receipt of facts, information, opinions, or thought, whether conveyed in writing, orally, electronically, or by any other means, including written memorializations of oral communications.

G. "**Company**," "**Company's**," "**You**," or "**Your**" means Lexium International, LLC, sometimes d/b/a Lexium Laboratories, its wholly or partially owned subsidiaries including Gentech Pharmaceutical, LLC, unincorporated divisions, joint ventures, operations under assumed names, and affiliates, and all directors, officers, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Tara Vest, Mary Lirette, and Dr. Stan Headley.

H. "**Component**" means any substance intended for use in the manufacture of a dietary supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients and other ingredients.

I. "**Continuity Program**" means any plan, arrangement, or system under which a consumer receives periodic shipments of products or the provision of services without prior notification by the seller before each shipment or service period, regardless of any trial or approval period

allowing the consumer to return or be reimbursed for the product or service.

J. "**Dietary ingredient**" means a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of above ingredients.

K. "**Document**" means the complete original and any non-identical copy (whether different from the original because of notations on the copy or otherwise), regardless of origin or location, of any written, typed, printed, transcribed, filmed, punched, or graphic matter of every type and description, however and by whomever prepared, produced, disseminated or made, including but not limited to any advertisement, book, pamphlet, periodical, contract, correspondence, file, invoice, memorandum, note, telegram, report, record, handwritten note, working paper, routing slip, chart, graph, paper, index, map, tabulation, manual, guide, outline, script, abstract, history, calendar, diary, agenda, minute, code book or label. **"Document" shall also include all documents, materials, and information, including Electronically Stored Information, within the meaning of the Federal Rules of Civil Procedure.**

L. "**Each**" shall be construed to include "**every**," and "**every**" shall be construed to include "**each**."

M. "**Electronically Stored Information**" or "**ESI**" means the complete original and any non-identical copy (whether different from the original because of notations, different metadata, or otherwise), regardless of origin or location, of any writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any electronic medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. This includes, but is not limited to, electronic mail, instant messaging, videoconferencing, and other electronic correspondence (whether active, archived, or in a deleted items folder), word processing files, spreadsheets, databases, and video and sound recordings, whether stored on: cards; magnetic or electronic tapes; disks; computer hard drives, network shares or servers, or other drives; cloud-based platforms; cell phones, PDAs, computer tablets, or other mobile devices; or other storage media.

N. "**FTC**" or "**Commission**" means the Federal Trade Commission.

O. "**Identify**" or "**the identity of**" shall be construed to require identification of (a) natural persons by name, title, present business affiliation, present business address and telephone number, or if a present business affiliation or present business address is not known, the last known business and home addresses; and (b) businesses or other organizations by name, address, identities of natural persons who are officers, directors or managers of the business or organization, and contact persons, where applicable.

P. "**Ingredient**" means any substance that is used in the manufacture of a dietary supplement and that is intended to be present in the finished dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient.

Q. "**Negative Option**" means, in an offer or agreement to sell or provide any goods or

services, a provision under which the customer's silence or failure to take an affirmative action to reject goods or services or to cancel the agreement is interpreted by the seller as acceptance of the offer. The term includes a provision in offers or agreements involving automatic renewals, Continuity Programs, and Prenotification Negative Option Plans covered by the Commission's Rule entitled the "Use of Prenotification Negative Option Plans," 16 C.F.R. Part 425 (2014) (Prenotification Negative Option Rule).

R. "**Person**" or "**persons**" means all natural persons, corporations, partnerships, or other business associations and all other legal entities, including all members, officers, predecessors, assigns, divisions, affiliates, and subsidiaries.

S. "**Product Specification**" means the criteria that a product must meet for identity, strength, and composition, as established pursuant to 21 C.F.R. § 111.70(e).

T. "**Promotional material**" means any document or thing designed or used to create interest in the purchasing of goods or services that is not normally counted as advertising, including, but not limited to: press releases, video news releases, and other communications with any print, television, or radio media, or any website designer, developer, manager, or host, or any online service; coupons; product information provided to bloggers; and payments for shelf space.

U. "**Referring to**" or "**relating to**" means discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting on, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.

V. "**Tabz Product(s)**" mean any of the following marketed or offered for sale by the Company:

1. Any cognitive function product, including ADDTabz and ADDTabzRX;

2. Any weight loss product, including PhenTabz, PhenTabz Teens, and PhenTabzRX; and

3. Any sleep aid product, including REMTabz and REMTabzRX.

W. The singular shall include the plural, and the plural shall include the singular.

II. INSTRUCTIONS

A. **Sharing of Information:** The Commission often makes its files available to other civil and criminal federal, state, local, or foreign law enforcement agencies. The Commission may make information supplied by you available to such agencies where appropriate pursuant to the Federal Trade Commission Act and 16 C.F.R. § 4.11 (c) and (j). Information you provide may be used in any federal, state, or foreign civil or criminal proceeding by the Commission or other agencies.

B. **Meet and Confer:** You must contact **Carolyn Hann** at **(202) 326-2745** as soon as possible to schedule a meeting (telephonic or in person) to be held within fourteen (14) days after receipt of this CID, or before the deadline for filing a petition to quash, whichever is first, in order to discuss compliance and to address and attempt to resolve all issues, including issues relating to protected status and the form and manner in which claims of protected status will be asserted, and the submission of ESI and other electronic productions as described in these Instructions. Pursuant to 16 C.F.R. § 2.7(k), you must make available personnel with the knowledge necessary for resolution of the issues relevant to compliance with this CID, including but not limited to personnel with knowledge about your information or records management systems, relevant materials such as organizational charts, and samples of material required to be produced. If any issues relate to ESI, you must make available a person familiar with your ESI systems and methods of retrieval.

C. **Applicable Time Period:** Unless otherwise directed in the specifications, the applicable time period for the request shall be from January 1, 2012, until the date of full and complete compliance with this CID.

D. **Claims of Privilege:** If any material called for by this CID is withheld based on a claim of privilege, work product protection, or statutory exemption, or any similar claim (*see* 16 C.F.R. § 2.7(a)(4)), the claim must be asserted no later than the return date of this CID. In addition, pursuant to 16 C.F.R. § 2.11(a)(1), submit, together with the claim, a detailed log of the items withheld. The information in the log shall be of sufficient detail to enable the Commission staff to assess the validity of the claim for each document, including attachments, without disclosing the protected information. Submit the log in a searchable electronic format, and, for each document, including attachments, provide:

1. Document control number(s);

2. The full title (if the withheld material is a document) and the full file name (if the withheld material is in electronic form);

3. A description of the material withheld (for example, a letter, memorandum, or email), including any attachments;

4. The date the material was created;

5. The date the material was sent to each recipient (if different from the date the material was created);

6. The email addresses, if any, or other electronic contact information to the extent used in the document, from which and to which each document was sent;

7. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all authors;

8. The names, titles, business addresses, email addresses or other electronic contact

information, and relevant affiliations of all recipients of the material;

9. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all persons copied on the material;

10. The factual basis supporting the claim that the material is protected; and

11. Any other pertinent information necessary to support the assertion of protected status by operation of law.

16 C.F.R. § 2.11(a)(1)(i)-(xi).

In the log, identify by an asterisk each attorney who is an author, recipient, or person copied on the material. The titles, business addresses, email addresses, and relevant affiliations of all authors, recipients, and persons copied on the material may be provided in a legend appended to the log. However, provide in the log the information required by Instruction D.6. 16 C.F.R. § 2.11(a)(2). The lead attorney or attorney responsible for supervising the review of the material and who made the determination to assert the claim of protected status must attest to the log. 16 C.F.R. § 2.11(a)(1).

If only some portion of any responsive material is privileged, all non-privileged portions of the material must be submitted. Otherwise, produce all responsive information and material without redaction. 16 C.F.R. § 2.11(c). The failure to provide information sufficient to support a claim of protected status may result in denial of the claim. 16 C.F.R. § 2.11(a)(1).

E. **Document Retention:** You shall retain all documentary materials used in the preparation of responses to the specifications of this CID. The Commission may require the submission of additional documents at a later time during this investigation. **Accordingly, you should suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents** that are in any way relevant to this investigation during its pendency, irrespective of whether you believe such documents are protected from discovery by privilege or otherwise. *See* 15 U.S.C. § 50; *see also* 18 U.S.C. §§ 1505, 1519.

F. **Petitions to Limit or Quash:** Any petition to limit or quash this CID must be filed with the Secretary of the Commission no later than twenty (20) days after service of the CID, or, if the return date is less than twenty (20) days after service, prior to the return date. Such petition shall set forth all assertions of protected status or other factual and legal objections to the CID, including all appropriate arguments, affidavits, and other supporting documentation. 16 C.F.R. § 2.10(a)(1). Such petition shall not exceed 5,000 words as set forth in 16 C.F.R. § 2.10(a)(1) and must include the signed separate statement of counsel required by 16 C.F.R. § 2.10(a)(2). **The Commission will not consider petitions to quash or limit absent a pre-filing meet and confer session with Commission staff and, absent extraordinary circumstances, will consider only issues raised during the meet and confer process. 16 C.F.R. § 2.7(k); *see also* § 2.11(b).**

G. **Modification of Specifications:** If you believe that the scope of the required search or

response for any specification can be narrowed consistent with the Commission's need for documents or information, you are encouraged to discuss such possible modifications, including any modifications of definitions and instructions, with **Carolyn Hann** at **(202) 326-2745**. All such modifications must be agreed to in writing by the Bureau Director, or a Deputy Bureau Director, Associate Director, Regional Director, or Assistant Regional Director. 16 C.F.R. § 2.7(l).

H. **Certification:** A duly authorized manager of the Company shall certify that the response to this CID is complete. This certification shall be made in the form set out on the back of the CID form, or by a declaration under penalty of perjury as provided by 28 U.S.C. § 1746.

I. **Scope of Search:** This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

J. **Document Production:** You shall produce the documentary material by making all responsive documents available for inspection and copying at your principal place of business. Alternatively, you may elect to send all responsive documents to **Connor Sands**, Federal Trade Commission, **600 Pennsylvania Avenue, NW, CC-10528, Washington, DC 20580**. Because postal delivery to the Commission is subject to delay due to heightened security precautions, please use a courier service such as Federal Express or UPS. Notice of your intended method of production shall be given by email or telephone to **Carolyn Hann** at **chann@ftc.gov** or **(202) 326-2745** at least five days prior to the return date.

K. **Document Identification:** Documents that may be responsive to more than one specification of this CID need not be submitted more than once; however, your response should indicate, for each document submitted, each specification to which the document is responsive. If any documents responsive to this CID have been previously supplied to the Commission, you may comply with this CID by identifying the document(s) previously provided and the date of submission. Documents should be produced in the order in which they appear in your files or as electronically stored and without being manipulated or otherwise rearranged; if documents are removed from their original folders, binders, covers, containers, or electronic source in order to be produced, then the documents shall be identified in a manner so as to clearly specify the folder, binder, cover, container, or electronic media or file paths from which such documents came. In addition, number by page (or file, for those documents produced in native electronic format) all documents in your submission, preferably with a unique Bates identifier, and indicate the total number of documents in your submission.

L. **Production of Copies:** Unless otherwise stated, legible photocopies (or electronically rendered images or digital copies of native electronic files) may be submitted in lieu of original documents, provided that the originals are retained in their state at the time of receipt of this CID. Further, copies of originals may be submitted in lieu of originals only if they are true, correct, and complete copies of the original documents; provided, however, that submission of a copy shall

constitute a waiver of any claim as to the authenticity of the copy should it be necessary to introduce such copy into evidence in any Commission proceeding or court of law; and provided further that you shall retain the original documents and produce them to Commission staff upon request. Copies of marketing materials and advertisements shall be produced in color, and copies of other materials shall be produced in color if necessary to interpret them or render them intelligible. A complete copy of each document should be submitted even though only a portion of the document is within the terms of the specification. The document shall not be edited, cut, or expunged and shall include all covering letters and memoranda, transmittal slips, appendices, tables, or other attachments and all other documents referred to in the document or attachments.

M. **Electronic Submission of Documents:** The following guidelines refer to the production of any ESI or digitally imaged hard copy documents. Before submitting any electronic production, you must confirm with the Commission counsel named above that the proposed formats and media types will be acceptable to the Commission. The FTC requests Concordance load-ready electronic productions, including DAT and OPT load files.

1. ESI: Documents created, utilized, or maintained in electronic format in the ordinary course of business should be delivered to the FTC as follows:

   a. Spreadsheet and presentation programs, including but not limited to Microsoft Access, SQL, and other databases, as well as Microsoft Excel and PowerPoint files, must be produced in native format with extracted text and metadata. Data compilations in Excel spreadsheets, or in delimited text formats, must contain all underlying data un-redacted with all underlying formulas and algorithms intact. All database productions (including structured data document systems) must include a database schema that defines the tables, fields, relationships, views, indexes, packages, procedures, functions, queues, triggers, types, sequences, materialized views, synonyms, database links, directories, Java, XML schemas, and other elements, including the use of any report writers and custom user data interfaces;

   b. All ESI other than those documents described in M.1.a above must be provided in native electronic format with extracted text or Optical Character Recognition (OCR) and all related metadata, and with corresponding image renderings as converted to Group IV, 300 DPI, single-page Tagged Image File Format (TIFF) or as color JPEG images (where color is necessary to interpret the contents);

   c. Each electronic file should be assigned a unique document identifier ("DocID") or Bates reference.

2. Hard Copy Documents: Documents stored in hard copy in the ordinary course of business should be submitted in an electronic format, subject to the following requirements:

   a. The documents should be true, correct, and complete copies of the original documents as converted to TIFF (or color JPEG) images with corresponding

document-level OCR text;

b. Each page shall be endorsed with a document identification number (which can be a Bates number or a document control number);

c. Logical document determination should be clearly rendered in the accompanying load file and should correspond to that of the original document; and

d. Documents shall be produced in color where necessary to interpret them or render them intelligible.

3. For each document electronically submitted to the FTC, include the following metadata fields in a standard ASCII delimited Concordance DAT file:

a. For electronic mail: begin Bates or unique document identification number ("DocID"), end Bates or DocID, mail folder path (location of email in personal folders, subfolders, deleted or sent items), custodian, from, to, cc, bcc, subject, date and time sent, date and time received, and complete attachment identification, including the Bates or DocID of the attachments (AttachIDs) delimited by a semicolon, MD5 or SHA Hash value, and link to native file;

b. For email attachments: begin Bates or DocID, end Bates or DocID, parent email ID (Bates or DocID), page count, custodian, source location/file path, file name, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

c. For loose electronic documents (as retrieved directly from network file stores, hard drives, etc.): begin Bates or DocID, end Bates or DocID, page count, custodian, source media, file path, filename, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

d. For imaged hard copy documents: begin Bates or DocID, end Bates or DocID, page count, source, and custodian; and where applicable, file folder name, binder name, attachment range, or other such references, as necessary to understand the context of the document as maintained in the ordinary course of business.

4. If you intend to utilize any de-duplication or email threading software or services when collecting or reviewing information that is stored in your computer systems or electronic storage media, or if your computer systems contain or utilize such software, you must contact the Commission counsel named above to determine whether and in what manner you may use such software or services when producing materials in response to this request.

5. Submit electronic productions as follows:

a. With passwords or other document-level encryption removed or otherwise provided to the FTC;

b. As uncompressed electronic volumes on size-appropriate, Windows-compatible, media;

c. All electronic media shall be scanned for and free of viruses; and

d. Data encryption tools may be employed to protect privileged or other personal or private information. The FTC accepts TrueCrypt, PGP, and SecureZip encrypted media. The passwords should be provided in advance of delivery, under separate cover. Alternate means of encryption should be discussed and approved by FTC counsel.

e. Please mark the exterior of all packages containing electronic media sent through the U.S. Postal Service or other delivery services as follows:

MAGNETIC MEDIA – DO NOT X-RAY
MAY BE OPENED FOR POSTAL INSPECTION.

6. All electronic files and images shall be accompanied by a production transmittal letter which includes:

a. A summary of the number of records and all underlying images, emails, and associated attachments, native files, and databases in the production; and

b. An index that identifies the corresponding consecutive document identification number(s) used to identify each person's documents and, if submitted in paper form, the box number containing such documents. If the index exists as a computer file(s), provide the index both as a printed hard copy and in machine-readable form (provided that the Commission counsel named above determines prior to submission that the machine-readable form would be in a format that allows the agency to use the computer files). The Commission counsel named above will provide a sample index upon request.

A Bureau of Consumer Protection Production Guide is available upon request from the Commission counsel named above. This guide provides detailed directions on how to fully comply with this instruction.

N. **Sensitive Personally Identifiable Information:** If any material called for by these requests contains sensitive personally identifiable information or sensitive health information of any individual, please contact us before sending those materials to discuss whether it would be appropriate to redact the sensitive information. If that information will not be redacted, contact us to discuss encrypting any electronic copies of such material with encryption software such as SecureZip and provide the encryption key in a separate communication.

For purposes of these requests, sensitive personally identifiable information includes: an individual's Social Security number alone; or an individual's name or address or phone number in combination with one or more of the following: date of birth; Social Security number; driver's license number or other state identification number or a foreign country equivalent; passport number; financial account number; credit card number; or debit card number. Sensitive health information includes medical records and other individually identifiable health information relating to the past, present, or future physical or mental health or conditions of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

O. **Information Identification:** Each specification and subspecification of this CID shall be answered separately and fully in writing under oath. All information submitted shall be clearly and precisely identified as to the specification(s) or subspecification(s) to which it is responsive.

P. **Certification of Records of Regularly Conducted Activity:** Attached is a Certification of Records of Regularly Conducted Activity, which may reduce the need to subpoena the Company to testify at future proceedings in order to establish the admissibility of documents produced in response to this CID. You are asked to execute this Certification and provide it with your response.

III. INTERROGATORIES

Demand is made for the following information from the **Company**:

1. State the Company's full legal name, principal address, telephone number, the date and state of incorporation or licensing, and all other names under which the Company has done business.

2. Identify all officers, directors, members, principals, and owners of the Company and all shareholders with five percent or more ownership of the Company, stating each shareholder's percentage of ownership, since the Company was formed.

3. Identify the names, addresses, officers, directors, owners, and states of incorporation of all of the Company's wholly or partially owned subsidiaries, parent companies, unincorporated divisions, joint ventures, partnerships, operations under assumed names, affiliates, and predecessor companies, and describe the relationship of each to the Company.

4. Identify each of the following entities and individuals and describe in detail their corporate or business relationship or other affiliation with the Company:

    a. Gentech Enterprises, LLC;

    b. Derek Vest;

c. CellMark Biopharma LLC;

d. Erika Boliek;

e. Axo International LLC;

f. nRXHealth.com;

g. Kalos Therapeutics, Inc.;

h. G&M Estates USA, Inc.;

i. George Colberg;

j. James Merrit, M.D.;

k. Planet Fitness Holdings, LLC;

l. Fitness International, LLC d/b/a LA Fitness;

m. Zoom Management d/b/a Zoom Tan;

n. Planet Beach International, LLC d/b/a Planet Beach;

o. AJS Weightloss LLC d/b/a Nuviva Medical Weight Loss Centers;

p. Alex Joseph;

q. Apothicare 360 LLC;

r. Apothicare Enterprises, Inc.;

s. Dr. Jim Bradley;

t. Mary Hoke, ARNP;

u. Dr. Julio Conrado;

v. Dr. Francisco M. Torres;

w. Linda Stevens;

x. Dr. Marc S. Schneider;

y. Dr. Fred J. Buford;

z. Dr. Robert J. Brueck; and

aa. Mandy Garrett.

5. State the following information for every product manufactured, marketed, offered for sale, sold, or distributed by you since January 1, 2012, under, or in connection with, the Company's name, copyright, trademark, or other identifying information:

   a. The name and a description of the nature of the product;

   b. The date when the product was first manufactured, marketed, and sold by you;

   c. The manufacturer of the product; and

   d. The supplier for each product or ingredient supplied to the Company by any third party.

6. Identify each person responsible for ensuring that each Tabz Product is manufactured, packaged, and labeled as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210).

7. Identify each component, including dietary ingredients, used in the manufacture of each Tabz Product. For each component used in the manufacture of such Tabz Product, state the identity specifications (established pursuant to 21 C.F.R. § 111.70(b)(1)) and the component specifications (established pursuant to 21 C.F.R. § 111.70(b)(2)) to ensure that the strength and composition of the components in such Tabz Product were met.

8. State the product specification (as defined in Definition S, above) of each Tabz Product.

9. If you received any Tabz Products from a supplier for packaging or labeling, state the product specifications (as defined in Definition S, above) established to provide assurance that such Tabz Products are adequately identified and consistent with your purchase order.

10. For each certificate of analysis provided by a supplier, state the steps taken to qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations and the basis for qualification of the supplier.

11. Specify the steps you have taken to ensure that the tests and examinations that you have used to determine whether the specifications as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each Tabz Product are met are appropriate, scientifically valid methods.

12. Identify the manufacturer of each Tabz Product and the supplier of each dietary ingredient or component used in the manufacture of such Tabz Product.

13. State the steps you have taken to identify and use an appropriate scientifically valid method for each specification established pursuant to 21 C.F.R. § 111.320(b) for which

testing or examination is required to determine whether the applicable specification is met.

14. With respect to each Tabz Product, state:

    a. The per unit wholesale price;

    b. The per unit retail price;

    c. The number of units sold at wholesale in 2012, 2013, 2014, 2015 and 2016 to date;

    d. The number of units sold at retail in 2012, 2013, 2014, 2015 and 2016 to date;

    e. The total dollar amount provided in refunds to consumers in 2012, 2013, 2014, 2015 and 2016 to date;

    f. The total dollar amount spent by the Company on advertising, marketing, or other promotion during 2012, 2013, 2014, 2015 and 2016 to date; and

    g. The total dollar amount spent by the Company on research and development during 2012, 2013, 2014, 2015 and 2016 to date.

If you maintain financial data on a fiscal schedule that differs from the calendar year schedule, provide this data according to those fiscal years and identify the dates of the fiscal year.

15. For each advertisement and promotional material produced in response to Document Specification 3, state the beginning and ending dates of dissemination, and the dates, times, and locations the ads were disseminated. For print ads and press releases, specify every publication, date, and community of dissemination; for television, radio, or Internet radio ads, provide every network, system or station, date, and community of dissemination; for Internet ads, specify every URL, date, and number of hits or visits; for all other materials, provide sufficient information to permit a determination of how many items were disseminated, when, where, and to whom.

16. State the full name and URL for each website operated by or on behalf of the Company, or affiliated entities or individuals, that describes, discusses, promotes, advertises, or sells any Tabz Product.

17. State any keywords, terms, phrases, or other criteria that the Company (or any person or entity acting for or on behalf of the company) has used to effect the placement or delivery of any advertisement or sponsored link for each Tabz Product in connection with any online advertising network or advertisement delivery or contextual marketing software or system, including, but not limited to, the placement or delivery of any advertisement or sponsored link in search results generated by Google or any other Internet search engine (*e.g.*, through the Google AdWords program).

18. For each advertisement requested in Document Specification 3, identify each person presented as a user of the products or providing a consumer testimonial for such products, and provide the following information for each individual. Your response should include, but not be limited to, the following individuals: Anya Garcia, Tanya Campos Garcia, Beth Bradley, Kathy Tindall, Mackenzie Pulis, Lorna Quereau , Mike Elles, Marlena Cecil, Tiffany Davis, Georgia Dion, Dr. Keith Krueger, and Will Taylor.

    a. Whether that individual is or was a purchaser of the Tabz Product;

    b. The product(s) purchased by that consumer, the date(s) of the purchase, and the total amount of purchases by that consumer;

    c. The circumstances under which the results given in the testimonial were achieved, including, but not limited to: (i) describing whether the individual was seeking medical treatment or advice at the time of using the product, and if so, identifying the source of treatment or advice; and (ii) describing whether the individual was using other medications or supplements at the time of using the product, and if so, identifying the other medications or supplements;

    d. The process the Company used to confirm that the individual actually achieved the reported results as represented in the advertisement.

    e. Whether the individual was compensated for appearing in the advertisement(s), and if so, state the amount of compensation;

    f. Whether the individual was compensated by the Company on an ongoing basis (*e.g.*, salary, royalty, promotion payments) and if so, state the amounts paid and schedule or dates of payment; and

    g. The individual's relationship to the Company or any consultant, shareholder, officer, or employee of the Company.

19. Describe in detail the process, procedures, guidelines, or standards that the Company followed in determining whether or not to post product reviews and satisfaction scores submitted by consumers via any of the Company's websites, including store.lexiuminternational.com.

20. State the full domain name for each website operated by or on behalf of the Company, including any website that has described, discussed, promoted, advertised, offered for sale or sold any Tabz Products, or directly linked to store.lexiuminternational.com. For each such website, identify the domain name registrant.

21. Regardless of time period, identify each retailer, affiliate, distributor, physician, or other person responsible for selling or distributing any Tabz Products. For each such entity or person, state the following:

    a. The manner of sale or distribution;

b. The full domain names and URLs of any websites through which such entity or individual advertises or sells any Tabz Products;

c. The total gross sales of Tabz Products by year; and

d. The manner in which such entity or individual is compensated for sales of any Tabz Products.

22. State the full name and URLs of all bloggers contacted, recruited, or hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any Tabz Product.

23. Identify all affiliate marketers and affiliate marketing networks hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any Tabz Product, and for each also provide the URL of any websites used by the affiliate to promote any of the products, and the total amount of compensation paid by the company to the affiliate to date.

24. Identify each person, company, agency, or other entity with responsibility for creating, designing, developing, reviewing, testing, evaluating, or approving any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

25. Without regard to time period, identify each person who participated in the development, formulation, research, or testing of any Tabz Product and describe in detail the specific work performed by each, the time period when they performed such work, and any compensation, remuneration, or thing of value provided to such person.

26. Without regard to time period, identify each academic institution, research facility, research organization, or other entity that participated in the development, formulation, research, or testing of any Tabz Product, and describe in detail the specific work performed by each, the time period when the entity performed such work, and any compensation, remuneration, or thing of value provided to such entity.

27. For any study produced in response to Document Specification 9, state the exact ingredients and the amount of each ingredient used in the study. In addition, state the source of each ingredient.

28. Without regard to time period, identify each person, company, agency, or other entity with responsibility for developing, reviewing, or evaluating substantiation, scientific or otherwise, for representations made in any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

29. Describe in detail the process, procedures, guidelines, or standards that the Company followed during the applicable time period in determining whether or not to approve the dissemination of advertisements for any Tabz Product, and identify the individual(s) responsible for formulating such procedures, guidelines, or standards, and the individual(s) responsible for approving such ads prior to dissemination.

30. Without regard to time period, identify all experts consulted by the Company or by any ad agency acting on behalf of the Company, or upon whose advice, opinion, or expertise the Company, or any ad agency acting on behalf of the Company, relied on to substantiate or refute the express or implied claims set forth in Document Specification 7.

31. For each of the following persons, without regard to time period, describe any current or previous scientific research, business, or other relationship or affiliation with you, state the dates during which such relationship or affiliation took place, and state any compensation, remuneration, or thing of value provided to that person:

    a. Dr. Stan Headley;

    b. Dr. Jim Bradley;

    c. Mary Hoke;

    d. Dr. Julio Conrado;

    e. Dr. Francisco M. Torres;

    f. Linda Stevens;

    g. Dr. Marc S. Schneider;

    h. Dr. Fred J. Buford; and

    i. Dr. Robert J. Brueck.

32. For each of the following persons, without regard to time period, provide all information about his or her college, graduate school, and post-graduate educations, including dates degrees were obtained, names of degrees (*e.g.*, B.A., M.A., M.D., Ph.D.), and majors or specializations; beginning and ending months and years of employment; positions held; and citations to publications:

    a. Tara Vest;

    b. Mary Lirette; and

    c. Dr. Stan Headley.

33. Describe the company's policies with regard to how and when consumers are placed into or become part of any continuity program or negative option.

34. Describe the company's policies with regard to how and when consumers may cancel their participation in any continuity program or negative option, and how and when consumers receive refunds for Tabz Products, including but not limited to any requirements, limits, or conditions relating to: time period, restocking fees, obtaining return merchandise authorization codes, and returning opened or unused product.

35. Identify each person or entity responsible for fulfilling consumers' orders of Tabz Product and provide the following information:

    a. Describe all procedures for obtaining, recording, and preserving consumers' records of ordering or authorizing the shipment of Tabz Product;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

36. Identify each person or entity responsible for customer service issues, refund requests, and consumer complaints regarding Tabz Products and provide the following information:

    a. Describe all procedures for handling, recording, and preserving records concerning customer service issues, refund requests, and consumer complaints;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

37. Identify each consumer who filed a complaint or requested a refund relating to Tabz Product. For each consumer, describe the complaint or the amount of refund requested, and state what, if anything, was the company's response.

38. State, as of the last day of each quarterly period from January 1, 2012 through the present:

    a. The number of active accounts of consumers who purchased any Tabz Products;

    b. The number of active accounts of consumers who purchased any Tabz Products where the purchaser was ever enrolled in a continuity program or negative option; and

    c. The number of closed accounts of consumers who purchased any Tabz Products.

39. State the number of accounts of consumers who purchased any Tabz Products that have experienced one or more:

    a. Chargebacks;

b. Refunds; and

c. Returns of any Tabz Products rejected by consumers as unordered.

40. Without regard to time period, identify all lawsuits or legal proceedings filed against the Company or otherwise involving the Company's advertising, marketing, and sales practices relating to any Tabz Products. Include in your identification the names of all parties, the jurisdiction in which the matter is or was pending, the case number, the date filed, the identity of counsel for all parties, and the current status or disposition of the matter.

41. Identify all persons at the Company who participated in preparing responses to this CID.

42. If, for any Document Specification in this CID, documents that would have been responsive were destroyed, mislaid, transferred, deleted, altered, or overwritten:

a. Describe in detail the document;

b. State the date such document was destroyed, mislaid, transferred, deleted, altered, or overwritten;

c. Describe the circumstance under which such document was destroyed, mislaid, transferred, deleted, altered, or overwritten; and

d. Identify the person authorizing such action.

IV. DOCUMENTS

Demand is made for the following documents and things:

1. A copy of each organization chart and personnel directory for the Company (including, but not limited to, Gentech Pharmaceutical, LLC), including email addresses, in effect since January 1, 2012.

2. Two packages, in their original packaging, of each version of every formulation of Tabz Products manufactured, marketed, offered for sale, sold, or distributed by you, or by any affiliated company.

3. A copy of every advertisement for each Tabz Product disseminated on or after January 1, 2012. Your response should include, but not be limited to, package labeling, package inserts, web pages (including metatags used for the purpose of search engine optimization or otherwise directing web traffic), user manuals or handbooks, customer support materials, promotional materials, and marketing materials, that have been disseminated to consumers, distributors or potential distributors (including Internet distributors), retailers, affiliates, physicians, or any other person since January 1, 2012, or that have been prepared for future dissemination or use.

4. All marketing or advertising plans for each Tabz Product, including, but not limited to, materials about advertising and marketing strategies, themes, or concepts; media recommendations, strategies, and plans; and marketing reports, business studies, and creative strategies relating to approaches for advertising, marketing, or promoting each of the Tabz Products, whether or not actually implemented.

5. All communications between the Company and any advertising agency, advertising placement agency, or network marketing agency that participated in the creation, production, or dissemination of any advertisement for each Tabz Product.

6. All documents relating to any communications between the Company or any ad agency acting on the Company's behalf, and any magazine or newspaper publisher, television or radio network, Internet radio platform, or any other media outlet concerning any claims, messages, or communications in any proposed or disseminated advertisement or promotional material for any Tabz Products. Your response should include, but not be limited to, *The Harvard Crimson* and other university-affiliated media outlets.

7. All documents relating to any communications between the Company or any ad agency acting on the Company's behalf, and any university, student group, or any other educational institution concerning any claims, messages, or communications in any proposed or disseminated advertisement or promotional material for any Tabz Products. Your response should include, but not be limited to, Harvard University, the University of Central Florida, and Ohio State University.

8. To the extent not already provided in response to another Specification of this CID, all marketing or consumer research relating to each Tabz Product.

9. Regardless of whether the Company believes these claims were made in advertising or promotional materials, and without regard to time period, all documents, including but not limited to, studies, tests, experiments, demonstrations, and written or oral statements or opinions, whether or not completed or published, substantiating each of the following claims:

   a. ADDTabz improves school and work performance by improving core cognitive skills, including memory, concentration, problem solving, critical thinking, reading comprehension, and listening comprehension;

   b. ADDTabz is as effective as prescription drugs such as Adderall, Ritalin, and Vyvanse for treating, curing, or mitigating Attention Deficit Disorder/Attention Hyperactivity Deficit Disorder (ADD/ADHD) symptoms including difficulty concentrating, difficulty listening, organizational problems, inattention, forgetfulness, trouble following directions, and anxiety;

   c. ADDTabz is as effective as prescription drugs including Adderall, Ritalin, and Vyvanse at treating, curing, or mitigating ADD/ADHD symptoms;

   d. ADDTabz provides a safe and effective "prescription strength" alternative to Adderall without any negative side effects;

   e. Millions of ADD/ADHD patients use ADDTabz instead of Adderall, Ritalin, or Vyvanse;

   f. ADDTabz is specifically designed to help students increase their grade point average (GPA);

   g. ADDTabzRX is a prescription drug that is approved by the Food and Drug Administration;

   h. ADDTabzRX is a prescription drug that can be prescribed only by physicians;

   i. PhenTabz will cause users to lose weight;

   j. PhenTabz will cause users to lose an average of 2.5 lb per week;

   k. PhenTabz is as effective as prescription drugs including Phentermine, Phendimetrazine, Xenical, Alli, and Adipex for treating, curing, or mitigating obesity;

   l. PhenTabz is a safe and effective "prescription strength" alternative to prescription drugs including Phentermine, Phendimetrazine, Xenical, Alli, and Adipex, without any negative side effects;

m. PhenTabz is clinically proven to cause users to lose weight by suppressing appetite, increasing metabolism, and accelerating fat mobilization;

n. PhenTabz is clinically proven to cause users to lose weight by reducing body fat;

o. PhenTabz Teens is a safe and effective weight loss product specifically designed for teenagers;

p. PhenTabz Teens is a safe and effective "prescription strength" alternative to prescription drugs including Phentermine and Phendimetrazine, without any negative side effects;

q. PhenTabzRX is a prescription drug that is approved by the Food and Drug Administration;

r. PhenTabzRX is a prescription drug that can be prescribed only by physicians;

s. REMTabz treats, cures, or mitigates a variety of sleep-related disorders, including insomnia, stress, anxiety, depression, circadian rhythm problems, and GABA/neurotransmitter insufficiency;

t. REMTabz is as effective as prescription drugs including Xanax for treating, curing, or mitigating stress or anxiety;

u. REMTabz is as effective as prescription drugs including Ambien and Lunesta for treating, curing, or mitigating insomnia, GABA/neurotransmitter insufficiency, and other sleep-related disorders;

v. REMTabz provides a safe and effective "prescription strength" alternative to Xanax, Ambien, and Lunesta without any negative side effects;

w. REMTabz is clinically proven to enable consumers to fall asleep and to reach deep sleep quickly;

x. REMTabzRX is a prescription drug that is approved by the Food and Drug Administration; and

y. REMTabzRX is a prescription drug that can be prescribed only by physicians.

10. All other documents, without regard to time period, not produced in response to Document Specification 9, relating to substantiation for the claims listed in Document Specification 9, including, but not limited to, documents that tend to call into question or disprove any of those claims, and documents that question the existence of substantiation for those claims.

11. All documents, without regard to time period, relating to any study conducted or sponsored by the Company, or the supplier of any active ingredients in any Tabz Products, examining the effectiveness of each of the Tabz Products, or any active

ingredient in the Tabz Products, for the claims listed in Document Specification 9 above, whether or not the study was completed or published, including, but not limited to:

a. All reports, articles, write-ups, or other accounts of the results of the study, and drafts of such documents reviewed by the study sponsor or any other person not employed by the research entity;

b. All final protocols and amendments to such protocols;

c. All documents relating to recruitment; randomization; instructions, including oral instructions, to participants; and subject compliance;

d. All raw data collected from participants enrolled in the study, including any participants who did not complete the study; source documents for such data; data dictionaries; and case report forms;

e. Documents sufficient to identify all study participants, including any participants who did not complete the study, and all communications with any participants relating to the study;

f. All documents relating to any statistical analysis of any study data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any study data;

g. All documents relating to attempts to publish articles or other publications based on the data from the study; and

h. All documents relating to the sponsorship of the study, including all communications, including contracts, between any sponsor and the study's researchers.

12. All documents sufficient to show the product specification (as defined in Definition S, above) of each Tabz Product.

13. All documents, including tests and examinations, sufficient to show, that each Tabz Product meets all product specifications (as defined in Definition S, above) as established in the master manufacturing record (pursuant to 21 C.F.R. §§ 111.205 & 111.210) for such Tabz Product.

14. A copy of each master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each Tabz Product.

15. If you received any Tabz Products from a supplier or manufacturer, all documents showing the means established to assure that such Tabz Products meet product specifications (as defined in Definition S, above) consistent with your purchase order.

16. All documents referring or relating to any tests or examinations, including results, conducted to confirm the identity, strength, or composition of any dietary ingredient contained in each Tabz Product.

17. For components that are not dietary ingredients, all documents referring or relating to any tests or examinations conducted to confirm the identity of those components or to determine whether those components comply with component specifications (as established pursuant to 21 C.F.R. 111.70(b)(2)).

18. For components that are not dietary ingredients, all documents referring or relating to any certificate of analysis from the supplier of the component.

19. All documents sufficient to show your qualification of any supplier for the purpose of relying on the supplier's certificate of analysis.

20. All documents referring or relating to your verification of the laboratory examination and testing methodologies used to determine whether any Tabz Products meets all product specifications(as defined in Definition S, above).

21. All documents referring or relating to consumer testimonials or expert endorsements for any of the Tabz Products, including, but not limited to, communications, contracts, and agreements between you and any person providing a testimonial or endorsement, compensation paid to such person, and any documents provided to expert endorsers prior to use of their endorsement.

22. If such documents exist, all curricula vitae ("CVs") or resumes for Tara Vest, Mary Lirette, and Dr. Stan Headley, without regard to time period.

23. All documents, without regard to time period, relating to the Company's decision to market or sell any of the Tabz Products as part of a continuity plan or negative option, including, but not limited to, emails, memos, market research, studies, reports, analyses, or surveys about consumer attitudes, beliefs, or understanding about any continuity program or negative option.

24. All documents, without regard to time period, relating to the Company's refund policies or practices.

25. All documents used in preparation for or during communications with any consumer, including scripts, outlines, guides, suggested responses to questions, policies, manuals, or procedures for handling consumer product requests and consumer complaints and inquiries, including communications about any continuity program or negative option, and refund or cancelation policies.

26. All documents, without regard to time period, relating to any communications concerning:

    a. Contracts or agreements;

b. Payments requested or received;

c. Consumers; or

d. Returns, refunds, or chargebacks

between the Company and any entities or individuals responsible for: shipping, handling or fulfilling orders; handling customer service; providing websites or arranging for the providing of websites; addressing any consumer complaints; returns; refunds; or chargeback requests for any Tabz Products.

27. All documents referring or relating to communications between sales or customer service representatives, working for the Company or on the Company's behalf, and consumers who purchased or were interested in purchasing Tabz Products, including:

a. Recordings of telephone calls;

b. Notes taken during or after telephone calls;

c. Online chat transcripts; and

d. Correspondence.

28. All documents and communications referring or relating to consumer complaints that they or a family member:

a. Never authorized or made more than a single purchase of the Tabz Product;

b. Never ordered the Tabz Product;

c. Canceled or wanted to cancel their order for the Tabz Product;

d. Were billed for a shipment of the Tabz Product that was returned;

e. Were billed for Tabz Products that were never ordered;

f. Were billed for Tabz Products that were never received;

g. Were billed for a Tabz Product that was sent or received after the account was canceled;

h. Did not understand that they would be receiving automatic shipments of the Tabz Product unless they took a specific action to cancel future shipments;

i. Did not authorize the company to interpret their failure to affirmatively cancel future shipments of the Tabz Product as their acceptance of such shipments; or

j. Were subject to improper, deceptive, or abusive debt collection practices.

29. To the extent not already provided in response to another Specification of this CID, all documents referring or relating to consumer complaints concerning the Tabz Products, including any communications between the Company and any affiliated person or entity and any consumer or any medical professional concerning any consumer injury or other adverse event relating to the use of the Tabz Products.

30. All documents relating to any communications between the Company or any affiliated entity or ad agency, and any company, website, blog, or organization that reviews or evaluates consumer products, concerning the use or performance of the Tabz Products.

31. All documents or communications received from or provided to any government agency, Better Business Bureau office, or consumer protection organization relating to consumer complaints about the Tabz Products and any continuity program or negative option, and any documents, charts, or other materials summarizing, analyzing, or discussing such complaints.

32. All documents referring or relating to any communications between you, or any affiliated person or entity, and the National Advertising Division of the Council of Better Business Bureaus or the Electronic Retailing Self-Regulation Program concerning any advertising for Tabz Products.

33. All documents referring or relating to any communication between the Company or any affiliated person or entity and the Food and Drug Administration concerning any Tabz Products.

34. All complaints and answers in any state or federal court litigation, initiated since January 1, 2012 or currently pending, in which the Company or any affiliated person or entity, is named as a defendant, and that relates or refers to Tabz Products.

35. All documents referring or relating to any communications between you, or any affiliated person or entity, and any magazine or newspaper publisher, television or radio network, Internet radio platform, or any other media outlet relating to you or any Tabz Products. Your response should include, but not be limited to, *The Harvard Crimson*, ABC News, Gawker Media d/b/a Jezebel.com, and *The New York Daily News*.

36. All documents referring or relating to any communications between you, or any affiliated person or entity and any medical or health interest group or organization relating to you or any Tabz Products. Your response should include, but not be limited to a letter dated May 29, 2013 from the National Eating Disorders Association, to Gentech Pharmaceutical, regarding the marketing of weight loss supplements to teenagers.

CERTIFICATION OF RECORDS OF REGULARLY CONDUCTED ACTIVITY
Pursuant to 28 U.S.C. § 1746

1. I, _____, have personal knowledge of the facts set forth below and am competent to testify as follows:

2. I have authority to certify the authenticity of the records produced by Lexium International, LLC and attached hereto.

3. The documents produced and attached hereto by Lexium International, LLC are originals or true copies of records of regularly conducted activity that:

   a) Were made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters;

   b) Were kept in the course of the regularly conducted activity of Lexium International, LLC; and

   c) Were made by the regularly conducted activity as a regular practice of Lexium International, LLC.

I certify under penalty of perjury that the foregoing is true and correct.

Executed on _____, 2016.

_____
Signature

PETITION EXHIBIT 13

FTC Civil Investigative Demand directed to
CellMark BioPharma, LLC
(issued May 24, 2016)

United States of America
Federal Trade Commission

CIVIL INVESTIGATIVE DEMAND

1. TO

CellMark Biopharma LLC
1591 Hayley Lane
Suite 201
Fort Myers, FL 33907

This demand is issued pursuant to Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1, in the course of an investigation to determine whether there is, has been, or may be a violation of any laws administered by the Federal Trade Commission by conduct, activities or proposed action as described in Item 3.

2. ACTION REQUIRED

☐ You are required to appear and testify.

LOCATION OF HEARING	YOUR APPEARANCE WILL BE BEFORE
	DATE AND TIME OF HEARING OR DEPOSITION

☒ You are required to produce all documents described in the attached schedule that are in your possession, custody, or control, and to make them available at your address indicated above for inspection and copying or reproduction at the date and time specified below.

☒ You are required to answer the interrogatories or provide the written report described on the attached schedule. Answer each interrogatory or report separately and fully in writing. Submit your answers or report to the Records Custodian named in Item 4 on or before the date specified below.

☒ You are required to produce the tangible things described on the attached schedule. Produce such things to the Records Custodian named in Item 4 on or before the date specified below.

DATE AND TIME THE DOCUMENTS, ANSWERS TO INTERROGATORIES, REPORTS, AND/OR TANGIBLE THINGS MUST BE AVAILABLE

JUN 14 2016

3. SUBJECT OF INVESTIGATION

See attached resolution

4. RECORDS CUSTODIAN/DEPUTY RECORDS CUSTODIAN	5. COMMISSION COUNSEL
Connor Sands/Lynne Colbert Federal Trade Commission 600 Pennsylvania Ave., NW Mail Drop CC-10528 Washington, DC 20580	Carolyn L. Hann Federal Trade Commission 600 Pennsylvania Ave., NW Mail Drop CC-10528 Washington, DC 20580 202-326-2745

DATE ISSUED	COMMISSIONER'S SIGNATURE
May 24, 2016	Tuell McSweeny

INSTRUCTIONS AND NOTICES

The delivery of this demand to you by any method prescribed by the Commission's Rules of Practice is legal service and may subject you to a penalty imposed by law for failure to comply. The production of documents or the submission of answers and report in response to this demand must be made under a sworn certificate, in the form printed on the second page of this demand, by the person to whom this demand is directed or, if not a natural person, by a person or persons having knowledge of the facts and circumstances of such production or responsible for answering each interrogatory or report question. This demand does not require approval by OMB under the Paperwork Reduction Act of 1980.

PETITION TO LIMIT OR QUASH

The Commission's Rules of Practice require that any petition to limit or quash this demand be filed within 20 days after service, or, if the return date is less than 20 days after service, prior to the return date. The original and twelve copies of the petition must be filed with the Secretary of the Federal Trade Commission, and one copy should be sent to the Commission Counsel named in Item 5.

YOUR RIGHTS TO REGULATORY ENFORCEMENT FAIRNESS

The FTC has a longstanding commitment to a fair regulatory enforcement environment. If you are a small business (under Small Business Administration standards), you have a right to contact the Small Business Administration's National Ombudsman at 1-888-REGFAIR (1-888-734-3247) or www.sba.gov/ombudsman regarding the fairness of the compliance and enforcement activities of the agency. You should understand, however, that the National Ombudsman cannot change, stop, or delay a federal agency enforcement action.

The FTC strictly forbids retaliatory acts by its employees, and you will not be penalized for expressing a concern about these activities.

TRAVEL EXPENSES

Use the enclosed travel voucher to claim compensation to which you are entitled as a witness for the Commission. The completed travel voucher and this demand should be presented to Commission Counsel for payment. If you are permanently or temporarily living somewhere other than the address on this demand and it would require excessive travel for you to appear, you must get prior approval from Commission Counsel.

A copy of the Commission's Rules of Practice is available online at http://bit.ly/FTCRulesofPractice. Paper copies are available upon request.

Form of Certificate of Compliance*

I/We do certify that all of the documents, information and tangible things required by the attached Civil Investigative Demand which are in the possession, custody, control, or knowledge of the person to whom the demand is directed have been submitted to a custodian named herein.

If a document or tangible thing responsive to this Civil Investigative Demand has not been submitted, the objections to its submission and the reasons for the objection have been stated.

If an interrogatory or a portion of the request has not been fully answered or a portion of the report has not been completed, the objections to its submission and the reasons for the objections have been stated.

Signature _____

Title _____

Sworn to before me this day

_____ _____

_____
Notary Public

_____

*In the event that more than one person is responsible for complying with this demand, the certificate shall identify the documents for which each certifying individual was responsible. In place of a sworn statement, the above certificate of compliance may be supported by an unsworn declaration as provided for by 28 U.S.C. § 1746.

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
Pamela Jones Harbour
William E. Kovacic
J. Thomas Rosch

RESOLUTION DIRECTING USE OF COMPULSORY PROCESS IN A NONPUBLIC INVESTIGATION OF UNNAMED PERSONS ENGAGED DIRECTLY OR INDIRECTLY IN THE ADVERTISING OR MARKETING OF DIETARY SUPPLEMENTS, FOODS, DRUGS, DEVICES, OR ANY OTHER PRODUCT OR SERVICE INTENDED TO PROVIDE A HEALTH BENEFIT OR TO AFFECT THE STRUCTURE OR FUNCTION OF THE BODY

File No. 0023191

Nature and Scope of Investigation:

To investigate whether unnamed persons, partnerships, or corporations, or others engaged directly or indirectly in the advertising or marketing of dietary supplements, foods, drugs, devices, or any other product or service intended to provide a health benefit or to affect the structure or function of the body have misrepresented or are misrepresenting the safety or efficacy of such products or services, and therefore have engaged or are engaging in unfair or deceptive acts or practices or in the making of false advertisements, in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The investigation is also to determine whether Commission action to obtain redress for injury to consumers or others would be in the public interest.

The Federal Trade Commission hereby resolves and directs that any and all compulsory processes available to it be used in connection with this investigation for a period not to exceed ten (10) years from the date of issuance of this resolution. The expiration of this ten (10) year period shall not limit or terminate the investigation or the legal effect of any compulsory process issued during the ten (10) year period. The Federal Trade Commission specifically authorizes the filing or continuation of actions to enforce any such compulsory process after expiration of the ten year period.

Authority to conduct investigation:

Sections 6, 9, 10, and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 46, 49, 50, and 57b-1, as amended; FTC Procedures and Rules of Practice, 16 C.F.R. § 1.1 et seq. and supplements thereto.

By direction of the Commission. Donald S. Clark

Donald S. Clark
Secretary

Issued: August 13, 2009

CIVIL INVESTIGATIVE DEMAND
SCHEDULE FOR PRODUCTION OF DOCUMENTS AND ANSWERS
TO WRITTEN INTERROGATORIES

I. DEFINITIONS

As used in this Civil Investigative Demand, the following definitions shall apply:

A. "**Advertisement**" or "**advertising**" or "**ad**" means any written or verbal statement, illustration, or depiction that promotes the sale of a good or service or is designed to increase consumer interest in a brand, good, or service. Advertising media include, but are not limited to, packaging and labeling; promotional materials; print; television; radio; and internet, social media, and other digital content.

B. "**And**," as well as "**or**," shall be construed both conjunctively and disjunctively, as necessary, in order to bring within the scope of any specification in this Schedule all information that otherwise might be construed to be outside the scope of the specification.

C. "**Any**" shall be construed to include "**all**," and "**all**" shall be construed to include the word "**any**."

D. "**CellMark Product(s)**" mean any of the following marketed or offered for sale by the Company:

1. Any cognitive function product, including Cognify; and

2. Any nutritional product, including CellAssure.

E. **"Chargeback"** shall mean a transaction that is returned as a financial liability to an acquirer by a card issuer, usually because of a disputed transaction. The acquirer may then return or "charge back" the transaction to the merchant.

F. "**CID**" means the Civil Investigative Demand, including the attached Resolution and this Schedule, and including the Definitions, Instructions, and Specifications.

G. "**Communication**" means any transmission or receipt of facts, information, opinions, or thought, whether conveyed in writing, orally, electronically, or by any other means, including written memorializations of oral communications.

H. "**Company**," shall mean CellMark Biopharma LLC, its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names or affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest, Craig Pisaris-Henderson, Dr. Stan Headley, Anthony Spotora, and Erika Boliek.

I. "**Component**" means any substance intended for use in the manufacture of a dietary

supplement, including those that may not appear in the finished batch of the dietary supplement. Component includes dietary ingredients and other ingredients.

J. "**Continuity Program**" means any plan, arrangement, or system under which a consumer receives periodic shipments of products or the provision of services without prior notification by the seller before each shipment or service period, regardless of any trial or approval period allowing the consumer to return or be reimbursed for the product or service.

K. "**Dietary ingredient**" means a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of above ingredients.

L. "**Document**" means the complete original and any non-identical copy (whether different from the original because of notations on the copy or otherwise), regardless of origin or location, of any written, typed, printed, transcribed, filmed, punched, or graphic matter of every type and description, however and by whomever prepared, produced, disseminated or made, including but not limited to any advertisement, book, pamphlet, periodical, contract, correspondence, file, invoice, memorandum, note, telegram, report, record, handwritten note, working paper, routing slip, chart, graph, paper, index, map, tabulation, manual, guide, outline, script, abstract, history, calendar, diary, agenda, minute, code book or label. **"Document" shall also include all documents, materials, and information, including Electronically Stored Information, within the meaning of the Federal Rules of Civil Procedure.**

M. "**Each**" shall be construed to include "**every**," and "**every**" shall be construed to include "**each**."

N. "**Electronically Stored Information**" or "**ESI**" means the complete original and any non-identical copy (whether different from the original because of notations, different metadata, or otherwise), regardless of origin or location, of any writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any electronic medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. This includes, but is not limited to, electronic mail, instant messaging, videoconferencing, and other electronic correspondence (whether active, archived, or in a deleted items folder), word processing files, spreadsheets, databases, and video and sound recordings, whether stored on: cards; magnetic or electronic tapes; disks; computer hard drives, network shares or servers, or other drives; cloud-based platforms; cell phones, PDAs, computer tablets, or other mobile devices; or other storage media.

O. "**FTC**" or "**Commission**" means the Federal Trade Commission.

P. "**Identify**" or "**the identity of**" shall be construed to require identification of (a) natural persons by name, title, present business affiliation, present business address and telephone number, or if a present business affiliation or present business address is not known, the last known business and home addresses; and (b) businesses or other organizations by name, address, identities of natural persons who are officers, directors or managers of the business or organization, and contact persons, where applicable.

Q. "**Ingredient**" means any substance that is used in the manufacture of a dietary supplement and that is intended to be present in the finished dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient.

R. "**Negative Option**" means, in an offer or agreement to sell or provide any goods or services, a provision under which the customer's silence or failure to take an affirmative action to reject goods or services or to cancel the agreement is interpreted by the seller as acceptance of the offer. The term includes a provision in offers or agreements involving automatic renewals, Continuity Programs, and Prenotification Negative Option Plans covered by the Commission's Rule entitled the "Use of Prenotification Negative Option Plans," 16 C.F.R. Part 425 (2014) (Prenotification Negative Option Rule).

S. "**Person**" or "**persons**" means all natural persons, corporations, partnerships, or other business associations and all other legal entities, including all members, officers, predecessors, assigns, divisions, affiliates, and subsidiaries.

T. "**Product Specification**" means the criteria that a product must meet for identity, strength, and composition, as established pursuant to 21 C.F.R. § 111.70(e).

U. "**Promotional material**" means any document or thing designed or used to create interest in the purchasing of goods or services that is not normally counted as advertising, including, but not limited to: press releases, video news releases, and other communications with any print, television, or radio media, or any website designer, developer, manager, or host, or any online service; coupons; product information provided to bloggers; and payments for shelf space.

V. "**Referring to**" or "**relating to**" means discussing, describing, reflecting, containing, analyzing, studying, reporting, commenting on, evidencing, constituting, setting forth, considering, recommending, concerning, or pertaining to, in whole or in part.

W. The singular shall include the plural, and the plural shall include the singular.

II. INSTRUCTIONS

A. **Sharing of Information:** The Commission often makes its files available to other civil and criminal federal, state, local, or foreign law enforcement agencies. The Commission may make information supplied by you available to such agencies where appropriate pursuant to the Federal Trade Commission Act and 16 C.F.R. § 4.11 (c) and (j). Information you provide may be used in any federal, state, or foreign civil or criminal proceeding by the Commission or other agencies.

B. **Meet and Confer:** You must contact **Carolyn Hann** at **(202) 326-2745** as soon as possible to schedule a meeting (telephonic or in person) to be held within fourteen (14) days after receipt of this CID, or before the deadline for filing a petition to quash, whichever is first, in order to discuss compliance and to address and attempt to resolve all issues, including issues relating to protected status and the form and manner in which claims of protected status will be

asserted, and the submission of ESI and other electronic productions as described in these Instructions. Pursuant to 16 C.F.R. § 2.7(k), you must make available personnel with the knowledge necessary for resolution of the issues relevant to compliance with this CID, including but not limited to personnel with knowledge about your information or records management systems, relevant materials such as organizational charts, and samples of material required to be produced. If any issues relate to ESI, you must make available a person familiar with your ESI systems and methods of retrieval.

C. **Applicable Time Period:** Unless otherwise directed in the specifications, the applicable time period for the request shall be from January 1, 2015, until the date of full and complete compliance with this CID.

D. **Claims of Privilege:** If any material called for by this CID is withheld based on a claim of privilege, work product protection, or statutory exemption, or any similar claim (*see* 16 C.F.R. § 2.7(a)(4)), the claim must be asserted no later than the return date of this CID. In addition, pursuant to 16 C.F.R. § 2.11(a)(1), submit, together with the claim, a detailed log of the items withheld. The information in the log shall be of sufficient detail to enable the Commission staff to assess the validity of the claim for each document, including attachments, without disclosing the protected information. Submit the log in a searchable electronic format, and, for each document, including attachments, provide:

1. Document control number(s);

2. The full title (if the withheld material is a document) and the full file name (if the withheld material is in electronic form);

3. A description of the material withheld (for example, a letter, memorandum, or email), including any attachments;

4. The date the material was created;

5. The date the material was sent to each recipient (if different from the date the material was created);

6. The email addresses, if any, or other electronic contact information to the extent used in the document, from which and to which each document was sent;

7. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all authors;

8. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all recipients of the material;

9. The names, titles, business addresses, email addresses or other electronic contact information, and relevant affiliations of all persons copied on the material;

10. The factual basis supporting the claim that the material is protected; and

11. Any other pertinent information necessary to support the assertion of protected status by operation of law.

16 C.F.R. § 2.11(a)(1)(i)-(xi).

In the log, identify by an asterisk each attorney who is an author, recipient, or person copied on the material. The titles, business addresses, email addresses, and relevant affiliations of all authors, recipients, and persons copied on the material may be provided in a legend appended to the log. However, provide in the log the information required by Instruction D.6. 16 C.F.R. § 2.11(a)(2). The lead attorney or attorney responsible for supervising the review of the material and who made the determination to assert the claim of protected status must attest to the log. 16 C.F.R. § 2.11(a)(1).

If only some portion of any responsive material is privileged, all non-privileged portions of the material must be submitted. Otherwise, produce all responsive information and material without redaction. 16 C.F.R. § 2.11(c). The failure to provide information sufficient to support a claim of protected status may result in denial of the claim. 16 C.F.R. § 2.11(a)(1).

E. **Document Retention:** You shall retain all documentary materials used in the preparation of responses to the specifications of this CID. The Commission may require the submission of additional documents at a later time during this investigation. **Accordingly, you should suspend any routine procedures for document destruction and take other measures to prevent the destruction of documents** that are in any way relevant to this investigation during its pendency, irrespective of whether you believe such documents are protected from discovery by privilege or otherwise. *See* 15 U.S.C. § 50; *see also* 18 U.S.C. §§ 1505, 1519.

F. **Petitions to Limit or Quash:** Any petition to limit or quash this CID must be filed with the Secretary of the Commission no later than twenty (20) days after service of the CID, or, if the return date is less than twenty (20) days after service, prior to the return date. Such petition shall set forth all assertions of protected status or other factual and legal objections to the CID, including all appropriate arguments, affidavits, and other supporting documentation. 16 C.F.R. § 2.10(a)(1). Such petition shall not exceed 5,000 words as set forth in 16 C.F.R. § 2.10(a)(1) and must include the signed separate statement of counsel required by 16 C.F.R. § 2.10(a)(2). **The Commission will not consider petitions to quash or limit absent a pre-filing meet and confer session with Commission staff and, absent extraordinary circumstances, will consider only issues raised during the meet and confer process. 16 C.F.R. § 2.7(k); *see also* § 2.11(b).**

G. **Modification of Specifications:** If you believe that the scope of the required search or response for any specification can be narrowed consistent with the Commission's need for documents or information, you are encouraged to discuss such possible modifications, including any modifications of definitions and instructions, with **Carolyn Hann** at **(202) 326-2745**. All such modifications must be agreed to in writing by the Bureau Director, or a Deputy Bureau Director, Associate Director, Regional Director, or Assistant Regional Director. 16 C.F.R. § 2.7(l).

H. **Certification:** A duly authorized manager of the Company shall certify that the response to this CID is complete. This certification shall be made in the form set out on the back of the CID form, or by a declaration under penalty of perjury as provided by 28 U.S.C. § 1746.

I. **Scope of Search:** This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

J. **Document Production:** You shall produce the documentary material by making all responsive documents available for inspection and copying at your principal place of business. Alternatively, you may elect to send all responsive documents to **Connor Sands**, Federal Trade Commission, **600 Pennsylvania Avenue, NW, CC-10528, Washington, DC 20580**. Because postal delivery to the Commission is subject to delay due to heightened security precautions, please use a courier service such as Federal Express or UPS. Notice of your intended method of production shall be given by email or telephone to **Carolyn Hann** at **chann@ftc.gov** or **(202) 326-2745** at least five days prior to the return date.

K. **Document Identification:** Documents that may be responsive to more than one specification of this CID need not be submitted more than once; however, your response should indicate, for each document submitted, each specification to which the document is responsive. If any documents responsive to this CID have been previously supplied to the Commission, you may comply with this CID by identifying the document(s) previously provided and the date of submission. Documents should be produced in the order in which they appear in your files or as electronically stored and without being manipulated or otherwise rearranged; if documents are removed from their original folders, binders, covers, containers, or electronic source in order to be produced, then the documents shall be identified in a manner so as to clearly specify the folder, binder, cover, container, or electronic media or file paths from which such documents came. In addition, number by page (or file, for those documents produced in native electronic format) all documents in your submission, preferably with a unique Bates identifier, and indicate the total number of documents in your submission.

L. **Production of Copies:** Unless otherwise stated, legible photocopies (or electronically rendered images or digital copies of native electronic files) may be submitted in lieu of original documents, provided that the originals are retained in their state at the time of receipt of this CID. Further, copies of originals may be submitted in lieu of originals only if they are true, correct, and complete copies of the original documents; provided, however, that submission of a copy shall constitute a waiver of any claim as to the authenticity of the copy should it be necessary to introduce such copy into evidence in any Commission proceeding or court of law; and provided further that you shall retain the original documents and produce them to Commission staff upon request. Copies of marketing materials and advertisements shall be produced in color, and copies of other materials shall be produced in color if necessary to interpret them or render them intelligible. A complete copy of each document should be submitted even though only a portion of the document is within the terms of the specification. The document shall not be edited, cut,

or expunged and shall include all covering letters and memoranda, transmittal slips, appendices, tables, or other attachments and all other documents referred to in the document or attachments.

M. **Electronic Submission of Documents:** The following guidelines refer to the production of any ESI or digitally imaged hard copy documents. Before submitting any electronic production, you must confirm with the Commission counsel named above that the proposed formats and media types will be acceptable to the Commission. The FTC requests Concordance load-ready electronic productions, including DAT and OPT load files.

1. ESI: Documents created, utilized, or maintained in electronic format in the ordinary course of business should be delivered to the FTC as follows:

   a. Spreadsheet and presentation programs, including but not limited to Microsoft Access, SQL, and other databases, as well as Microsoft Excel and PowerPoint files, must be produced in native format with extracted text and metadata. Data compilations in Excel spreadsheets, or in delimited text formats, must contain all underlying data un-redacted with all underlying formulas and algorithms intact. All database productions (including structured data document systems) must include a database schema that defines the tables, fields, relationships, views, indexes, packages, procedures, functions, queues, triggers, types, sequences, materialized views, synonyms, database links, directories, Java, XML schemas, and other elements, including the use of any report writers and custom user data interfaces;

   b. All ESI other than those documents described in M.1.a above must be provided in native electronic format with extracted text or Optical Character Recognition (OCR) and all related metadata, and with corresponding image renderings as converted to Group IV, 300 DPI, single-page Tagged Image File Format (TIFF) or as color JPEG images (where color is necessary to interpret the contents);

   c. Each electronic file should be assigned a unique document identifier ("DocID") or Bates reference.

2. Hard Copy Documents: Documents stored in hard copy in the ordinary course of business should be submitted in an electronic format, subject to the following requirements:

   a. The documents should be true, correct, and complete copies of the original documents as converted to TIFF (or color JPEG) images with corresponding document-level OCR text;

   b. Each page shall be endorsed with a document identification number (which can be a Bates number or a document control number);

c. Logical document determination should be clearly rendered in the accompanying load file and should correspond to that of the original document; and

d. Documents shall be produced in color where necessary to interpret them or render them intelligible.

3. For each document electronically submitted to the FTC, include the following metadata fields in a standard ASCII delimited Concordance DAT file:

a. For electronic mail: begin Bates or unique document identification number ("DocID"), end Bates or DocID, mail folder path (location of email in personal folders, subfolders, deleted or sent items), custodian, from, to, cc, bcc, subject, date and time sent, date and time received, and complete attachment identification, including the Bates or DocID of the attachments (AttachIDs) delimited by a semicolon, MD5 or SHA Hash value, and link to native file;

b. For email attachments: begin Bates or DocID, end Bates or DocID, parent email ID (Bates or DocID), page count, custodian, source location/file path, file name, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

c. For loose electronic documents (as retrieved directly from network file stores, hard drives, etc.): begin Bates or DocID, end Bates or DocID, page count, custodian, source media, file path, filename, file extension, file size, author, date and time created, date and time modified, date and time printed, MD5 or SHA Hash value, and link to native file;

d. For imaged hard copy documents: begin Bates or DocID, end Bates or DocID, page count, source, and custodian; and where applicable, file folder name, binder name, attachment range, or other such references, as necessary to understand the context of the document as maintained in the ordinary course of business.

4. If you intend to utilize any de-duplication or email threading software or services when collecting or reviewing information that is stored in your computer systems or electronic storage media, or if your computer systems contain or utilize such software, you must contact the Commission counsel named above to determine whether and in what manner you may use such software or services when producing materials in response to this request.

5. Submit electronic productions as follows:

a. With passwords or other document-level encryption removed or otherwise provided to the FTC;

b. As uncompressed electronic volumes on size-appropriate,

Windows-compatible, media;

c. All electronic media shall be scanned for and free of viruses; and

d. Data encryption tools may be employed to protect privileged or other personal or private information. The FTC accepts TrueCrypt, PGP, and SecureZip encrypted media. The passwords should be provided in advance of delivery, under separate cover. Alternate means of encryption should be discussed and approved by FTC counsel.

e. Please mark the exterior of all packages containing electronic media sent through the U.S. Postal Service or other delivery services as follows:

MAGNETIC MEDIA – DO NOT X-RAY
MAY BE OPENED FOR POSTAL INSPECTION.

6. All electronic files and images shall be accompanied by a production transmittal letter which includes:

a. A summary of the number of records and all underlying images, emails, and associated attachments, native files, and databases in the production; and

b. An index that identifies the corresponding consecutive document identification number(s) used to identify each person's documents and, if submitted in paper form, the box number containing such documents. If the index exists as a computer file(s), provide the index both as a printed hard copy and in machine-readable form (provided that the Commission counsel named above determines prior to submission that the machine-readable form would be in a format that allows the agency to use the computer files). The Commission counsel named above will provide a sample index upon request.

A Bureau of Consumer Protection Production Guide is available upon request from the Commission counsel named above. This guide provides detailed directions on how to fully comply with this instruction.

N. **Sensitive Personally Identifiable Information:** If any material called for by these requests contains sensitive personally identifiable information or sensitive health information of any individual, please contact us before sending those materials to discuss whether it would be appropriate to redact the sensitive information. If that information will not be redacted, contact us to discuss encrypting any electronic copies of such material with encryption software such as SecureZip and provide the encryption key in a separate communication.

For purposes of these requests, sensitive personally identifiable information includes: an individual's Social Security number alone; or an individual's name or address or phone number in combination with one or more of the following: date of birth; Social Security number; driver's license number or other state identification number or a foreign country equivalent; passport

number; financial account number; credit card number; or debit card number. Sensitive health information includes medical records and other individually identifiable health information relating to the past, present, or future physical or mental health or conditions of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

O. **Information Identification:** Each specification and subspecification of this CID shall be answered separately and fully in writing under oath. All information submitted shall be clearly and precisely identified as to the specification(s) or subspecification(s) to which it is responsive.

P. **Certification of Records of Regularly Conducted Activity:** Attached is a Certification of Records of Regularly Conducted Activity, which may reduce the need to subpoena the Company to testify at future proceedings in order to establish the admissibility of documents produced in response to this CID. You are asked to execute this Certification and provide it with your response.

III. INTERROGATORIES

Demand is made for the following information from the **Company**:

1. State the Company's full legal name, principal address, telephone number, the date and state of incorporation or licensing, and all other names under which the Company has done business.

2. Identify all officers, directors, members, principals, and owners of the Company and all shareholders with five percent or more ownership of the Company, stating each shareholder's percentage of ownership, since the Company was formed.

3. Identify the names, addresses, officers, directors, owners, and states of incorporation of all of the Company's wholly or partially owned subsidiaries, parent companies, unincorporated divisions, joint ventures, partnerships, operations under assumed names, affiliates, and predecessor companies, and describe the relationship of each to the Company.

4. Identify each of the following entities and individuals and describe in detail their corporate or business relationship or other affiliation with the Company:

    a. Lexium International, LLC, including Gentech Pharmaceutical, LLC;

    b. Mary Lirette;

    c. Tara Vest;

    d. Gentech Enterprises, LLC;

    e. Kalos Therapeutics, Inc.;

f. George Colberg;

g. James Merrit, M.D.;

h. Axo International LLC;

i. G&M Estates USA, Inc.;

j. RNCG Angel Foundation, Inc.;

k. WeVets, LLC d/b/a WeVets.us; and

l. Worldwide Cancer Research.

5. State the following information for every product manufactured, marketed, offered for sale, sold, or distributed by you since January 1, 2015, under, or in connection with, the Company's name, copyright, trademark, or other identifying information:

a. The name and a description of the nature of the product;

b. The date when the product was first manufactured, marketed, and sold by you;

c. The manufacturer of the product; and

d. The supplier for each product or ingredient supplied to the Company by any third party.

6. Identify each person responsible for ensuring that each CellMark Product is manufactured, packaged, and labeled as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210).

7. Identify each component, including dietary ingredients, used in the manufacture of each CellMark Product. For each component used in the manufacture of such CellMark Product, state the identity specifications (established pursuant to 21 C.F.R. § 111.70(b)(1)) and the component specifications (established pursuant to 21 C.F.R. § 111.70(b)(2)) to ensure that the strength and composition of the components in such CellMark Product were met.

8. State the product specification (as defined in Definition T, above) of each CellMark Product.

9. If you received any CellMark Products from a supplier for packaging or labeling, state the product specifications (as defined in Definition T, above) established to provide assurance that such CellMark Products are adequately identified and consistent with your purchase order.

10. For each certificate of analysis provided by a supplier, state the steps taken to qualify the supplier by establishing the reliability of the supplier's certificate of analysis through

confirmation of the results of the supplier's tests or examinations and the basis for qualification of the supplier.

11. Specify the steps you have taken to ensure that the tests and examinations that you have used to determine whether the specifications as specified in the master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each CellMark Product are met are appropriate, scientifically valid methods.

12. Identify the manufacturer of each CellMark Product and the supplier of each dietary ingredient or component used in the manufacture of such CellMark Product.

13. State the steps you have taken to identify and use an appropriate scientifically valid method for each specification established pursuant to 21 C.F.R. § 111.320(b) for which testing or examination is required to determine whether the applicable specification is met.

14. With respect to each CellMark Product, state:

    a. The per unit wholesale price;

    b. The per unit retail price;

    c. The number of units sold at wholesale in 2015 and 2016 to date;

    d. The number of units sold at retail in 2015 and 2016 to date;

    e. The total dollar amount provided in refunds to consumers in 2015 and 2016 to date;

    f. The total dollar amount spent by the Company on advertising, marketing, or other promotion during 2015 and 2016 to date; and

    g. The total dollar amount spent by the Company on research and development during 2015 and 2016 to date.

If you maintain financial data on a fiscal schedule that differs from the calendar year schedule, provide this data according to those fiscal years and identify the dates of the fiscal year.

15. For each advertisement and promotional material produced in response to Document Specification 3, state the beginning and ending dates of dissemination, and the dates, times, and locations the ads were disseminated. For print ads and press releases, specify every publication, date, and community of dissemination; for television, radio, or Internet radio ads, provide every network, system or station, date, and community of dissemination; for Internet ads, specify every URL, date, and number of hits or visits; for all other materials, provide sufficient information to permit a determination of how many items were disseminated, when, where, and to whom.

16. State the full name and URL for each website operated by or on behalf of the Company, or affiliated entities or individuals, that describes, discusses, promotes, advertises, or sells any CellMark Product.

17. State any keywords, terms, phrases, or other criteria that the Company (or any person or entity acting for or on behalf of the company) has used to effect the placement or delivery of any advertisement or sponsored link for each CellMark Product in connection with any online advertising network or advertisement delivery or contextual marketing software or system, including, but not limited to, the placement or delivery of any advertisement or sponsored link in search results generated by Google or any other Internet search engine (*e.g.*, through the Google AdWords program).

18. For each advertisement requested in Document Specification 3, identify each person presented as a user of the products or providing a consumer testimonial for such products, and provide the following information for each individual. Your response should include, but not be limited to, the following individual: Sue Haberkorn.

    a. Whether that individual is or was a purchaser of the CellMark Product;

    b. The product(s) purchased by that consumer, the date(s) of the purchase, and the total amount of purchases by that consumer;

    c. The circumstances under which the results given in the testimonial were achieved, including, but not limited to: (i) describing whether the individual was seeking medical treatment or advice at the time of using the product, and if so, identifying the source of treatment or advice; and (ii) describing whether the individual was using other medications or supplements at the time of using the product, and if so, identifying the other medications or supplements;

    d. The process the Company used to confirm that the individual actually achieved the reported results as represented in the advertisement.

    e. Whether the individual was compensated for appearing in the advertisement(s), and if so, state the amount of compensation;

    f. Whether the individual was compensated by the Company on an ongoing basis (*e.g.*, salary, royalty, promotion payments) and if so, state the amounts paid and schedule or dates of payment; and

    g. The individual's relationship to the Company or any consultant, shareholder, officer, or employee of the Company.

19. Describe in detail the process, procedures, guidelines, or standards that the Company followed in determining whether or not to post product reviews and satisfaction scores submitted by consumers via any of the Company's websites, including store.cellmarkbiopharma.com.

20. State the full domain name for each website operated by or on behalf of the Company, including any website that has described, discussed, promoted, advertised, offered for sale or sold any CellMark Products, or directly linked to store.cellmarkbiopharma.com. For each such website, identify the domain name registrant.

21. To the extent not already provided in response to another Specification of this CID, identify any and all domain names for which Derek Vest is the registrant.

22. Regardless of time period, identify each retailer, affiliate, distributor, physician, or other person responsible for selling or distributing any CellMark Products. For each such entity or person, state the following:

    a. The manner of sale or distribution;

    b. The full domain names and URLs of any websites through which such entity or individual advertises or sells any CellMark Products;

    c. The total gross sales of CellMark Products by year; and

    d. The manner in which such entity or individual is compensated for sales of any CellMark Products.

23. State the full name and URLs of all bloggers contacted, recruited, or hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any CellMark Product.

24. Identify all affiliate marketers and affiliate marketing networks hired by the Company or by any person, company, agency, or other entity working for or on behalf of the Company, in connection with any advertising or promotional campaign regarding any CellMark Product, and for each also provide the URL of any websites used by the affiliate to promote any of the products, and the total amount of compensation paid by the company to the affiliate to date.

25. Identify each person, company, agency, or other entity with responsibility for creating, designing, developing, reviewing, testing, evaluating, or approving any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

26. Without regard to time period, identify each person who participated in the development, formulation, research, or testing of any CellMark Product and describe in detail the specific work performed by each, the time period when they performed such work, and any compensation, remuneration, or thing of value provided to such person.

27. Without regard to time period, identify each academic institution, research facility, research organization, or other entity that participated in the development, formulation, research, or testing of any CellMark Product, and describe in detail the specific work

performed by each, the time period when the entity performed such work, and any compensation, remuneration, or thing of value provided to such entity.

28. For any study produced in response to Document Specification 9, state the exact ingredients and the amount of each ingredient used in the study. In addition, state the source of each ingredient.

29. Without regard to time period, identify each person, company, agency, or other entity with responsibility for developing, reviewing, or evaluating substantiation, scientific or otherwise, for representations made in any advertisement or promotional material submitted in response to Document Specification 3, and give a brief description of the functions performed by each.

30. Describe in detail the process, procedures, guidelines, or standards that the Company followed during the applicable time period in determining whether or not to approve the dissemination of advertisements for any CellMark Product, and identify the individual(s) responsible for formulating such procedures, guidelines, or standards, and the individual(s) responsible for approving such ads prior to dissemination.

31. Without regard to time period, identify all experts consulted by the Company or by any ad agency acting on behalf of the Company, or upon whose advice, opinion, or expertise the Company, or any ad agency acting on behalf of the Company, relied on to substantiate or refute the express or implied claims set forth in Document Specification 7.

32. For each of the following persons, without regard to time period, describe any current or previous scientific research, business, or other relationship or affiliation with you, state the dates during which such relationship or affiliation took place, and state any compensation, remuneration, or thing of value provided to that person:

    a. Dr. Stan Headley;

    b. Erika Boliek; and

    c. Anthony Spotora.

33. For each of the following persons, without regard to time period, provide all information about his or her college, graduate school, and post-graduate educations, including dates degrees were obtained, names of degrees (*e.g.*, B.A., M.A., M.D., Ph.D.), and majors or specializations; beginning and ending months and years of employment; positions held; and citations to publications:

    a. Derek Vest;

    b. Erika Boliek;

    c. Anthony Spotora; and

d. Dr. Stan Headley.

34. Describe the company's policies with regard to how and when consumers are placed into or become part of any continuity program or negative option.

35. Describe the company's policies with regard to how and when consumers may cancel their participation in any continuity program or negative option, and how and when consumers receive refunds for CellMark Products, including but not limited to any requirements, limits, or conditions relating to: time period, restocking fees, obtaining return merchandise authorization codes, and returning opened or unused product.

36. Identify each person or entity responsible for fulfilling consumers' orders of CellMark Product and provide the following information:

    a. Describe all procedures for obtaining, recording, and preserving consumers' records of ordering or authorizing the shipment of CellMark Product;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

37. Identify each person or entity responsible for customer service issues, refund requests, and consumer complaints regarding CellMark Products and provide the following information:

    a. Describe all procedures for handling, recording, and preserving records concerning customer service issues, refund requests, and consumer complaints;

    b. State the location(s) of such records; and

    c. Identify the custodian(s) of such records.

38. Identify each consumer who filed a complaint or requested a refund relating to CellMark Product. For each consumer, describe the complaint or the amount of refund requested, and state what, if anything, was the company's response.

39. State, as of the last day of each quarterly period from January 1, 2015 through the present:

    a. The number of active accounts of consumers who purchased any CellMark Products;

    b. The number of active accounts of consumers who purchased any CellMark Products where the purchaser was ever enrolled in a continuity program or negative option; and

    c. The number of closed accounts of consumers who purchased any CellMark Products.

40. State the number of accounts of consumers who purchased any CellMark Products that have experienced one or more:

    a. Chargebacks;

    b. Refunds; and

    c. Returns of any CellMark Products rejected by consumers as unordered.

41. Without regard to time period, identify all lawsuits or legal proceedings filed against the Company or otherwise involving the Company's advertising, marketing, and sales practices relating to any CellMark Products. Include in your identification the names of all parties, the jurisdiction in which the matter is or was pending, the case number, the date filed, the identity of counsel for all parties, and the current status or disposition of the matter.

42. Identify all persons at the Company who participated in preparing responses to this CID.

43. If, for any Document Specification in this CID, documents that would have been responsive were destroyed, mislaid, transferred, deleted, altered, or overwritten:

    a. Describe in detail the document;

    b. State the date such document was destroyed, mislaid, transferred, deleted, altered, or overwritten;

    c. Describe the circumstance under which such document was destroyed, mislaid, transferred, deleted, altered, or overwritten; and

    d. Identify the person authorizing such action.

IV. DOCUMENTS

Demand is made for the following documents and things:

1. A copy of each organization chart and personnel directory for the Company, including email addresses, in effect since January 1, 2015.

2. Two packages, in their original packaging, of each version of every formulation of CellMark Products manufactured, marketed, offered for sale, sold, or distributed by you, or by any affiliated company.

3. A copy of every advertisement for each CellMark Product disseminated on or after January 1, 2015. Your response should include, but not be limited to, package labeling, package inserts, web pages (including metatags used for the purpose of search engine optimization or otherwise directing web traffic), user manuals or handbooks, customer support materials, promotional materials, and marketing materials, that have been disseminated to consumers, distributors or potential distributors (including Internet distributors), retailers, or any other person since January 1, 2015, or that have been prepared for future dissemination or use.

4. All marketing or advertising plans for each CellMark Product, including, but not limited to, materials about advertising and marketing strategies, themes, or concepts; media recommendations, strategies, and plans; and marketing reports, business studies, and creative strategies relating to approaches for advertising, marketing, or promoting each of the CellMark Products, whether or not actually implemented.

5. All communications between the Company and any advertising agency, advertising placement agency, or network marketing agency that participated in the creation, production, or dissemination of any advertisement for each CellMark Product.

6. All documents relating to any communications between the Company or any ad agency acting on the Company's behalf, and any magazine or newspaper publisher, television or radio network, Internet radio platform, or any other media outlet concerning any claims, messages, or communications in any proposed or disseminated advertisement or promotional material for any CellMark Products.

7. To the extent not already provided in response to another Specification of this CID, all marketing or consumer research relating to each CellMark Product.

8. Regardless of whether the Company believes these claims were made in advertising or promotional materials, and without regard to time period, all documents, including but not limited to, studies, tests, experiments, demonstrations, and written or oral statements or opinions, whether or not completed or published, substantiating each of the following claims:

    a. Cognify treats, cures, mitigates, or prevents cognitive dysfunction caused by chemotherapy ("chemo brain"), including Mild Cognitive Impairment;

b. Cognify treats, cures, mitigates, or prevents chemo brain symptoms including memory loss regarding names, places, dates, or appointments, difficulty finding the right word for common objects, and trouble concentrating or focusing;

c. Cognify is specifically formulated to alleviate chemo brain symptoms;

d. Cognify repairs brain tissue, reduces inflammation, increases neurotransmitters, and stimulates the growth of new brain cells;

e. Cognify is a "pharmaceutical grade" dietary supplement;

f. Cognify is clinically proven to prevent chemo brain;

g. CellAssure is specifically formulated to meet the nutritional needs of cancer patients undergoing treatment including surgery, radiation, chemotherapy, and nutritional turmoil;

h. CellAssure was formulated based on direct requests from physicians, dietitians, and cancer patients;

i. CellAssure is clinically proven to meet the nutritional needs of cancer patients undergoing chemotherapy; and

j. CellAssure is clinically proven to exhibit anti-cancer and anti-tumor properties, mitigate anemia, improve liver functions, and help reduce inflammation and pain.

9. All other documents, without regard to time period, not produced in response to Document Specification 8, relating to substantiation for the claims listed in Document Specification 8, including, but not limited to, documents that tend to call into question or disprove any of those claims, and documents that question the existence of substantiation for those claims.

10. All documents, without regard to time period, relating to any study conducted or sponsored by the Company, or the supplier of any active ingredients in any CellMark Products, examining the effectiveness of each of the CellMark Products, or any active ingredient in the CellMark Products, for the claims listed in Document Specification 8 above, whether or not the study was completed or published, including, but not limited to:

a. All reports, articles, write-ups, or other accounts of the results of the study, and drafts of such documents reviewed by the study sponsor or any other person not employed by the research entity;

b. All final protocols and amendments to such protocols;

c. All documents relating to recruitment; randomization; instructions, including oral instructions, to participants; and subject compliance;

d. All raw data collected from participants enrolled in the study, including any participants who did not complete the study; source documents for such data; data dictionaries; and case report forms;

e. Documents sufficient to identify all study participants, including any participants who did not complete the study, and all communications with any participants relating to the study;

f. All documents relating to any statistical analysis of any study data, including, but not limited to, any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any study data;

g. All documents relating to attempts to publish articles or other publications based on the data from the study; and

h. All documents relating to the sponsorship of the study, including all communications, including contracts, between any sponsor and the study's researchers.

11. All documents sufficient to show the product specification (as defined in Definition T, above) of each CellMark Product.

12. All documents, including tests and examinations, sufficient to show, that each CellMark Product meets all product specifications (as defined in Definition T, above) as established in the master manufacturing record (pursuant to 21 C.F.R. §§ 111.205 & 111.210) for such CellMark Product.

13. A copy of each master manufacturing record (established pursuant to 21 C.F.R. §§ 111.205 & 111.210) for each CellMark Product.

14. If you received any CellMark Products from a supplier or manufacturer, all documents showing the means established to assure that such CellMark Product meets product specifications (as defined in Definition T, above) consistent with your purchase order.

15. All documents referring or relating to any tests or examinations, including results, conducted to confirm the identity, strength, or composition of any dietary ingredient contained in each CellMark Product.

16. For components that are not dietary ingredients, all documents referring or relating to any tests or examinations conducted to confirm the identity of those components or to determine whether those components comply with component specifications (as established pursuant to 21 C.F.R. 111.70(b)(2)).

17. For components that are not dietary ingredients, all documents referring or relating to any certificate of analysis from the supplier of the component.

18. All documents sufficient to show your qualification of any supplier for the purpose of relying on the supplier's certificate of analysis.

19. All documents referring or relating to your verification of the laboratory examination and testing methodologies used to determine whether any CellMark Products meet all product specifications (as defined in Definition S, above).

20. All documents referring or relating to consumer testimonials or expert endorsements for any of the CellMark Products, including, but not limited to, communications, contracts, and agreements between you and any person providing a testimonial or endorsement, compensation paid to such person, and any documents provided to expert endorsers prior to use of their endorsement.

21. If such documents exist, all curricula vitae ("CVs") or resumes for Derek Vest, Erika Boliek, Anthony Sporota, and Dr. Stan Headley, without regard to time period.

22. All documents, without regard to time period, relating to the Company's decision to market or sell any of the CellMark Products as part of a continuity plan or negative option, including, but not limited to, emails, memos, market research, studies, reports, analyses, or surveys about consumer attitudes, beliefs, or understanding about any continuity program or negative option.

23. All documents, without regard to time period, relating to the Company's refund policies or practices.

24. All documents used in preparation for or during communications with any consumer, including scripts, outlines, guides, suggested responses to questions, policies, manuals, or procedures for handling consumer product requests and consumer complaints and inquiries, including communications about any continuity program or negative option, and refund or cancelation policies.

25. All documents, without regard to time period, relating to any communications concerning:

    a. Contracts or agreements;

    b. Payments requested or received;

    c. Consumers; or

    d. Returns, refunds, or chargebacks

between the Company and any entities or individuals responsible for: shipping, handling or fulfilling orders; handling customer service; providing websites or arranging for the providing of websites; addressing any consumer complaints; returns; refunds; or chargeback requests for any CellMark Products.

26. All documents referring or relating to communications between sales or customer service representatives, working for the Company or on the Company's behalf, and consumers who purchased or were interested in purchasing CellMark Products, including:

    a. Recordings of telephone calls;

    b. Notes taken during or after telephone calls;

    c. Online chat transcripts; and

    d. Correspondence.

27. All documents and communications referring or relating to consumer complaints that they or a family member:

    a. Never authorized or made more than a single purchase of the CellMark Product;

    b. Never ordered the CellMark Product;

    c. Canceled or wanted to cancel their order for the CellMark Product;

    d. Were billed for a shipment of the CellMark Product that was returned;

    e. Were billed for CellMark Products that were never ordered;

    f. Were billed for CellMark Products that were never received;

    g. Were billed for a CellMark Product that was sent or received after the account was canceled;

    h. Did not understand that they would be receiving automatic shipments of the CellMark Product unless they took a specific action to cancel future shipments;

    i. Did not authorize the company to interpret their failure to affirmatively cancel future shipments of the CellMark Product as their acceptance of such shipments; or

    j. Were subject to improper, deceptive, or abusive debt collection practices.

28. To the extent not already provided in response to another Specification of this CID, all documents referring or relating to consumer complaints concerning the CellMark Products, including any communications between the Company and any affiliated person or entity and any consumer or any medical professional concerning any consumer injury or other adverse event relating to the use of the CellMark Products.

29. All documents relating to any communications between the Company or any affiliated entity or ad agency, and any company, website, blog, or organization that reviews or

evaluates consumer products, concerning the use or performance of the CellMark Products.

30. All documents or communications received from or provided to any government agency, Better Business Bureau office, or consumer protection organization relating to consumer complaints about the CellMark Products and any continuity program or negative option, and any documents, charts, or other materials summarizing, analyzing, or discussing such complaints.

31. All documents referring or relating to any communications between you, or any affiliated person or entity, and the National Advertising Division of the Council of Better Business Bureaus or the Electronic Retailing Self-Regulation Program concerning any advertising for CellMark Products.

32. All documents referring or relating to any communication between the Company or any affiliated person or entity and the Food and Drug Administration concerning any CellMark Products.

33. All complaints and answers in any state or federal court litigation, initiated since January 1, 2015 or currently pending, in which the Company or any affiliated person or entity, is named as a defendant, and that relates or refers to CellMark Products.

34. All documents referring or relating to any communications between you, or any affiliated person or entity, and any non-profit or charity organization including, but not limited to, RNCG Angel Foundation, Inc., WeVets, LLC d/b/a WeVets.us, and Worldwide Cancer Research relating to you or any CellMark Products.

CERTIFICATION OF RECORDS OF REGULARLY CONDUCTED ACTIVITY
Pursuant to 28 U.S.C. § 1746

1. I, _____, have personal knowledge of the facts set forth below and am competent to testify as follows:

2. I have authority to certify the authenticity of the records produced by CellMark Biopharma LLC and attached hereto.

3. The documents produced and attached hereto by CellMark Biopharma LLC are originals or true copies of records of regularly conducted activity that:

   a) Were made at or near the time of the occurrence of the matters set forth by, or from information transmitted by, a person with knowledge of those matters;

   b) Were kept in the course of the regularly conducted activity of CellMark Biopharma LLC; and

   c) Were made by the regularly conducted activity as a regular practice of CellMark Biopharma LLC**.**

I certify under penalty of perjury that the foregoing is true and correct.

Executed on _____, 2016.

_____
Signature

PETITION EXHIBIT 14

Target Letter from the United States Attorney for the Middle District of Florida Directed to Derek Vest (issued March 21, 2016)

2110 First Street, Suite 3-137
Fort Myers, Florida 33901
239/461-2200
239/461-2219 (Fax)

300 N. Hogan Street, Suite 700
Jacksonville, Florida 32202
904/301-6300
904/301-6310 (Fax)

35 SE 1st Avenue, Suite 300
Ocala, Florida 34471
352/547-3600
352/547-3623 (Fax)

U.S. Department of Justice
United States Attorney
Middle District of Florida

400 West Washington Street, Suite 3100
Orlando, Florida 32801
407/648-7500
407/648-7643 (Fax)

Main Office
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
813/274-6000
813/274-6358 (Fax)

Reply to: **Fort Myers, FL**

March 21, 2016

Derek Vest
11561 Isle Of Palm Drive
Fort Myers Beach, Florida 33931

Re: Grand Jury Investigation
USAO No. 2014R00530

Dear Mr. Vest:

This letter is to advise you that you are now a target of a Federal Grand Jury investigation in this District into introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws. The United States is prepared to proceed before a Federal Grand Jury to seek charges against you.

Before we proceed to bring these formal charges against you, we would like to discuss the matter with you and your attorney. Please have your attorney contact me as soon as possible at (239) 461-2200 so that we may schedule an appointment. If you do not have an attorney and believe you cannot afford to employ an attorney, you may call me yourself.

If we do not hear from you or your attorney on or before April 6, 2016, we shall assume that you do not wish to discuss the matter and will proceed accordingly.

Sincerely,

A. LEE BENTLEY, III
United States Attorney

By: Yolande G. Viacava
Yolande G. Viacava
Assistant United States Attorney

PETITION EXHIBIT 15

Email Exchange between Richard J. Oparil and FTC Attorney Carolyn L. Hann (June 6 & 8, 2016)

From: Oparil, Richard J.
To: Hann, Carolyn Lee; scott@reinkelawgroup.com
Cc: Sands, Connor
Subject: RE: CellMark meet and confer -- IT consult
Date: Wednesday, June 08, 2016 1:28:11 PM

Carolyn, I spoke to CellMark today. Subject to the petition to quash or limit on the Fifth Amendment privilege issue, the company believes that it can meet the deadlines we discussed during our call on Monday. My notes reflect the following:

ROUND 1 – due June 14:

Interrogatories 1-3
Document Specification 1

ROUND 2 – due June 28:

Interrogatories 4-6, 12, 14-16, 20-22, 25-31, 33
Document Specifications 2-4, 8, 10, 21, 29

ROUND 3 – due July 12:

Interrogatories 7-11, 13, 17-19, 23, 24, 32, 34-41
Document Specifications 5-7, 11-19, 22-28, 30-34

ROUND 4 – due July 26:

Interrogatories 42, 43
Document Specification 20

Please let me know if our understanding is correct. Thanks.

Richard

From: Hann, Carolyn Lee [mailto:chann@ftc.gov]
Sent: Monday, June 06, 2016 11:42 AM
To: Oparil, Richard J.; scott@reinkelawgroup.com

Cc: Sands, Connor
Subject: CellMark meet and confer -- IT consult

Richard and Scott,

To help expedite our call today, our Litigation Support Team has offered to participate in the call in case your client has any questions about producing electronically stored information (ESI). Please let us know if you plan to include an IT person on your call to have this type of discussion. We look forward to speaking at 3 pm today.

Best,

Carolyn

Carolyn L. Hann, Attorney
Federal Trade Commission
Bureau of Consumer Protection
Division of Advertising Practices
600 Pennsylvania Avenue, NW
Mail Drop CC-10528
Washington, DC 20580
direct: 202-326-2745
fax: 202-326-3259
chann@ftc.gov

Richard J. Oparil, Esq.
PORZIO, BROMBERG & NEWMAN, P.C.
1200 New Hampshire Avenue, NW, Suite 710 | Washington, DC 20036-6802

P: 202.517.6323 | F: 202.517.6322 | vCard | CV
rjoparil@pbnlaw.com | www.pbnlaw.com

PETITION EXHIBIT 16

Email Exchange between Richard Oparil and Carolyn Hann (June 10 & 13, 2016)

From: Oparil, Richard J.
To: Hann, Carolyn Lee
Subject: RE: Lexium CID production schedule - checking in
Date: Monday, June 13, 2016 11:48:47 AM

Lexium believes that it can meet the discovery schedule discussed on June 8.

From: Hann, Carolyn Lee [mailto:chann@ftc.gov]
Sent: Friday, June 10, 2016 4:20 PM
To: Oparil, Richard J.
Subject: RE: Lexium CID production schedule - checking in

Thanks, Richard. Do you also anticipate being able to tell us by COB today whether your client can meet the production schedule deadlines we requested? As I mentioned during our meet and confer, we need Division management to review the proposed production schedule and then issue a letter by Tuesday. If COB today is not possible, please let us know your client's responses to our proposed production schedule no later than noon on Monday, June 13.

I am in the office if you would prefer to speak by phone.

Best,

Carolyn

From: Oparil, Richard J. [mailto:RJOparil@pbnlaw.com]
Sent: Friday, June 10, 2016 11:49 AM
To: Hann, Carolyn Lee
Subject: RE: Lexium CID production schedule - checking in

I doubt it, but will need to confirm.

From: Hann, Carolyn Lee [mailto:chann@ftc.gov]
Sent: Friday, June 10, 2016 11:44 AM
To: Oparil, Richard J.
Subject: Lexium CID production schedule - checking in

Richard,

Thank you again for getting back to us regarding CellMark.

Do you anticipate needing a call with our litigation support team to discuss any electronically stored information (ESI) production issues for your client, Lexium International? I'm in the office today and Monday in case you need to schedule that type of call. I'm also available in case you want to discuss any of the proposed deadlines that we had discussed on Wednesday,

Best,

Carolyn

Carolyn L. Hann, Attorney
Federal Trade Commission
Bureau of Consumer Protection
Division of Advertising Practices
600 Pennsylvania Avenue, NW
Mail Drop CC-10528
Washington, DC 20580
direct: 202-326-2745
fax: 202-326-3259
chann@ftc.gov

Richard J. Oparil, Esq.
PORZIO, BROMBERG & NEWMAN, P.C.
1200 New Hampshire Avenue, NW, Suite 710 | Washington, DC 20036-6802

P: 202.517.6323 | F: 202.517.6322 | vCard | CV
rjoparil@pbnlaw.com | www.pbnlaw.com

PETITION EXHIBIT 17

CellMark BioPharma's Petition to
Limit or Quash Civil Investigative Demand
(filed June 13, 2016)

BEFORE THE FEDERAL TRADE COMMISSION

In the Matter of

CELLMARK BIOPHARMA LLC.

PETITION TO LIMIT OR QUASH CIVIL INVESTIGATIVE DEMAND BY CELLMARK BIOPHARMA LLC

Petitioner, CellMark Biopharma LLC ("CellMark"), hereby petitions the Federal Trade Commission ("FTC" or "Commission"), pursuant to 16 C.F.R. § 2.7(d), to limit or quash the Civil Investigative Demand ("CID") that it served on May 26, 2016. The FTC issued the CID pursuant to its alleged authority under § 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1. An officer and the sole shareholder, Derek Vest ("Vest"), has received a target letter from the U.S. Attorney for the Middle District of Florida. In order to ensure that his Fifth Amendment right against self-incrimination is not waived by the production of information to the FTC, CellMark files this Petition to limit the production of any privileged information pursuant to the CID.

BACKGROUND

CellMark is a Delaware limited liability company formed in 2015. Vest is the company's sole shareholder. In 2016, CellMark began selling two products, CellAssure™ and Cognify™ made by contract manufacturers. CellAssure is a supplemental protein nutrition drink. Cognify is a mental cognition supplement. On May 26, 2016, the Commission served a Civil Investigative Demand ("CID") with 43 interrogatories (not counting subparts) and 34 document specifications. Ex. 1. The CID seeks information on broad topics, including corporate information, product

development and formulation, manufacturing, labels and advertising, claim substantiation, sales, and return/refund policies. The CID defines "Company" to mean:

> CellMark Biopharma LLC, its wholly or partially owned subsidiaries, unincorporated divisions, joint ventures, operations under assumed names or affiliates, and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest, Craig Pisaris-Henderson, Dr. Stan Headley, Anthony Spotora, and Erika Boliek.

Ex. 1 § I.H. The scope of search provision is similarly broad:

> This CID covers documents and information in your possession or under your actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of your attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity.

Id. § II.I. The return date on the CID is June 14, 2016.

The Commission staff and CellMark had a meet and confer teleconference on June 6, 2016. During that conference, the parties discussed a schedule for producing information to the Commission, and the scope of the definitions and requests. CellMark informed the staff that Vest had received a criminal target letter from the U.S. Attorney for the Middle District of Florida. Ex. 2. The letter to Vest states that "you are now a target of a Federal Grand Jury investigation in this District into introducing and delivering for introduction into interstate commerce misbranded drugs and other matters and possible violations of federal criminal laws. The United States is prepared to proceed before a Federal Grand Jury to seek charges against you." On June 8, CellMark provided staff with a copy of that letter.

ARGUMENT

The act of compelling the production of interrogatory responses and documents implicates Vest's Fifth Amendment rights and the CID should be limited. The CID, while served on CellMark, requires Vest to produce information to the FTC. *See* Ex. 1 § I.H ("'Company' shall

mean CellMark ... and all directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest"). The CID further requires a search for documents and information in the possession of CellMark and its "attorneys, accountants, directors, officers, employees, and other agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity." *Id.* § II.I.

Vest's turning over of the extensive information and documents specified in the CID would admit their existence and authenticity. Accordingly, CellMark seeks to limit the CID to ensure that its officer and sole shareholder, Vest, can protect and assert his Fifth Amendment privilege.

The Fifth Amendment protects a person from being compelled to produce information that would incriminate that person. *See, e.g.*, *Fisher v. United States*, 425 U.S. 391, 397 (1976). The U.S. Supreme Court has long held that a government subpoena cannot compel the holder of documents and information to perform an act that may have testimonial aspects and an incriminating effect. See, e.g., *United States v. Doe*, 465 U.S. 605, 612 (1984). The act of production is privileged under the Fifth Amendment and cannot be compelled without a statutory grant of use immunity pursuant to 18 U. S. C. §§ 6002 and 6003. *Id.* at 617.

In *United States v. Hubbell*, 530 U.S. 27 (2000), the Court found that the act of producing documents in response to a subpoena may have a compelled testimonial aspect. The act of production itself may implicitly communicate statements of fact. By producing documents in compliance with a subpoena, the witness would admit that the papers existed, were in his possession or control, and were authentic. *Id.* at 36.

Hubbell also found that the Fifth Amendment protects a person who would be compelled to identify information and them produce it:

> It is apparent from the text of the subpoena itself that the prosecutor needed respondent's assistance both to identify potential sources of information and to produce those sources. See Appendix, infra. Given the breadth of the description of the 11 categories of documents called for by the subpoena, the collection and production of the materials demanded was tantamount to answering a series of interrogatories asking a witness to disclose the existence and location of particular documents fitting certain broad descriptions. The assembly of literally hundreds of pages of material in response to a request for "any and all documents reflecting, referring, or relating to any direct or indirect sources of money or other things of value received by or provided to" an individual or members of his family during a 3-year period, ... is the functional equivalent of the preparation of an answer to either a detailed written interrogatory or a series of oral questions at a discovery deposition. Entirely apart from the contents of the 13,120 pages of materials that respondent produced in this case, it is undeniable that providing a catalog of existing documents fitting within any of the 11 broadly worded subpoena categories could provide a prosecutor with a "lead to incriminating evidence," or "a link in the chain of evidence needed to prosecute."

Id. at 41-42. The Court concluded that:

> In sum, we have no doubt that the constitutional privilege against self-incrimination protects the target of a grand jury investigation from being compelled to answer questions designed to elicit information about the existence of sources of potentially incriminating evidence. That constitutional privilege has the same application to the testimonial aspect of a response to a subpoena seeking discovery of those sources. Before the District Court, the Government arguably conceded that respondent's act of production in this case had a testimonial aspect that entitled him to respond to the subpoena by asserting his privilege against self-incrimination.

Id. at 43-44.

On its face, the CID seeks the production of information and documents in Vest's possession by defining "Company" to include CellMark and "its directors, officers, members, employees, agents, consultants, and other persons working for or on behalf of the foregoing, including Derek Vest...." Ex. 1 § I.H; *see also id.* § II.I (requiring the search for and production of material by CellMark and its "attorneys, accountants, directors, officers, employees, and other

agents and consultants, whether or not such documents and information were received from or disseminated to any person or entity."). Compelling Vest to produce such information implicates his Fifth Amendment right against self-incrimination. CellMark understands that Vest does not intend to waive his constitutional rights. As such, the CID should be limited or quashed to the extent its requires the production of such protected material.

In addition, the Fifth Amendment is implicated when a witness is "compelled to take the witness stand and answer questions designed to determine whether he has produced everything demanded by the subpoena." *Hubbell*, 530 U.S. at 37. Here, the CID's instructions require a sworn certificate that "all of the documents, information and tangible things required" by the CID have been produced. Ex. 1 at 1-2. Thus, the CID should be limited to exclude the requirement that CellMark certify that all documents and information of Vest have been provided to the FTC.

Finally, CellMark, as a limited liability company and on behalf of its directors, officers, members, employees, agents, consultants and representatives, object to the CID based on the Fifth Amendment privilege against self-incrimination. Cases holding that the Fifth Amendment does not apply to corporate entities are no longer good law in light of *Citizens United v. FEC*, 558 U.S. 310 (2010) and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). In *Citizens United*, the Supreme Court ruled that the government cannot prohibit political expenditures by corporations based on the speaker's corporate identity. The *Hobby Lobby* decision recognized that a closely-held corporation had religious liberties.

Citizens United rejected the premise that a corporate entity's status, advantages of using the corporate form, or the potentially corrupting influence of corporations could justify denial of First Amendment rights. *Citizens United* requires a reexamination of the outdated rationales used to deny a corporation's right against self-incrimination. First, because *Citizens United* treats corporate entities as

persons capable of exercising their constitutional rights, the government can hardly still claim that the Fifth Amendment is a "purely personal" privilege belonging only to natural persons – especially because criminal statutes, as well as all the other prongs of the Fifth Amendment, treat a corporation as a "person." Second, because *Citizens United* explicitly rejects discrimination against corporations based upon the "special advantages" of the corporate form, that rationale can no longer serve as a basis to deny corporations a right against self-incrimination. Finally, the government's asserted interest in enforcing criminal laws against corporations can no longer stand as a reason for differential treatment, because there is no for applying that interest solely to corporate crime and not to crimes committed by individuals.

Corporations can invoke rights under other prongs of the Fifth Amendment. *See, e.g., United States v. Martin Linen Supply Co.*, 430 U.S. 564, 569 (1977) (applying Fifth Amendment double jeopardy clause to corporation); *Mackin v. United States*, 117 U.S. 348 (1886) (applying grand jury clause to corporation); *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 412 (1922) (applying Fifth Amendment takings clause to corporation); *Noble v. Union River Logging R.R. Co.*, 147 U.S. 165, 171, 177 (1893) (applying Fifth Amendment due process clause to corporation). For four of the five prongs of the single-sentence Amendment, its subject – the word "person" – includes corporations. Only as to self-incrimination has the same word been given a different meaning.

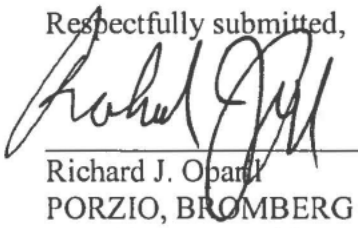
Thus, the Commission should quash or limit the CID to allow "the Company" (as broadly defined in the CID) to withhold information and documents pursuant to the Fifth Amendment's right against self-incrimination.

CONCLUSION

For the foregoing reasons, to the extent that the CID compels the production of interrogatory responses and documents protected by the Fifth Amendment, CellMark's Petition to Limit or Quash the CID should be granted.

Dated: June 13, 2016

Respectfully submitted,



Richard J. Oparil
PORZIO, BROMBERG & NEWMAN P.C.
1200 New Hampshire Ave. NW, Suite 710
Washington, DC 20036
(202) 517-1888
(202) 517-6322 (fax)
rjoparil@pbnlaw.com

Counsel for Petitioner
CellMark BioPharma LLC

CERTIFICATION

Pursuant to 16 C.F.R. § 2.7(d)(2), counsel for CellMark hereby certifies that counsel met and conferred with FTC counsel in a good faith attempt to resolve by agreement the issues set forth in this Petition, but the parties were unable to reach agreement.

Richard J. Oparil

CERTIFICATE OF SERVICE

I hereby certify that on June 13, 2016, I caused the original and 12 copies to the foregoing Petition to Limit or Quash with attached exhibits to be filed by hand delivery to the Secretary of the Federal Trade Commission, 601 New Jersey Ave., NW, Washington, DC 20580, and one copy to be served by email and hand delivery to Carolyn L. Hann, Esq., Federal Trade Commission, 600 Pennsylvania Ave., NW, Mail Drop CC-10528, Washington, DC 20580.

Richard J. Oparil

CellMark's exhibits in support of its administrative Petition to Limit or Quash the CID have been omitted.

These documents already appear in the record as the FTC's Petition Exhibit 13 (CellMark CID) and Petition Exhibit 14 (target letter from the U.S. Attorney's Office).

PETITION EXHIBIT 18

Letter from Mary K. Engle, Associate Director, FTC Division of Advertising Practices, to Richard Oparil regarding CellMark BioPharma, LLC (dated June 14, 2016)

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

June 14, 2016

VIA U.S. MAIL AND ELECTRONIC MAIL
Richard J. Oparil, Esq.
Porzio, Bromberg & Newman P.C.
1200 New Hampshire Avenue NW, Suite 710
Washington, DC 20036-6802
rjoparil@pbnlaw.com

Re: CellMark BioPharma LLC, FTC Matter No. 162-3134

Dear Mr. Oparil:

This letter is in response to your request to Carolyn L. Hann for an extension of the deadline for responding to the Civil Investigative Demand ("CID") served by the Federal Trade Commission on your client, CellMark BioPharma LLC ("CellMark"). Although the deadline for responding to the CID currently expires today, Ms. Hann advised me that you and she discussed a rolling production schedule to accommodate your client's time constraints and its recent retention of your law firm as outside counsel. We also understand that on June 13, your client filed a Petition to Quash those portions of the CID specifications that directly pertain to one of CellMark's principals, Mr. Derek Vest.[1] The filing of any such petition does not alter CellMark's obligation to produce documents and information to specifications unaffected by the petition. *See* 16 C.F.R. § 2.10(b) (timely filing of petition to quash stays compliance period only for "portion or portions of the challenged specifications or provisions").

In addition, as Ms. Hann explained via email, two Interrogatory Specifications in the CID contain typos. First, the corrected language for Interrogatory Specification 28 is:

> For any study produced in response to Document Specification 8, state the exact ingredients and the amount of each ingredient used in the study. In addition, state the source of each ingredient. (Emphasis added.)

Second, the corrected language for Interrogatory 31 is:

> Without regard to time period, identify all experts consulted by the Company or by any ad agency acting on behalf of the Company, or upon whose advice,

[1] You have advised that Mr. Vest currently is under criminal investigation by the U.S. Attorney's Office for the Middle District of Florida.

> opinion, or expertise the Company, or any ad agency acting on behalf of the Company, relied on to substantiate or refute the express or implied claims set forth in Document Specification 8. (Emphasis added.)

Pursuant to your meet and confer with Ms. Hann, I am writing to inform you that the deadlines by which CellMark must provide its responses are as follows. A failure to meet any one of these deadlines will be viewed as a default on the CID as a whole.

Round 1: Tuesday, June 14, 2016 (today)

Interrogatory Specifications:

- 1-3; and

Document Specification:

- 1.

Round 2: Tuesday, June 28, 2016

Interrogatory Specifications:

- 4-6, 9, 12, 14-16, 20-22, 25-31,[2] and 33; and

Document Specifications:

- 2-4, 8, 10, 21, and 29.

Round 3: Tuesday, July 12, 2016

Interrogatories Specifications:

- 7-11, 13, 17-19, 23, 24, 32, 34-41; and

Document Specifications:

- 5-7, 11-19, 22-28, and 30-34.

Round 4: Tuesday, July 26, 2016

Interrogatory Specifications:

- 42 and 43; and

Document Specification:

- 20.

[2] As Interrogatory Specifications 28 and 31 are corrected pursuant to this letter.

If you have any questions, please contact Ms. Hann at 202-326-2745 or chann@ftc.gov.

Very Truly Yours,

Mary K. Engle

Mary K. Engle
Associate Director

cc: Carolyn L. Hann, Esq.

PETITION EXHIBIT 19

Letter from Mary Engle to Richard Oparil regarding Lexium International LLC (dated June 14, 2016)

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

June 14, 2016

VIA U.S. MAIL AND ELECTRONIC MAIL
Richard J. Oparil, Esq.
Porzio, Bromberg & Newman P.C.
1200 New Hampshire Avenue NW, Suite 710
Washington, DC 20036-6802
rjoparil@pbnlaw.com

Re: Lexium International, LLC, FTC Matter No. 162-3133

Dear Mr. Oparil:

This letter is in response to your June 6, 2016 request to Carolyn L. Hann for an extension of the deadline for responding to the Civil Investigative Demand ("CID") served by the Federal Trade Commission on your client, Lexium International, LLC ("Lexium"). Although the deadline for responding to the CID currently expires today, Ms. Hann advised me that you and she discussed a rolling production schedule to accommodate your client's time constraints and its recent retention of your law firm as outside counsel. We also understand that on June 13, your client filed a Petition to Quash those portions of the CID specifications that directly pertain to one of Lexium's former principals, Mr. Derek Vest.[1] The filing of any such petition does not alter Lexium's obligation to produce documents and information to specifications unaffected by the petition. *See* 16 C.F.R. § 2.10(b) (timely filing of petition to quash stays compliance period only for "portion or portions of the challenged specifications or provisions").

In addition, as Ms. Hann explained during your meet and confer, Interrogatory Specification 30 in the CID contains a typo. The corrected language is:

> Without regard to time period, identify all experts consulted by the Company or by any ad agency acting on behalf of the Company, or upon whose advice, opinion, or expertise the Company, or any ad agency acting on behalf of the Company, relied on to substantiate or refute the express or implied claims set forth in Document Specification 9. (Emphasis added.)

Pursuant to your meet and confer with Ms. Hann, I am writing to inform you that the deadlines by which Lexium must provide its responses are as follows. A failure to meet any of the deadlines will be viewed as a default on the CID as a whole.

---

[1] You have advised that Mr. Vest currently is under criminal investigation by the U.S. Attorney's Office for the Middle District of Florida.

Round 1: Tuesday, June 14, 2016 (today)

Interrogatory Specifications:

- 1-3; and

Document Specification:

- 1.

Round 2: Tuesday, July 5, 2016

Interrogatory Specifications:

- 4-6, 12, 14-16, 20-21, 24-30,[2] and 32; and

Document Specifications:

- 2-4, 9-11, 22, 30, and 35.

Round 3: Tuesday, July 26, 2016

Interrogatories Specifications:

- 7-11, 13, 17-19, 22-23, 31, and 33-40; and

Document Specifications:

- 5-8, 12-20, 23-29, 31-34 and 36.

Round 4: Tuesday, August 16, 2016

Interrogatory Specifications:

- 41 and 42; and

Document Specification:

- 21

If you have any questions, please contact Ms. Hann at 202-326-2745 or chann@ftc.gov.

Very Truly Yours,

Mary K. Engle
Associate Director

[2] As Interrogatory Specification 30 is corrected pursuant to this letter.

cc: Carolyn L. Hann, Esq.

PETITION EXHIBIT 20

FTC Order Denying Petitions to Limit or Quash Civil Investigative Demands (issued July 25, 2016)

UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Edith Ramirez, Chairwoman**
Maureen K. Ohlhausen
Terrell McSweeny

In the Matter of	)	
CIVIL INVESTIGATIVE DEMANDS TO	)	**File No. 152-3133**
CELLMARK BIOPHARMA LLC AND	)	**File No. 152-3134**
LEXIUM INTERNATIONAL, LLC DATED MAY 24, 2016	)	**July 25, 2016**

ORDER DENYING PETITIONS TO LIMIT OR QUASH CIVIL INVESTIGATIVE DEMANDS

By McSWEENY, Commissioner:

CellMark Biopharma LLC ("CellMark") and Lexium International, LLC ("Lexium") have petitioned to limit or quash Civil Investigative Demands (CIDs) issued by the Commission under Section 20 of the Federal Trade Commission Act, 15 U.S.C. § 57b-1. For the reasons stated below, the petitions are denied.

I. BACKGROUND

CellMark is a limited liability company formed in 2015. It sells and promotes two dietary supplements – "CellAssure" and "Cognify." In advertising and promotional materials, CellMark claims that these products mitigate the negative effects of chemotherapy and related cancer treatments. Derek Vest is an officer and the sole shareholder of Cellmark.

Lexium is a limited liability company that, according to its petition, used to be known as Gentech Pharmaceutical, LLC ("Gentech"). Gentech, which was formed in 2010, developed and sold dietary supplement products for cognitive function, weight loss, and sleep aid, which Lexium continues to market and sell. Mr. Vest was a former officer of both Gentech and Lexium, but no longer has such roles; he currently serves as a consultant to Lexium.

On May 24, 2016, the Commission issued CIDs to CellMark and Lexium as part of an investigation of the companies' marketing claims about their products. Each CID calls for responsive "documents and information in [the company's] possession or under [its] actual or constructive custody or control including, but not limited to, documents and information in the possession, custody, or control of [the company's] . . . directors, officers, employees, and other agents and consultants." Pets. Exh. 1 ¶ II.I. Each CID defines "Company" to include "affiliates,

and all directors, officers, employees, agents, consultants, and other persons working for or on behalf of the foregoing." Cellmark Pet. Exh. 1 ¶ I.H; Lexium Pet. Exh. 1 ¶ I.G. Thus, the CIDs require Cellmark and Lexium to produce all responsive documents in their possession, custody, and control, including any such documents held by their officers and consultants.

On June 13, 2016, Cellmark and Lexium filed almost identical petitions to limit or quash the CIDs, and both attach a copy of a "target letter" issued by the U.S. Attorney's Office for the Middle District of Florida to Mr. Vest. This letter informs Mr. Vest that he is the "target of a Federal Grand Jury investigation . . . [for] introducing and delivering for introduction into interstate commerce misbranded drugs and other matters, and possible violations of federal criminal laws." Pets. Exh. 2. Cellmark and Lexium state that they filed their petitions "to ensure that [Mr. Vest's] Fifth Amendment right against self-incrimination is not waived by the production of information to the FTC." Pets. at 1. They ask the Commission to strike the requirement that they produce responsive documents and information that Mr. Vest has or controls. Additionally, they ask the Commission to relieve the companies from their obligation under the CIDs to certify that all responsive documents and information have been produced. For the reasons stated below, we deny both petitions.

II. ANALYSIS

It is well established that the Fifth Amendment "privilege against self-incrimination is essentially a personal one, applying only to natural individuals." *United States v. White*, 322 U.S. 694, 698 (1944). As a result, courts have held for over a century that a corporate officer may not invoke his personal Fifth Amendment privilege as a basis for resisting compliance with compulsory process seeking corporate records. *See, e.g., Wilson v. United States*, 221 U.S. 361 (1911). "If the corporation were guilty of misconduct, [its officer] could not withhold its books to save it; and if he were implicated in the violations of law, he could not withhold the books to protect himself from the effect of their disclosures." *Id.* at 384. A corporate officer's personal privilege against self-incrimination does not prevent the production of corporate records even when the corporate officer is the sole shareholder and the only person authorized to manage a corporation's business affairs. *See, e.g.*, *Braswell v. United States*, 487 U.S. 99, 101-02, 119 (1988) (finding sole shareholder and officer "could not resist the subpoena for corporate documents"); *Bellis v. United States*, 417 U.S. 85, 100 (1974) ("[N]o privilege can be claimed by the custodian of corporate records, regardless of how small the corporation may be."); *United States v. McDonald Chevrolet & Oldsmobile, Inc.*, 514 F. Supp. 83, 90 (N.D. Ga. 1981) ("[A] corporate officer may be compelled to produce corporate documents, even though he is the sole shareholder or alter ego of the corporation and the records may incriminate him.").

Cellmark and Lexium do not, nor can they, dispute this well-established law. Instead, they cite a supposed exception established by the Supreme Court in *United States v. Hubbell*, 530 U.S. 27 (2000), and argue they may invoke the protections of the Fifth Amendment on behalf of Mr. Vest because, in producing responsive documents, Mr. Vest would tacitly "admit their existence and authenticity." Pets. at 3. Cellmark and Lexium misinterpret the Supreme Court's holding in *Hubbell.*

In *Hubbell*, the Supreme Court recognized that the compelled production of documents can be "testimonial" and thus implicate the Fifth Amendment to the extent that the production communicates a statement of fact – for example, that papers existed and were in the control of the custodian. *Id*. at 34-37. The Court held that, in such circumstances, the government could not rely on the act of production in a *subsequent* criminal proceeding against the custodian. *Id.* at 35-36. Nowhere in the *Hubbell* opinion does the Court address, let alone deviate from, the fundamental principle endorsed most recently by the Supreme Court in *Braswell* – that an individual may not rely on the privilege against compulsory self-incrimination to avoid the production of corporate records that he holds in a representative capacity, even if those records might incriminate him. *Braswell*, 487 U.S. at 101-02, 119; *see also Bellis*, 417 U.S. at 88-89.

Not surprisingly, courts that have examined whether the *Hubbell* case changed the law have concluded, as we do, that the rule remains the same; corporate officers cannot rely on the Fifth Amendment to avoid the production of corporate records. *See, e.g., In re Grand Jury Empaneled on May 9, 2014*, 786 F.3d 255, 263 n.2 (3d Cir. 2015) ("[T]here is no reason to suspect that *Hubbell* altered, in any way, the analysis set forth in *Braswell*."); *Amato v. United States*, 450 F.3d 46, 51 (1st Cir. 2006) (noting that post-*Hubbell*, "the act-of-production doctrine is not an exception to the collective-entity doctrine even when the corporate custodian is the corporation's sole shareholder, officer and employee"); *Armstrong v. Guccione*, 470 F.3d 89, 98 (2d Cir. 2006) ("[W]e reject any suggestion that *Hubbell* so undermined *Braswell* that we are no longer compelled to follow its holding. . . . We remain bound by the Supreme Court's holding in *Braswell*."); *S.E.C. v. Narvett*, 16 F. Supp. 3d 979, 981-83 (E.D.Wis. 2014) (act-of-production doctrine provides no support for a corporation's sole employee and shareholder to refuse to comply with SEC subpoena).

The CIDs at issue are directed to the corporations and seek only corporate documents. Mr. Vest is an officer of Cellmark and a consultant of Lexium – in both cases, he is acting in a representative capacity as a corporate agent. The documents demanded by the CID, including those within Mr. Vest's possession, custody, or control, are corporate records that are within the companies' control, *see, e.g., Flagg v. City of Detroit*, 252 F.R.D. 346, 353 (a company is under an "affirmative duty to seek that information reasonably available to [it] from [its] employees, agents, or others subject to [its] control"), and the corporations and Mr. Vest must produce them even if the documents are incriminating to Mr. Vest personally.[1] Accordingly, there is no basis for limiting or quashing the CIDs to excuse the production of documents in Mr. Vest's possession, custody, or control. Nor do we excuse Cellmark or Lexium from their obligation to certify that they have produced all responsive documents and information.

Cellmark and Lexium also assert that the production of the information requested in the CIDs' interrogatories would "implicate[] Vest's Fifth Amendment rights." Pets. at 2. Interrogatories are inherently testimonial in nature. Therefore, individuals who properly assert a privilege against self-incrimination cannot be compelled to answer them. Nonetheless, a corporation is still obligated to respond, and must do so by selecting an officer, employee, or "agent who could, without fear of self-incrimination, furnish such requested information as was

[1] Lexium also claims that, as an ex-employee, Mr. Vest may assert a Fifth Amendment privilege to refuse to produce documents belonging to his former employer. Lexium Pet. at 5. However, Mr. Vest has a continuing "connection to Lexium . . . as a consultant." Lexium Pet. at 1.

available to the corporation." *See United States v. Kordel*, 397 U.S. 1, 8 (1970) (quoting *United States v. 3963 Bottles . . . of . . . Enerjol Double Strength*, 265 F.2d 332, 336 (7th Cir. 1959) ("It would indeed be incongruous to permit a corporation to select an individual to verify the corporation's answers, who because he fears self-incrimination may thus secure for the corporation the benefits of a privilege it does not have."). Both CIDs at issue identify and list officers and employees other than Mr. Vest. Cellmark and Lexium can call on any of them to respond on behalf of the corporations without impinging on Mr. Vest's personal Fifth Amendment rights.

Finally, Cellmark and Lexium contend that the Supreme Court's decisions in *Citizens United v. F.E.C.*, 558 U.S. 310 (2010), and *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), should be read expansively to extend the Fifth Amendment privilege against compulsory self-incrimination to corporations and other collective entities and thereby provide a basis to quash the two CIDs. Pets. at 5-6. This argument is also meritless. Those cases address the application of the First Amendment to corporations. Nothing in those decisions signals any departure from century-old precedents recognizing the Fifth Amendment privilege against self-incrimination as a uniquely individual right. *See In re Grand Jury Empaneled on May 9, 2014*, 786 F.3d at 263 n.1 (stating the court can "discern nothing in Supreme Court jurisprudence that suggests the Court has, in any way, signaled its readiness to depart from its longstanding precedent regarding corporate custodians' inability to invoke the Fifth Amendment privilege against self-incrimination").

III. CONCLUSION

For the foregoing reasons, we deny Cellmark's and Lexium's petitions to limit or quash the Commission's CIDs.

IT IS HEREBY ORDERED THAT the Petitions to Limit or Quash Civil Investigative Demand filed by CellMark Biopharma LLC and Lexium International, LLC be, and they hereby are **DENIED**.

IT IS FURTHER ORDERED THAT all documents and information responsive to the specifications in the Civil Investigative Demands to CellMark Biopharma LLC and Lexium International, LLC must now be produced on or before August 15, 2016.

By the Commission.

Donald S. Clark
Secretary

Issued: July 25, 2016

PETITION EXHIBIT 21

Letter from Oparil to Hann regarding
CellMark BioPharma, LLC
(dated August 3, 2016)

PORZIO
BROMBERG&NEWMAN P.C.
ATTORNEYS AT LAW
MORRISTOWN NJ • NEW YORK NY • PRINCETON NJ • WASHINGTON DC • WESTBOROUGH MA

RICHARD J. OPARIL
MEMBER, DC & NY BARS
DIRECT DIAL NO.: 202-517-6323
E-MAIL ADDRESS: RJOPARIL@PBNLAW.COM

August 3, 2016

By Email

Carolyn Hann, Esq.
Federal Trade Commission
600 Pennsylvania Ave. NW
Mail Drop CC10528
Washington, DC 20580

Re: *In re Cellmark Biopharma LLC, File No. 162-3133*

Dear Carolyn:

My client, CellMark Biopharma LLC has received the July 25, 2016 order denying its petition to limit or quash civil investigative demands. CellMark disagrees with and objects to the order. Derek Vest, who has received a target letter from the U.S. Attorney for the Middle District of Florida, has informed CellMark that he will continue to invoke his Fifth Amendment right against self-incrimination and will not provide documents in his possession to CellMark for production to the FTC in response to the Civil Investigative Demand.

Further, CellMark objects to the order that the company cannot invoke any Fifth Amendment privilege. The U.S. Supreme Court has acted to grant corporations rights under the Constitution that they were not previously entitled to assert. As such, CellMark notes its objection to that part of the Order.

With the exception of Mr. Vest's documents as to which there is a privilege objection, CellMark believes that it has produced all responsive documents to the FTC in compliance with the CID.

Please let me know if you have any questions.

1200 NEW HAMPSHIRE AVENUE NW, SUITE 710
WASHINGTON, DC 20036-6802
TELEPHONE (202) 517-1888
FAX (202) 517-6322
www.pbnlaw.com

Sincerely,

Richard J. Oparil

PETITION EXHIBIT 22

Email Exchange between Hann and Oparil
(August 15, 2016)

From: Hann, Carolyn Lee
To: "Oparil, Richard J."
Cc: Sands, Connor; Rodriguez, Edwin
Subject: RE: File Request - Lexium International CID Response
Date: Monday, August 15, 2016 7:34:00 PM

Richard,

The July 25, 2016 Commission's ruling denying Lexium's and CellMark's Petitions to Quash made clear that the CID production deadline is today, Aug. 15, 2016. Your client, Lexium, neither has requested an extension nor has provided any explanation for missing the Commission's deadline.

My Assistant Director has authorized me to grant Lexium a short extension to complete its CID production – i.e., all documents and interrogatory responses -- by close of business **Thursday, August 18, 2016**. We will grant no further extensions beyond that date.

Best,

Carolyn

From: Oparil, Richard J. [mailto:RJOparil@pbnlaw.com]
Sent: Monday, August 15, 2016 5:29 PM
To: Hann, Carolyn Lee
Cc: Sands, Connor; Rodriguez, Edwin
Subject: RE: File Request - Lexium International CID Response

Carolyn, Lexium will have more to produce but I'm not going to get more today. It is also working on the written discovery. I will update you.

Regards,

Richard

From: Hann, Carolyn Lee [mailto:chann@ftc.gov]
Sent: Monday, August 15, 2016 4:28 PM
To: Oparil, Richard J.
Cc: Sands, Connor; Rodriguez, Edwin
Subject: RE: File Request - Lexium International CID Response

Dear Richard,

Thank you for your FTP transfer. We see that the FTP contains only one file. Is this Lexium's complete response to the FTC's CID? If you have more documents to produce, we will need to send you a new FTP.

In addition, please advise on the status of Lexium's interrogatory responses, which also are due by COB today. Thus far, they have responded to only 3 interrogatories.

Best,

Carolyn

From: RJOparil@pbnlaw.com [mailto:RJOparil@pbnlaw.com]
Sent: Monday, August 15, 2016 4:22 PM
To: Sands, Connor
Cc: Hann, Carolyn Lee

Subject: Re: File Request - Lexium International CID Response

You have received 1 secure file from RJOparil@pbnlaw.com.
Use the secure link below to download.

Secure File Downloads:
Available until: **19 August 2016**

Click link to download:

LX000126-172.pdf
3.18 MB

You have received attachment link(s) within this email sent via the FTC Secure Mail system. To retrieve the attachment(s), please click on the link(s).

Secured by Accellion

Richard J. Oparil, Esq.
PORZIO, BROMBERG & NEWMAN, P.C.
1200 New Hampshire Avenue, NW, Suite 710 | Washington, DC 20036-6802

P: 202.517.6323 | F: 202.517.6322 | vCard | CV
rjoparil@pbnlaw.com | www.pbnlaw.com

JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
Federal Trade Commission

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Bradley D. Grossman, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580; 202-326-2994, bgrossman@ftc.gov

DEFENDANTS
Lexium International LLC; and
CellMark BioPharma, LLC

County of Residence of First Listed Defendant Lee
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Richard J. Oparil, Porzio Bromberg & Newman P.C., 1200 New Hampshire Avenue, NW, Suite 710, Washington, DC 20036-6802 (counsel for Lexium International and CellMark BioPharma)

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☒ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
15 U.S.C. s 57b-1(e)
Brief description of cause:
Enforcement of administrative investigative process

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. **DEMAND $** CHECK YES only if demanded in complaint: **JURY DEMAND:** ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE 9/15/16 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

FEDERAL TRADE COMMISSION,	)	
Petitioner,	)	**Misc. No. _____**
v.	)	
LEXIUM INTERNATIONAL LLC, and	)	
CELLMARK BIOPHARMA, LLC,	)	
Respondents.	)	

(PROPOSED) ORDER TO SHOW CAUSE WHY RESPONDENTS LEXIUM INTERNATIONAL LLC AND CELLMARK BIOPHARMA, LLC SHOULD NOT COMPLY WITH FEDERAL TRADE COMMISSION ADMINISTRATIVE INVESTIGATIVE PROCESS

Pursuant to the authority conferred by Sections 16 and 20 of the Federal Trade Commission Act, 15 U.S.C. §§ 56 and 57b-1, Petitioner, the Federal Trade Commission (FTC), has invoked the aid of this Court for an order requiring Respondents, Lexium International LLC and CellMark BioPharma, LLC, to comply in full with the May 24, 2016 civil investigative demands (CIDs) issued in aid of an FTC investigation (FTC File Nos. 162-3133 and 162-3134).

The Court has considered the Commission's Petition for an Order to Enforce Administrative Investigative Process and the papers filed in support thereof; and it appears to the Court that Petitioner has shown good cause for the entry of this Order. It is by this Court hereby

ORDERED that Respondents Lexium International LLC and CellMark BioPharma, LLC appear at _____ a.m./p.m. on the _____ day of _____, 2016, in Courtroom No. _____ of the United States Courthouse for the Middle District of Florida, 2110 First Street, in Fort Myers, Florida, and show cause, if any there be, why this Court should not grant said Petition and enter an Order enforcing the CIDs and directing them to produce the documents and information requested by the CIDs within ten (10) days of the receipt of the Court's enforcement order, or at such later time as may be directed by the FTC. Unless the Court determines otherwise, notwithstanding the filing or pendency of any procedural or other motions, all issues raised by the Petition and supporting papers, and any opposition to the Petition, will be considered at the hearing on the Petition, and the allegations of said Petition shall be deemed admitted unless controverted by a specific factual showing.

IT IS FURTHER ORDERED that, if Respondents believe it necessary for the Court to hear live testimony, they must file an affidavit reflecting such testimony (or if a proposed witness is not available to provide such an affidavit, a specific description of the witness's proposed testimony) and explain why Respondents believe live testimony is required.

IT IS FURTHER ORDERED that, if Respondents intend to file pleadings, affidavits, exhibits, motions or other papers in opposition to said Petition or to the entry of the Order requested therein, such papers must be filed with the Court and received by Petitioner's counsel by _____ a.m./p.m. on _____, 2016. Such submission shall include, in the case of any affidavits or exhibits not previously

submitted, or objections not previously made to the Federal Trade Commission, an explanation as to why such objections were not made or such papers or information not submitted to the Commission. Any reply by Petitioner shall be filed with the Court and received by Respondents by _____ a.m./p.m. on _____, 2016.

IT IS FURTHER ORDERED, pursuant to Fed. R. Civ. P. 26(a)(1)(B)(v) and 81(a)(5), that this is a summary proceeding and that no party shall be entitled to discovery without further order of the Court upon a specific showing of need; and that the dates for a hearing and the filing of papers established by this Order shall not be altered without prior order of the Court upon good cause shown; and

IT IS FURTHER ORDERED, pursuant to Fed. R. Civ. P. 81(a)(5), that a copy of this Order and copies of said Petition and Memorandum in support thereof filed herein, be served forthwith by Petitioner upon Respondents or their counsel by personal service, or by certified or registered mail with return receipt requested, or by overnight express delivery service.

SO ORDERED:

_____
United States Magistrate Judge

Dated: _____, Ft. Myers, Florida

PRESENTED BY:

DAVID C. SHONKA
Acting General Counsel

LESLIE RICE MELMAN
Assistant General Counsel for Litigation

BRADLEY GROSSMAN
Litigation Counsel
Office of the General Counsel
Federal Trade Commission
600 Pennsylvania Ave., N.W.
Washington, D.C. 20580
(202) 326-2994
(202) 326-2477 (fax)
bgrossman@ftc.gov

Of Counsel:

CAROLYN L. HANN
EDWIN RODRIGUEZ
Division of Advertising Practices

Dated: September 15, 2016