

Complaint

IN THE MATTER OF

**FRESENIUS MEDICAL CARE AG & CO. KGaA,
AND
DAIICHI SANKYO COMPANY, LTD.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT

Docket C-4236; File No. 081 0146

Complaint, October 20, 2008 – Decision, October 20, 2008

This consent order relates to a proposed agreement between subsidiaries of Fresenius Medical Care and Daiichi Sankyo to grant an exclusive license to Fresenius subsidiary FMC USA Manufacturing to manufacture, distribute, and sell Venofer, a preparation used to treat dialysis patients, to independent outpatient dialysis clinics in the United States. Luitpold Pharmaceuticals, a subsidiary of Daiichi Sankyo, retains the right to sell Venofer in the United States to any other customer, including doctor's offices, hospitals and hospital-based dialysis clinics. The transaction may enable Fresenius to increase prices it charges its own clinics, which, in turn, would raise reimbursement rates that the Centers for Medicare & Medicaid Services pays for Venofer. Under the order, Fresenius is restricted from reporting an intra-company transfer price higher than the level set forth in the order, which is derived from current market prices. The order further provides that if a generic Venofer product receives final approval by the U.S. Food and Drug Administration, Fresenius would be required to report its intra-company transfer price at either the level set forth in the order or the lowest price at which Fresenius sells Venofer to any customer, whichever is lowest, until December 31, 2011. On January 1, 2012, the order removes the lowest-priced-customer restriction, while the level set forth in the order remains in place. The order also provides that if Medicare & Medicaid Services implements regulations that eliminate the potential anticompetitive harm of this transaction, those regulations will supersede the order. The order prohibits Luitpold and Fresenius from sharing confidential business information relating to the manufacture, sale, or distribution of Venofer, and requires the parties to provide notice to the Commission prior to modifying the license agreement. Finally, the order provides that the Commission may appoint a Monitor Trustee if necessary.

Complaint

Participants

For the *Commission*: *Sylvia M. Brooks, Lisa De Marchi Sleigh, Daniel P. Ducore, David A. Garcia, Michael R. Moiseyev, Christina R. Perez, James E. Southworth, and Steven Tenn.*

For the *Respondents*: *Larri A. Short, Arent Fox LLP; Robert L. Magielnicki, Sheppard, Mullin, Richter & Hampton LLP; and Susan S. DeSanti and Katherine Funk, Sonnenschein Nath & Rosenthal LLP.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Fresenius Medical Care AG & Co. KGaA (“Fresenius”) and Daiichi Sankyo Company, Ltd. (“Daiichi”), have violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and, in addition, violated Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges in that respect as follows:

I. DEFINITIONS

1. “IV Iron” means second-generation intravenous iron therapy products, including Venofer (iron sucrose) and Ferrlecit (sodium ferric gluconate).
2. “Independent Outpatient Dialysis Clinics” means facilities that provide dialysis services and that are not hospital-based facilities and do not meet all of the criteria set forth in 42 C.F.R. §413.174(c) (and any successor or amended regulations).
3. “Medicare Part B” means Section 1847A(b); 42 U.S.C. § 1395w-3a(c).

Complaint

4. Manufacturers' Average Sales Price has the same meaning as that in 42 U.S.C. § 1395w-3a(c).

5. "CMS" means Centers for Medicare & Medicaid Services of the United States Department of Health & Human Services.

6. "Respondents" means Fresenius and Daiichi, individually and collectively.

7. "Medicare Improvements for Patients and Providers Act of 2008" or "MIPPA," means Public Law No. 110-275.

8. "Bundled Payment System" means the system created under Section 153(b) of the MIPPA whereby, among other things, reimbursement to providers of dialysis services for IV Iron administered to dialysis patients will be included in a single payment, and no longer billed separately, by January 1, 2015.

II. RESPONDENTS

9. Fresenius Medical Care AG & Co. KGaA is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its offices and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius Medical Care AG & Co. KGaA is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America ("FMCNA") with its office and principal place of business located at 920 Winter St., Waltham, MA 023451-1457. Renal Therapies Group ("RTG"), a division of FMCNA, manufactures, sells and distributes equipment, supplies and pharmaceuticals to dialysis providers. RTG is the parent entity of FMC USA Manufacturing ("FMCUSA"), which is the Fresenius signatory to the Proposed Transaction.

Complaint

10. Daiichi Sankyo Company, Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Japan, with its office and principal place of business located at 3-5-1, Nihonbashi Honcho, Chuo-Ku, Tokyo 103-8426, Japan. Daiichi Sankyo, Inc. (“DSI”), a wholly owned subsidiary of Daiichi Sankyo Company, Ltd., is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at Two Hilton Court, Parsippany, New Jersey 07054. Luitpold Pharmaceuticals, Inc., a wholly owned subsidiary of DSI, is a corporation organized, existing and doing business under and by virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York 11967. American Regent, Inc., a wholly owned subsidiary of Luitpold Pharmaceuticals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York. 11967. Luitpold licences Venofer from Vifor (International) Inc. (“Vifor”), the Swiss pharmaceutical company that developed the product. Luitpold’s subsidiary, American Regent, Inc. (“American Regent”), markets and distributes all of Luitpold’s injectable products, including Venofer, to customers around the United States.

11. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. §12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

Complaint

III. THE PROPOSED TRANSACTION

12. Pursuant to a License, Distribution, Manufacturing and Supply Agreement dated July 8, 2008, Luitpold and Vifor agreed to grant FMCUSA an exclusive sublicense to distribute, manufacture and sell Venofer to Independent Outpatient Dialysis Clinics in the United States for a term of ten years with an option to extend the agreement for an additional ten years (hereinafter “Proposed Transaction”). Luitpold retains the right to sell Venofer in the United States to any other customer, including doctor’s offices, hospitals and hospital-based dialysis clinics.

IV. THE RELEVANT MARKET

13. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Proposed Transaction is the manufacture, distribution and sale of IV Iron. IV Iron is critical for the effective treatment of dialysis patients, the vast majority of whom suffer from chronic anemia.

14. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Proposed Transaction in the relevant line of commerce.

V. THE STRUCTURE OF THE MARKET

15. The U.S. market for IV Iron is highly concentrated. Luitpold and Watson Pharmaceuticals (“Watson”) are the only two suppliers of IV Iron in the United States. Luitpold manufactures, distributes and sells Venofer, and Watson manufactures, distributes and sells Ferrlecit.

16. CMS reimburses Independent Outpatient Dialysis Clinics for the vast majority of the IV Iron used in the United States. Currently, CMS’s reimbursement rate for Venofer is one hundred and six percent of the Manufacturers’ Average Sales Price to all

Complaint

purchasers. Each calendar quarter, pursuant to Medicare Part B, drug manufacturers are required to submit the Manufacturers' Average Sales Price to CMS and that information is used to calculate the CMS reimbursement rate for each IV Iron product.

VI. ENTRY CONDITIONS

17. Entry into the relevant line of commerce described in Paragraphs 13 and 14 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Transaction.

VII. EFFECTS OF THE PROPOSED TRANSACTION

18. The effects of the Proposed Transaction, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by, among others, enabling Fresenius to report higher prices for Venofer used in its own clinics to CMS thereby increasing the Manufacturer's Average Sales Price and, therefore, the reimbursement rate for Venofer. By increasing the reimbursement rate for Venofer, CMS would be forced to pay higher prices for Venofer administered to dialysis patients covered by Medicare.

19. The effects described in Paragraph 18 would persist until the Bundled Payment System is fully implemented.

VIII. VIOLATIONS CHARGED

20. The Proposed Transaction described in Paragraph 12 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

21. The Proposed Transaction described in Paragraph 12, if consummated, would constitute a violation of Section 7 of the

Decision and Order

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twentieth day of October, 2008, issues its Complaint against said Respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed exclusive sublicense and manufacturing and supply agreement for Venofer, an intravenous iron drug used for the treatment of anemia, to free-standing outpatient dialysis clinics, between Fresenius Medical Care AG & Co. KGaA, a German partnership limited by shares, and including entities and divisions controlled by Fresenius Medical Care AG & Co. KGaA, including (1) Fresenius Medical Care Holdings, Inc., a New York corporation wholly owned by Fresenius Medical Care AG & Co. KGaA, d/b/a Fresenius Medical Care North America, (2) Fresenius Medical Services, which operates dialysis clinics throughout North America, (3) Renal Therapies Group, which manufactures, sells and distributes equipment, supplies and pharmaceuticals to dialysis providers, and (4) Renal Research Institute, which engages in dialysis research and development (hereafter collectively referred to as “Respondent Fresenius”) and Daiichi Sankyo Company, Ltd., a Japanese pharmaceutical company, and entities controlled by Daiichi Sankyo Company, Ltd., including (1) Daiichi Sankyo, Inc., a Delaware corporation, wholly owned by Daiichi Sankyo Company, Ltd., (2) Luitpold

Decision and Order

Pharmaceuticals, Inc., a New York corporation, wholly owned by Daiichi Sankyo, Inc., and (3) American Regent, Inc., a New York corporation, wholly owned by Luitpold Pharmaceuticals, Inc. (hereafter collectively referred to as “Respondent Daiichi”) (collectively referred to as “Respondents”); Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Fresenius Medical Care AG & Co. KGaA is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic

Decision and Order

of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius Medical Care AG & Co. KGaA is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America (“FMCNA”) with its office and principal place of business located at 920 Winter St., Waltham, MA 023451-1457. Within FMCNA there are three main operating units: (1) Fresenius Medical Services, which provides dialysis services; (2) Renal Therapies Group, which manufactures, sells and distributes equipment, supplies and pharmaceuticals used primarily in the treatment of hemodialysis, and (3) Renal Research Institute, which engages in dialysis research and development.

2. Respondent Daiichi Sankyo Company, Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of Japan, with its office and principal place of business located at 3-5-1, Nihonbashi Honcho, Chuo-Ku, Tokyo 103-8426, Japan. Daiichi Sankyo, Inc. (“DSI”), a wholly owned subsidiary of Daiichi Sankyo Company, Ltd., is a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at Two Hilton Court, Parsippany, New Jersey 07054. Luitpold Pharmaceuticals, Inc., a wholly owned subsidiary of DSI, is a corporation organized, existing and doing business under and by virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York 11967. American Regent, Inc., a wholly owned subsidiary of Luitpold Pharmaceuticals, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of New York, with its office and principal place of business located at One Luitpold Drive, Shirley, New York 11967.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

Decision and Order

ORDER**I.**

IT IS ORDERED that, as used in this Order, the following definitions shall apply:

- A. “Fresenius” means Fresenius Medical Care AG & Co. KGaA, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Fresenius Medical Care Holdings, Inc.), divisions, groups, and affiliates controlled by Fresenius Medical Care AG & Co. KGaA, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Daiichi” means Daiichi Sankyo Company, Ltd., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including Daiichi Sankyo, Inc., Luitpold Pharmaceuticals, Inc., and American Regent, Inc.), divisions, groups and affiliates controlled by Daiichi Sankyo Company, Ltd., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Luitpold” means Luitpold Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including American Regent, Inc.), divisions, groups and affiliates controlled by Luitpold Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. “Commission” means the Federal Trade Commission.

Decision and Order

- E. “ANDA” means Abbreviated New Drug Application filed with the United States Food and Drug Administration pursuant to 21 C.F.R. Part 314.
- F. “Clinic” means a facility that provides hemodialysis or peritoneal dialysis services to patients suffering from end stage renal disease. For purposes of this Order, “Clinic” does not include in-hospital-based dialysis units for acute kidney events or hospital-based clinics managed by Respondent Fresenius.
- G. “CMS” means the Centers for Medicare & Medicaid Services.
- H. “Fresenius Clinic” means a Clinic that is wholly owned, managed, or controlled by Respondent Fresenius or is a joint venture between Respondent Fresenius and another Person.
- I. “HHS” means the United States Department of Health & Human Services including all of its agencies and offices including, but not limited to, CMS.
- J. “HHS-CMS Requirement” means:
 - 1. any statute or regulation, including, but not limited to, 42 U.S.C. § 1395w-3a, and 42 C.F.R. Part 414, Subparts J and K;
 - 2. any HHS review or study of Manufacturer’s Average Sales Price and other prices, comparisons of such prices, or modifications of payment amounts for drug products, including, but not limited to 42 U.S.C. § 1395w-3a(d); and
 - 3. any HHS or CMS guidance, ruling, statement of policy, or agreement Relating To or affecting the

Decision and Order

average sales price payment methodology as set forth in 42 U.S.C. § 1395w-3a, including, but not limited to the valuation of intra-company transfer prices for the purposes of calculating, or determining payment of, the Manufacturer's Average Sales Price for Venofer.

- K. "License Agreement" means the "License, Distribution, Manufacturing and Supply Agreement by and between Luitpold Pharmaceuticals, Inc., American Regent, Inc. and Fresenius USA Manufacturing, Inc. July 8, 2008," attached as Confidential Exhibit A to this Order. For purposes of this Order, the License Agreement includes sales and distribution contracts between Respondent Daiichi and its Venofer customers that have or will be assumed and serviced by Respondent Fresenius.
- L. "Manufacturer's Average Sales Price" has the same meaning as that in 42 U.S.C. § 1395w-3a(c), including any supplements, modifications, amendments, or changes, thereto, and any HHS or CMS guidance, ruling, statement of policy, or agreement relating thereto.
- M. "Material Confidential Information" means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person's business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, patents, technologies, processes, or other trade secrets.
- N. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, division, or department, including HHS and CMS, or other business or legal entity.

Decision and Order

- O. “Relating To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- P. “Venofer” means a drug product covered by NDA 21-135, in all dosage forms, formulations, line extensions and package configurations and comprising iron sucrose as an active ingredient, used for the treatment of anemia in end stage renal disease kidney dialysis patients, and any improvements to such formulations or dosages as hereafter may be developed and marketed, and including any next generation parenteral iron product, including VIT-45 (ferric carboxymaltose) that may be developed and marketed in the United States.

II.**IT IS FURTHER ORDERED** that:

- A. Respondent Fresenius shall:
 - 1. For purposes of reporting the Manufacturer’s Average Sales Price for Venofer to CMS as required under the provisions of 42 U.S.C. § 1395w-3a, include the value of all intra-company transfers of Venofer to Fresenius Clinics; and
 - 2. For purposes of calculating the Manufacturer’s Average Sales Price for Venofer, report the price of each such intra-company transfer described in Paragraph II.A.1. at no greater than the lesser of:
 - a. the lowest per unit (as established by the Secretary of HHS under 42 U.S.C. § 1395w-3a(b)(2)(B)) price of Venofer sold by Luitpold to a purchaser (excluding sales exempted in 42 U.S.C. § 1395w-

Decision and Order

3a(c)(2)) in the United States, attached as Confidential Exhibit B, as of the date the Agreement Containing Consent Order was signed by Respondent Fresenius, or

- b. the lowest per unit (as established by the Secretary of HHS under 42 U.S.C. § 1395w-3a(b)(2)(B)) price of Venofer sold by Respondent Fresenius to any purchaser (excluding sales exempted in 42 U.S.C. § 1395w-3a(c)(2)) in the United States. *Provided, however*, Respondent Fresenius:
 - (1) shall not be required to comply with this Paragraph II.A.2.b. unless and until the date that the United States Food and Drug Administration has issued its final approval of a generic Venofer ANDA; and
 - (2) the provisions of this Paragraph II.A.2.b. shall expire on December 31, 2011, after which date Respondent Fresenius shall comply with Paragraph II.A.2.a.
3. If any change or modification to an HHS-CMS Requirement is implemented that changes or modifies Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order ("Change"), such that Paragraph II.A. conflicts or interferes with Respondent Fresenius' ability to comply with, or CMS's ability to enforce, such Change, then the Change shall terminate Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order. *Provided, however*, CMS, in its sole authority, shall determine whether Paragraph II.A. conflicts or interferes with Respondent Fresenius' ability to comply with, or CMS's ability to enforce, such Change. *Provided, further, however*, that before Respondent Fresenius' obligations under

Decision and Order

Paragraph II.A. terminate, Respondent Fresenius (1) shall receive a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the value of intra-company transfers of Venofer to Fresenius Clinics for purposes of reporting the Manufacturer's Average Sales Price for Venofer to CMS, and (2) shall have complied with the reporting requirements of Paragraph VII.

- B. Respondent Fresenius shall not, directly or indirectly, discuss with, or provide, disclose or otherwise make available to, Respondent Daiichi, or any person working on behalf of Respondent Daiichi, any Material Confidential Information Relating To Respondent Fresenius' pricing of Venofer or Respondent Fresenius' costs of manufacture, sale, or distribution of Venofer, unless specifically provided for in the License Agreement.
- C. The purpose of Paragraph II of this Order is to ensure the continuation of the supply and competitive pricing of Venofer in the same manner as existed at the time of the announcement of the License Agreement, and to remedy the lessening of competition alleged in the Commission's Complaint.

III.

IT IS FURTHER ORDERED that Respondent Daiichi shall not, directly or indirectly, discuss with, or provide, disclose or otherwise make available to, Respondent Fresenius, or any Person working on behalf of Respondent Fresenius, any Material Confidential Information Relating To Respondent Daiichi's pricing of Venofer or Respondent Daiichi's costs of manufacture, sale, or distribution of Venofer, unless specifically provided for in the License Agreement.

Decision and Order

IV.**IT IS FURTHER ORDERED** that:

- A. Nothing in this Order shall prevent Respondent Fresenius from complying with any HHS-CMS Requirement; and
- B. Nothing in this Order shall release Respondent Fresenius from any potential civil or administrative claim the United States has or may have under the False Claims Act, 31 U.S.C. §§ 3729-33; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the exclusion statute, 42 U.S.C. § 1320a-7(b)(7); or any common law theories of fraud, unjust enrichment, payment by mistake, breach of contract, or disgorgement, in connection with its calculation and reporting of the Manufacturer's Average Sales Price.

V.

IT IS FURTHER ORDERED that, for the term of this Order, Respondents shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly modify, change or amend the License Agreement. Said advance written notification shall contain (i) a detailed description of the proposed modification, change, or amendment to such agreements, and (ii) documents discussing the reasons for the proposed modification, change, or amendment (hereinafter referred to as "the Notification"), *provided, however*, (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice. Respondents shall provide the Notification to the Commission at least thirty (30) days prior to instituting the modifications, changes, or amendments (hereinafter referred to as the "first

Decision and Order

waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondents shall not institute changes to the agreements until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

VI.**IT IS FURTHER ORDERED** that:

- A. The Commission may, at any time after the Order becomes final, appoint a Monitor to assure that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. Not later than ten (10) days after appointment of a Monitor, Respondent Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Fresenius’ compliance with the terms of this Order in a manner consistent with the purposes of this Order.
- C. No later than one (1) day after the Monitor is appointed pursuant to this Paragraph, Respondent Fresenius shall, pursuant to the Monitor Agreement and to this Order, transfer to the Monitor all the rights, powers, and authorities necessary to permit the Monitor to perform his or her duties and responsibilities in a manner consistent with the purposes of this Order.

Decision and Order

- D. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed Monitor, Respondent Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Respondent Fresenius shall comply with the terms of Paragraph VI.B. and VI.C. after the appointment of the substitute Monitor.
- E. Respondent Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent Fresenius' compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission, including, but not limited to:
 - a. Assuring that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order; and
 - b. Assuring that Material Confidential Information is not received or used by Respondent Fresenius, except as allowed in this Order.
 2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.

Decision and Order

3. The Monitor shall serve for such time as is necessary to monitor Respondent Fresenius' compliance with the provisions of this Order.
4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Fresenius' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent Fresenius' compliance with its obligations under this Order. Respondent Fresenius shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Fresenius' compliance with this Order.
5. The Monitor shall serve, without bond or other security, at the expense of Respondent Fresenius on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
6. Respondent Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with

Decision and Order

the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

7. Respondent Fresenius shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent Fresenius, with respect to the performance of Respondent Fresenius' obligations under this Order.
 8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondent Fresenius of its obligations under this Order.
 9. Respondent Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.

Decision and Order

- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph VI.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.

VII.**IT IS FURTHER ORDERED** that:

- A. Beginning thirty (30) days after the date this Order becomes final, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order.
- B. Within thirty (30) days after Respondent Fresenius terminates its reporting of the Manufacturer's Average Sale Price of Venofer to CMS, Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such termination. Respondent Fresenius shall include in such report a written statement from CMS documenting the termination of its reporting of the Manufacturer's Average Sale Price for Venofer to CMS.
- C. Within ten (10) days after the United States Food and Drug Administration has approved a generic Venofer ANDA, Respondent Fresenius shall submit to the Commission and CMS a report stating that the ANDA was approved.

Decision and Order

D. Within ten (10) days after Respondent Fresenius sells Venofer to a purchaser at a price pursuant to Paragraph II.A.2.b., Respondent Fresenius shall submit to the Commission and CMS a report stating:

1. the price it is charging for Venofer to a purchaser pursuant to Paragraph II.A.2.b., and
2. when it began selling Venofer at that price.

The reporting requirements of this Paragraph VII.C. shall apply every time Respondent Fresenius changes the price it is selling Venofer to a purchaser pursuant to Paragraph II.A.2.b.

E. If, pursuant to Paragraph II.A.2.b., Respondent Fresenius changes how it reports the price of each intra-company transfer described in Paragraph II.A.1, for purposes of calculating the Manufacturer's Average Sales Price for Venofer, then by January 10, 2012, Respondent Fresenius shall submit to the Commission and CMS a report stating when and if Respondent will revert to the obligations in Paragraph II.A.2.a.

F. Within thirty (30) days after any Change as described in Paragraph II.A. of this Order and before Respondent Fresenius terminates its obligations under Paragraph II.A., Respondent Fresenius shall submit to the Commission a written report detailing the circumstances of such Change and an explanation of why such Change supercedes Respondent Fresenius' obligations pursuant to Paragraph II.A. of this Order. Such report shall include a statement from CMS notifying Respondent Fresenius that the Change now regulates Respondent Fresenius' calculation of the Manufacturer's Average Sales Price for Venofer to CMS.

Decision and Order

- G. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, until the Order terminates, each Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent is complying and has complied with this Order. Respondent Fresenius shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

VIII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of that Respondent;
- B. Any proposed acquisition, merger, or consolidation of that Respondent; or
- C. Any other change in that Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to each Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission to:

Decision and Order

- A. access, during business office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate the earlier of:

- A. Ninety (90) days after CMS ceases to require Respondent Fresenius to report the Manufacturer's Average Sales Price for Venofer to CMS; or
- B. On October 20, 2018.

By the Commission.

CONFIDENTIAL EXHIBIT A
[Redacted From Public Record But Incorporated By Reference]

Analysis to Aid Public Comment

CONFIDENTIAL EXHIBIT B
[Redacted From Public Record But Incorporated By
Reference]

ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT

I. Introduction

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Fresenius Medical Care Ag & Co. KGaA (“Fresenius”) and Daiichi Sankyo Company, Ltd. (“Daiichi”), which is designed to remedy the effects that would otherwise result from Fresenius’s proposed acquisition of an exclusive sublicense from Daiichi’s wholly owned subsidiary Luitpold Pharmaceuticals, Inc. (“Luitpold”) to manufacture and supply Venofer in the United States (hereinafter “License Agreement”). Venofer is an intravenously-administered preparation of iron sucrose that is used primarily to treat iron deficiency anemia in patients with chronic kidney disease undergoing dialysis treatment.

Pursuant to a License, Distribution, Manufacturing and Supply Agreement dated July 8, 2008, Luitpold and Vifor (International) Inc. agreed to grant Fresenius an exclusive sublicense to distribute, manufacture and sell Venofer to independent outpatient dialysis clinics in the United States for a term of ten years with an option to extend the agreement for an additional ten years. Luitpold retains the right to sell Venofer in the United States to any other customer, including hospitals, doctor’s offices, and

Analysis to Aid Public Comment

hospital-based dialysis clinics. The transaction is purely vertical since Fresenius does not sell products that compete with Venofer.

The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by enabling Fresenius to increase prices it charges its own clinics, which, in turn, would raise reimbursement rates that the Centers for Medicare & Medicaid Services ("CMS") pays for Venofer. The proposed Consent Agreement would remedy the alleged violations by limiting Fresenius's ability to inflate the intra-company transfer price it reports to CMS for Venofer as a mechanism to increase reimbursement rates.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order.

II. The Parties

Fresenius is the world's largest provider of dialysis products and services to patients suffering from chronic kidney disease, a condition that affects 1.6 million people worldwide. Fresenius is already vertically integrated in that it provides dialysis services through its approximately 1,650 owned or managed dialysis clinics and supplies its own and other clinics with a broad range of dialysis-related products, such as hemodialysis machines, dialyzers and related disposable products.

Daiichi, through its wholly owned subsidiary Luitpold, licenses Venofer from Vifor (International) Inc., a Swiss

Analysis to Aid Public Comment

pharmaceutical company that developed the product. Luitpold's subsidiary, American Regent, Inc., markets and distributes all of Luitpold's injectable products, including Venofer, to customers in the United States.

III. Intravenous Iron

Intravenous ("IV") iron is critical for the effective treatment of dialysis patients, the vast majority of whom suffer from chronic anemia. Without IV iron treatments, dialysis patients would suffer significantly higher mortality rates and a lower quality of life. In the United States, Luitpold's Venofer and Ferrlecit, which is manufactured by Watson Pharmaceutical Inc. ("Watson"), are the two IV iron products used most commonly to treat iron deficiency anemia in patients undergoing chronic hemodialysis. These second-generation IV iron drugs do not induce the side effects associated with first-generation IV iron products. Because of these side effects, sales of first generation IV irons in the United States are minimal.

The U.S. market for second-generation IV iron is highly concentrated. Luitpold and Watson are the only two suppliers of these drugs in the United States. In addition, entry into this market would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the effects of the proposed transaction.

IV. Reimbursement for Intravenous Iron

Approximately 80 percent of outpatient dialysis services, for patients of all ages, are reimbursed under the Medicare Part B end-stage renal disease ("ESRD") program, at an annual cost of \$7.9 billion, of which \$2.9 billion was for separately billable drugs, with IV iron payments accounting for \$400 million. Medicare reimburses dialysis clinics based on the drug manufacturer's Average Sales Price ("ASP") plus six percent.

Analysis to Aid Public Comment

ASP is calculated by averaging the prices paid by all customers, including any discounts or rebates. A clinic's profit depends not just on how much it pays for the product but the difference between the clinic's acquisition price and the average sale price. An independent clinic, one not vertically integrated with the sale of the product, prefers, all other things equal, an acquisition price that maximizes the difference between its acquisition cost and the average selling price.

The reimbursement system will change, beginning as early as 2011 and completely by 2014. On July 15, 2008, Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA"), which will make substantial changes to the Medicare program relating to dialysis services and, once fully implemented, would eliminate the regulations that give rise to the concerns created by the proposed transaction. MIPPA mandates that CMS start a process of shifting from a system in which it pays separately for physician-administered drugs for dialysis patients to a system in which all the costs of providing care to dialysis patients would be bundled together into a single capitated payment, beginning on January 1, 2011 and phased in until full implementation is achieved on January 1, 2014. Once the change from a separately-billed, ASP-based payment for Venofer to a universal bundled payment for dialysis services is in effect, the adverse effects of the proposed transaction on reimbursement rates will disappear.

IV. Competitive Effects

Unremedied, the proposed transaction would give Fresenius, the largest provider of ESRD dialysis services in the United States, the ability to increase Medicare reimbursement payments for Venofer. After the transaction, the competitive market will no longer determine the price that Fresenius's clinics will pay for IV iron. Instead, the price Fresenius's clinics pay will become an internal transfer price, and that internal transfer price could become the price that Fresenius reports as the price it charges its

Analysis to Aid Public Comment

own clinics for the product. Increasing the internal transfer price would, in turn, increase ASP and, hence, reimbursement to clinics, including Fresenius, for their use of Venofer. Unlike a “real” price increase, it would be costless for Fresenius to inflate its internal transfer price to CMS because it would not impact Fresenius’s actual cost of providing Venofer to its patients, nor would it adversely affect demand. In fact, artificially raising ASP would increase the demand for Venofer among other dialysis clinics because it would cause reimbursement levels to go up.

V. The Consent Agreement

The proposed order reduces Fresenius’s ability to report inflated intra-company transfer prices to CMS for Venofer. Under the proposed order, Fresenius would be restricted from reporting an intra-company transfer price higher than the level set forth in the order. That level is derived from current market prices. The order further provides that if a generic Venofer product receives final approval by the United States Food and Drug Administration, Fresenius would be required to report its intra-company transfer price at either (1) the level set forth in the order or (2) the lowest price at which Fresenius sells Venofer to any customer, whichever is lowest, until December 31, 2011. On January 1, 2012, the order removes the lowest-priced-customer restriction, while the level set forth in the order remains in place. By 2012, at least 50 percent of ESRD dialysis services will be covered under the capitated reimbursement system implemented by MIPPA. The order also provides that if CMS implements regulations that eliminate the potential anticompetitive harm of this transaction, those regulations will supersede the order.

The order accomplishes two goals. First, it prevents the acquisition from driving up ASP and reimbursement rates by requiring Fresenius to report its transfer price in line with current market conditions. Second, it is designed to capture potential near-term changes in the market caused by generic entry, should it

Analysis to Aid Public Comment

occur, and to ensure that the price Fresenius reports to CMS reflects the competitive impact of such future generic competition. When fully implemented, the reimbursement methodology of the new bundled pricing system will eliminate the concerns raised by the transaction. Therefore, the price-adjustment provision expires as the reimbursement mechanism changes.¹

The order also prohibits Luitpold and Fresenius from sharing confidential business information relating to the manufacture, sale, or distribution of Venofer, as Luitpold will continue to sell Venofer to non-dialysis clinics, and requires the parties to provide notice to the Commission prior to modifying the License Agreement. Finally, to enable the Commission to ensure compliance with the order, the proposed order provides that the Commission may appoint a Monitor Trustee. The Commission has not determined to appoint a monitor at this time, however, because currently it does not appear that compliance with the order would be time consuming or require particular expertise. Nevertheless, should it become necessary or appropriate, the proposed order requires Fresenius and Daiichi to execute an agreement conferring upon the Interim Monitor all of the rights and powers necessary to permit the monitor to satisfy his responsibilities.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

¹ The Commission is grateful to CMS staff for assisting the Commission as it considered the competitive implications of the proposed transaction and crafted an appropriate remedy.

Complaint

IN THE MATTER OF

**BIOQUE TECHNOLOGIES, INC.,
VITTORIO A. BONOMO,
AND
CHRISTINE A. GUILMAN**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4237; File No. 082 3095
Complaint, October 22, 2008 – Decision, October 22, 2008*

This consent order addresses advertising for Serum GV, represented by the respondents to be an effective treatment for skin cancer. The order requires the respondents to have competent and reliable scientific evidence substantiating any claims that a covered product or service is an effective treatment for skin cancer, including melanoma; prevents melanoma; is recognized by the medical profession as an effective treatment for skin cancer; or is clinically proven to prevent or treat melanoma. The order further requires that such claims be true and non-misleading. The order requires the respondents to possess competent and reliable scientific evidence for any claims about the absolute or comparative benefits, performance, efficacy, safety, or side effects of any covered product or service. The claims also must be true and non-misleading. The order prohibits the respondents from making misrepresentations about the existence, contents, validity, results, conclusions, or interpretations of any test or study. The order does not prohibit the respondents from making representations for any drug that are permitted by the Food and Drug Administration. The order requires the respondents to send to the consumers identified in the order a notification letter drafted by the FTC to inform them about the consent agreement. The order provides for the payment of \$9,035.85, the full amount of sales of the product, to the Commission. Additional provisions require the respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure (for the corporate respondent) and changes in employment (for the individual respondents) that might affect compliance obligations under the order; and to file compliance reports with the Commission.

Complaint

Participants

For the *Commission*: *Richard L. Cleland, Mary K. Engle, Diana Finegold, Karen Mandel, and Rosemary Rosso.*

For the *Respondents*: *Not represented by counsel.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Bioque Technologies, Inc., a corporation, and Vittorio A. Bonomo, individually and as a director of the corporation, and Christine A. Guilman, individually and as an officer of the corporation (“Respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Bioque Technologies, Inc. (“Bioque”) is a Virginia corporation with its principal office or place of business at 200 Country Club Drive SW, Blacksburg, Virginia 24060.

2. Respondent Vittorio A. Bonomo is a director of Bioque. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Bioque, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of the corporation.

3. Respondent Christine A. Guilman is an officer of Bioque. Individually or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Bioque, including the acts and practices alleged in this complaint. Her principal office or place of business is the same as that of the corporation.

4. Respondents have labeled, advertised, offered for sale, sold, and distributed Serum GV, a purported cancer treatment, to

Complaint

the public. Serum GV is a topical serum containing *annona muricata* as the purported active ingredient. *Annona muricata*, also known as graviola, is an extract from the soursop or guanabana tropical fruit tree. Serum GV is a “drug” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

5. The acts and practices of Respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

6. Respondents have disseminated or have caused to be disseminated advertisements for Serum GV, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements:

a. **SERUM GV**

Extraordinarily effective topical skin cancer treatment
*Clinically proven and professionally endorsed
formulation—active ingredient prevents and helps
correct melanoma*

Stamp of approval—The medical profession has recognized Serum GV as the only available and effective topical treatment for skin cancer.

Keep the doctor away—Clinical trials and research studies have demonstrated that Serum GV’s active ingredient—a glycol isolate of *annona muricata*—prevents development of melanoma; it has a natural affinity to cancer cells in their earliest stages and destroys them by cutting off their energy supply. Serves as an excellent non-surgical alternative for abnormal skin conditions—such as moles, lumps and warts.

Complaint

Support System—In cases where cancer has already appeared in the skin tissue, Serum GV boosts the body's own defense system to destroy the cancer cells.

* * *

Gently massage a small amount of Serum GV into and around targeted areas of abnormality — such as moles, lumps, and warts. Apply at least once daily; applying twice will speed up results.

[Exhibit A, Page 1 (bold and italics in original).]

7. Through the means described in Paragraph 6, Respondents have represented, expressly or by implications, that Serum GV:

- a. is an effective treatment for skin cancer, including melanoma; and
- b. prevents melanoma.

8. Through the means described in Paragraph 6, Respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made.

9. In truth and in fact, Respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made. Therefore, the representation set forth in Paragraph 8 was, and is, false and misleading.

10. Through the means described in Paragraph 6, Respondents have represented, expressly or by implication, that Serum GV:

- a. is recognized by the medical profession as an effective treatment for skin cancer; and

Complaint

b. is clinically proven to prevent or treat melanoma.

11. In truth and in fact, Serum GV is not recognized by the medical profession as an effective treatment for skin cancer and is not clinically proven to prevent or treat melanoma. Therefore, the representations set forth in Paragraph 10 were, and are, false and misleading.

12. The acts and practices of Respondents as alleged in this complaint constitute unfair or deceptive acts or practices and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-second day of October, 2008, has issued this complaint against Respondents.

By the Commission.

Complaint

EXHIBIT A

11:31:52 AM 12/21/2007

Bioque Scientific Skincare That Works

HOME NOBEL PRIZE PRODUCTS FAQS WORLD FANS PRESS SHOP CONTACT

PRIZE-WINNING PRODUCTS

SERUM GV
Extraordinarily effective topical skin cancer treatment
Clinically proven and professionally endorsed formulation—active ingredient prevents and helps correct melanoma

Stamp of approval—The medical profession has recognized Serum GV as the only available and effective topical treatment for skin cancer


Keep the doctor away—Clinical trials and research studies have demonstrated that Serum GV's active ingredient—a glycol borate of amino acid surfactants—prevents development of melanoma; it has a natural affinity to cancer cells in their earliest stages and destroys them by cutting off their energy supply. Serum GV is an excellent non-surgical alternative to abnormal skin conditions—such as moles, lumps and warts.

Support Systems—In cases where cancer has already appeared in the skin tissue, Serum GV boosts the body's own defense systems to destroy the cancer cells.

Directions for use*
Cleanse and dry skin. If using Serum XL and/or Serum Rejuvenate, apply first and wait for thorough absorption. Gently massage a small amount of Serum GV into and around targeted areas of abnormality—such as moles, lumps and warts. Apply at least once daily; applying twice will speed up results. Allow for full absorption before applying creams, moisturizers, foundations and/or makeup.

***IMPORTANT**—Although Serum GV requires no prescription, consult your doctor if you feel your medical history suggests Serum GV for any condition may not be right for you. As with all Bioque products, you need only apply a small amount. Improper application is wasteful and may cause unnecessary irritation. Avoid contact with eyes or mucous membranes. Not to be taken internally and, as with all cosmetics, keep out of the reach of children.

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Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by the Respondents that the law has been violated as alleged in the complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Bioque Technologies, Inc. (“Bioque”) is a Virginia corporation with its principal office or place of business at 200 Country Club Drive SW, Blacksburg, Virginia 24060.

Decision and Order

2. Respondent Vittorio A. Bonomo is a director of Bioque. Individually or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Bioque, including the acts and practices alleged in the complaint. His principal office or place of business is the same as that of the corporation.

3. Respondent Christine A. Guilman is an officer of Bioque. Individually or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Bioque, including the acts and practices alleged in the complaint. Her principal office or place of business is the same as that of the corporation.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - A. Bioque Technologies, Inc. (“Bioque”), a corporation, its successors and assigns and its officers;
 - B. Vittorio A. Bonomo (“Bonomo”), individually, and as a director of Bioque;
 - C. Christine A. Guilman (“Guilman”), individually, and as an officer of Bioque;

Decision and Order

and each of the above's agents, representatives, and employees.

2. "Serum GV" shall mean Serum GV and any other product containing *annona muricata*, soursop, *guanabana*, or *graviola*.
3. "Commerce" shall mean as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.
4. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
5. "Covered product or service" shall mean any health-related service or program; or any food, dietary supplement, device, or drug, including, but not limited to, Serum GV.
6. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
7. "Food," "drug," and "device" shall mean as defined in Section 15 of the FTC Act, 15 U.S.C. § 55.
8. The term "including" shall mean "without limitation."
9. The terms "and" and "or" shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

Decision and Order

I.

IT IS ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale of Serum GV or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement, that such product or service:

- A. is an effective treatment for skin cancer, including melanoma;
- B. prevents melanoma;
- C. is recognized by the medical profession as an effective treatment for skin cancer; or
- D. is clinically proven to prevent or treat melanoma,

unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name or endorsement, about the absolute or comparative benefits, performance, efficacy, safety, or side effects of such covered product or service, unless the representation is true, non-misleading, and, at the time it is

Decision and Order

made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the advertising, promotion, offering for sale, or sale of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name or endorsement, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

IT IS FURTHER ORDERED that:

- A. Nothing in this Order shall prohibit Respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this Order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the National Labeling and Education Act of 1990.

Decision and Order

V.**IT IS FURTHER ORDERED** that:

- A. Respondents shall, within seven (7) days after the date of entry of this Order, deliver to the Commission a list, in the form of a sworn affidavit, of all consumers who purchased Serum GV, on or after January 1, 2003 through the date of entry of this Order, to the extent they have such information in their possession or control. Such list shall include each consumer's name and address, the product(s) purchased, the total amount of moneys paid less any amount credited for returns or refunds, and, if available, the consumer's telephone number and email address; and
- B. Except as provided in this Order, Respondents, and their officers, agents, servants, employees, and attorneys and all other persons or entities who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined from selling, renting, leasing, transferring, or otherwise disclosing the name, address, telephone number, credit card number, bank account number, email address, or other identifying information of any person who paid any money to any Respondent, at any time prior to entry of this Order, in connection with the purchase of Serum GV. *Provided, however,* that Respondents may disclose such identifying information as required in Subparagraph A above, or to any law enforcement agency, or as required by any law, regulation, or court order.

VI.

IT IS FURTHER ORDERED that within forty-five (45) days after the date of entry of this Order, Respondents shall send by first class mail, postage prepaid, an exact copy of the notice

Decision and Order

attached as Attachment A to all persons identified in Part V(A). The mailing shall not include any other documents.

VII.

IT IS FURTHER ORDERED that Respondents shall pay to the Federal Trade Commission the sum of nine thousand, thirty-five dollars and eighty-five cents (\$9,035.85). This payment shall be made in the following manner:

- A. The payment shall be made by wire transfer or certified or cashier's check made payable to the Federal Trade Commission, the payment to be made no later than fifteen (15) days after the date that this order becomes final.
- B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961(a), from the date of default to the date of payment, shall immediately become due and payable to the Commission.
- C. The funds paid by Respondents, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of Serum GV in connection with the acts and practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment as herein

Decision and Order

provided shall be deemed a payment of any fine, penalty, or punitive assessment.

- D. Respondents relinquish all dominion, control, and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of any Respondent, Respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

VIII.

IT IS FURTHER ORDERED that Respondent Bioque, and its successors and assigns, and Respondents Bonomo and Guilman shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

IX.

Decision and Order

IT IS FURTHER ORDERED that Respondent Bioque, and its successors and assigns, and Respondents Bonomo and Guilman shall deliver a copy of this order to all current and future principals, officers, directors, and other employees with managerial authority having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

X.

IT IS FURTHER ORDERED that Respondent Bioque, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondents learn less than thirty (30) days prior to the date of such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XI.

Decision and Order

IT IS FURTHER ORDERED that Respondents Bonomo and Guilman, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their individual current business or employment, or of their individual affiliation with any new business or employment. The notice shall include the Respondent's new business address and telephone number and a description of the nature of the business or employment and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C., 20580.

XII.

IT IS FURTHER ORDERED that Respondent Bioque, and its successors and assigns, and Respondents Bonomo and Guilman shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XIII.

This order will terminate on October 22, 2028, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint; and

Decision and Order

- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Decision and Order

ATTACHMENT A

ATTACHMENT A
LETTER TO BE SENT BY FIRST CLASS MAIL
[on letterhead of Bioque Technologies, Inc.]

[Name and address of recipient]

[Date]

Dear [recipient's name]:

Our records show that you bought Serum GV from our website, www.bioque.com. We are writing to tell you that the Federal Trade Commission ("FTC") has alleged that our advertising claims for Serum GV were false or unsubstantiated. To resolve these charges, we have entered into a settlement with the FTC that prohibits us from making misleading claims about Serum GV or any other health-related product. The settlement with the FTC does not constitute an admission that we have violated the law. As part of the settlement, however, we agreed to send you the following information about the scientific evidence on Serum GV.

Very little scientific research has been done concerning Serum GV or any other product that contains *annona muricata* for the prevention, treatment, or cure of skin cancer, including melanoma, in humans. The scientific studies that have been done do not demonstrate that Serum GV or *annona muricata* effectively prevent or treat melanoma or other forms of skin cancer.

It is very important that you talk to your doctor or health care provider before using *any* alternative or herbal product, including Serum GV or any other product that contains *annona muricata*. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including Serum GV or any other product that contains *annona muricata*, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

- 10. The National Cancer Institute: www.cancer.gov/cancertopics/pdq; or
- 11. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov.

You also can contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER or 1-800-422-6237.

Sincerely,

Christine Guilman, President
Bioque Technologies, Inc.

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Bioque Technologies, Inc., Vittorio A. Bonomo, and Christine A. Guilman (together, “Respondents”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves the advertising and promotion of Serum GV, a topical serum that, according to its label, contains, among other ingredients, extract of *annona muricata*, also known as graviola, derived from the soursop or guanabana tree. According to the FTC complaint, Respondents represented that Serum GV is an effective treatment for skin cancer, including melanoma, and that it prevents melanoma. The complaint alleges that Respondents failed to have substantiation for these claims. Also according to the FTC complaint, Respondents represented that Serum GV is recognized by the medical profession as an effective treatment for skin cancer and that it is clinically proven to prevent or treat melanoma. The complaint alleges that these claims are false and misleading because Serum GV is not recognized by the medical profession as an effective treatment for skin cancer and is not clinically proven to prevent or treat melanoma. The proposed consent order contains provisions designed to prevent Respondents from engaging in similar acts and practices in the future.

Analysis to Aid Public Comment

Part I of the proposed order requires Respondents to have competent and reliable scientific evidence substantiating any claims that a covered product or service is an effective treatment for skin cancer, including melanoma; prevents melanoma; is recognized by the medical profession as an effective treatment for skin cancer; or is clinically proven to prevent or treat melanoma. The provision further requires that such claims be true and non-misleading. A “covered product or service” is defined in the order as “any health-related service or program; or any food, dietary supplement, device, or drug, including, but not limited to, Serum GV.”

Part II of the proposed order requires the Proposed Respondents to possess competent and reliable scientific evidence for any claims about the absolute or comparative benefits, performance, efficacy, safety, or side effects of any covered product or service. The claims also must be truthful and non-misleading.

Part III of the proposed order prohibits Respondents from making future misrepresentations about the existence, contents, validity, results, conclusions, or interpretations of any test or study.

Part IV of the proposed order provides that the order does not prohibit Respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration (“FDA”) standard or under any new drug application approved by the FDA and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires Respondents to provide the FTC with a list of all consumers that they know purchased Serum GV and prohibits Respondents from using or disclosing the

Analysis to Aid Public Comment

consumer information, except to a law enforcement agency or as required by law.

Part VI of the proposed order requires Respondents to send to the consumers identified in Part V a notification letter drafted by the FTC to inform them about the consent agreement.

Part VII of the proposed order provides for the payment of \$9,035.85, the full amount of sales of the product, to the Commission.

Parts VIII through XII of the proposed order require Respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure (for the corporate respondent) and changes in employment (for the individual respondents) that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**HOLLY A. BACON,
D/B/A CLEANSING TIME PRO**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4238; File No. 082 3119
Complaint, October 22, 2008 – Decision, October 22, 2008*

This consent order relates to claims made by Holly A. Bacon, doing business as Cleansing Time Pro, that Cleansing Time Pro Black Salve & Tablets were effective to treat, prevent, or cure numerous forms of cancer and various viral infections. The order requires the respondent to have competent and reliable scientific evidence substantiating any claim that Cleansing Time Pro Black Salve & Tablets, or any other covered product or service, is effective in the prevention, treatment, or cure of cancer, hepatitis, HIV, SARS, West Nile Virus, or Avian Bird Flu. The order requires that any future claim about the absolute or comparative benefits, performance, efficacy, safety or side effects of any covered product or service be truthful and supported by competent and reliable scientific evidence. The order also addresses the charge of deceptive endorsement by requiring that respondent disclose any material connection between an endorser and respondent, if such a connection exists. The order does not prohibit the respondent from making representations for any drug that are permitted by the Food and Drug Administration. The order requires the respondent to compile a list of all consumers who purchased Cleansing Time Pro Black Salve & Tablets since July 1, 2005, and to mail a letter to each purchaser describing the scientific evidence related to these products. The respondent is prohibited from providing any identifying information about her purchasers to anyone other than the Commission, another law enforcement agency, or as required by law. Additional provisions require the respondent to keep copies of relevant advertisements and materials that substantiate claims made in the advertisements; to provide copies of the order to certain of her employees; to notify the Commission of her affiliation with any new health-related business or employment; and to file compliance reports with the Commission.

Participants

For the *Commission*: *Kenneth Abbe and Matthew D. Gold.*

Complaint

For the *Respondent*: Marie C. Mirch, Mirch & Mirch.

COMPLAINT

The Federal Trade Commission, having reason to believe that Holly A. Bacon, doing business as Cleansing Time Pro (“respondent”), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is the sole proprietor of Cleansing Time Pro, a Nevada company with its principal office or place of business at 9732 State Rt. 445, #114, Sparks, Nevada 89436.

2. Respondent has advertised, labeled, offered for sale, sold, and distributed herbal products to the public, including Cleansing Time Pro Black Salve & Tablets. Respondent offers these products through her website, www.cleansingtimepro.com. Cleansing Time Pro Black Salve & Tablets are “foods” and/or “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

3. According to respondent’s promotional materials, Cleansing Time Pro Black Salve & Tablets contain “blood root, galangal & zinc chloride in a base of blended synergistic herbs (+ calcium in the tablets).” Cleansing Time Pro Black Salve is an ointment that respondent recommends for external use. Alternatively, respondent recommends that consumers take the product internally by purchasing Black Salve Tablets or by placing an amount of the Black Salve ointment into a gelatin capsule.

4. Respondent promotes her Cleansing Time Pro Black Salve Tablets and Gelatin Capsules as an internal treatment or cure for many kinds of cancer including stomach, colon, prostate, testicular, bladder, throat, thyroid, mouth, cervical, uterine,

Complaint

ovarian, pancreatic, breast, lung, liver, kidney, brain, and bone cancers, as well as lymphoma. Respondent also promotes these products as an internal treatment for various viral infections, including hepatitis, HIV, SARS, West Nile Virus, and Avian Bird Flu. Respondent promotes her Cleansing Time Pro Black Salve as an external treatment for carcinoma, melanoma, and other skin cancers. Excluding shipping and handling fees, respondent charges \$49.95 for a one-ounce jar of Cleansing Time Pro Black Salve, and \$34.95 for a 15-day supply of Cleansing Time Pro Black Salve Tablets (60 tablets).

5. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

6. Respondent has disseminated or caused to be disseminated advertisements for Cleansing Time Pro Black Salve & Tablets, including but not necessarily limited to the attached Exhibits A and B. These advertisements contain the following statements:

Internet Advertising (respondent’s website, www.cleansingtimepro.com)

A. “Cleansing Time Pro

CANCER, VIRUS & HEART DISEASE PRODUCTS
NATURAL - EASY TO USE
USE IN THE COMFORT OF YOUR OWN HOME
NO HEALTH INSURANCE REQUIRED

We have many testimonials to support our products from people who have used them to avoid major operations, radiation, chemotherapy & other drugs! We invite you to read this entire page & click on the buttons to the left to learn more about these wonderful products.

Complaint

Cleansing Time_{TM} Pro Black Salve & Tablets:

All natural herbal cancer & virus treatment & preventative that is **the** 'ORIGINAL FORMULA' and is the **Grandfather** of black salve used for over 116 years! This product has been used successfully on humans, pets & animals to prevent cancer, treat & overcome a wide range of internal & external cancers, viruses and other illnesses. It starts working in 5 seconds!

Known Uses for Cleansing Time_{TM} Pro Black Salve & Tablets

- Used in place of radiation therapy treatments & chemotherapy treatments
- Used to attack all known forms of cancer in & on the human & animal
- Used to eliminate fluid build up around tumors & shink [sic] them
- Used to normalize a-typical cells with the capability of becoming a cancer
- Used **internally** to treat & overcome a variety of cancers, malignancies & tumors. Used for stomach cancer, colon cancer, prostate cancer, testicular cancer, bladder cancer, throat cancer, thyroid cancer, mouth cancer, cervical cancer, uterine cancer, ovarian cancer, pancreatic cancer, breast cancer, lung cancer, liver cancer, kidney cancer, brain cancer & brain tumors, lymphoma, blood diseases, bone cancer & all types of viruses
- Used **externally** as a skin cancer treatment, treating carcinoma, melanoma, warts, moles & as a drawing salve
- People with in-operable cancers sent home to die have used black salve with astonishing results

Complaint

- ...
- Used to treat all types of hepatitis viruses, HIV, SARS & West Nile Virus
- ...

Testimonials and classic examples:

Unfortunately there is not enough room on this site to cover all the testimonials from people who have used these products to treat minor conditions to very serious conditions by both humans and their pets & animals. You are always welcome to use the products first hand to discern their value and/or pass the information along to those who may benefit.

I had lymphoma B cancer & used this herbal **Black Salve** internally & **Black Salve Tablets** instead of a doctors prescribed 68 radiation treatments with excellent results! I avoided all the unwanted long term side effects of radiation by using black salve. I have chosen to share my experience with others so that they may benefit from it as I have. My cancer is gone and as an added bonus I have a lot more energy. My oncologist told me near the middle of my black salve treatment I had 'the blood of a child' but he didn't know why. I had serious reservations about having radiation because of all I've heard & seen from people who have had it. After all these years of humans being subjected to radiation and all the testing they've done with it, people are still dying from it! In my opinion, black salve is the safest and most effective alternative to radiation. Holly B.

I have been plagued for 20 years with malignant basil cell carcinoma. [sic] My face & forehead have seven scars from the doctor's knife. Recently my daughter, who used black salve for her horse's melanoma, gave

Complaint

me a little dab of black salve. I used it on what I was sure was another malignant cancer. I made 1 application & about 10 days [sic] the tumor came off in the bandaid. There was a hole about 1/8 of an inch deep. It has now filled in & I don't believe there will be much of a scar, if any. I have the salve on another & hopefully the last, cancer & it's working just like the first. To me this is a miracle salve. Bill P., TX.

...

About Cleansing Time Pro

Cleansing Time Pro was established to meet the concerns and problems faced by cancer, virus, heart & vascular diseased victims who are seeking treatment for their conditions.

We began on the frontiers and over 116 years later are on the cutting edge of protecting people from such deadly diseases as the Bird Flu, SARS and the West Nile Virus worldwide! It was only months ago we first heard of these and they spread quickly to the U.S. It is common knowledge there is little that can be done once infected, according to health professionals. Medical facilities have even tried to hide the number of people infected! This is because they are not knowledgeable about and did not use our herbal treatment that is effective against viruses but instead relied on traditional medical paths. They soon discovered they were faced with full blown epidemics and most recently of SARS and the West Nile Virus. Cleansing Time Pro is all about revealing the facts. With Cleansing Time Pro's Black Salve Tablets, why not protect or treat yourself? It starts working within 5 seconds!

...

Complaint

While traditional medical paths have helped many they have also made many, many people sick. In contrast, Cleansing Time Pro is here to make people aware there is an alternative & there is something you can do right now even if you have no insurance! Our alternative treatment products have over 116 years of history behind them with many, many testimonials to prove their weight for treating & overcoming a long list of conditions unrelated & related to viruses & cancer in & on the human body as well as most pets & animals. Do you have heart or vascular problems? We have helped thousands with that too!

We believe our products are key to treatment of cancer, viruses, heart & vascular disease and prevention can be attained here in the U.S. as well as abroad.

...”

[Exhibit A, respondent’s website *www.cleansingtimepro.com*, as accessed on February 6, 2008]

Print Advertising (respondent’s Black Salve & Tablet Information & Instruction Package)

B. “**DIRECTIONS FOR HUMAN USE:**

...

Black Salve - Used Externally (Read carefully - starts working within 5 seconds)

Black Salve has been used to draw out all kinds of foreign material from the body such as glass, wood, shrapnel as well as cancer tumors and abnormal cells and tissue.

...

Complaint

The medical approach is successful in some peoples lives. However, some people who use Black Salve do not have medical operations, chemotherapy or radiation treatments with reported results. Some people have had all operations, chemotherapy and radiation either in whole or in part and have taken Black Salve with reported results. Some people with inoperable cancer/tumors have taken Black Salve with reported results. So it doesn't matter where you are in your treatment, just that you are doing something, because time is of the essence. Most people like the fact that Black Salve, a natural holistic folk remedy, can be taken in the comfort of their own home without insurance.

...

IMPORTANT WARNING NOTES:

...

Black salve can cause swelling. Because of this, people with brain tumors should not take black salve. However, if treating a brain tumor(s) with black salve you may need a qualified surgeon to insert a small hole(s) in the skull [sic] to relieve pressure. Do not think this is odd in any way. Many brain tumors are inoperable. However, a small hole is far superior to the sort of treatment one would receive from the full blown standard medical procedures.

...

Known Uses For Cleansing time™ Pro Black Salve & Tablets:

- Used in place of radiation therapy treatments & chemotherapy treatments
- Used to attack all known forms of cancer in & on the human & animal bodies

Complaint

- Used to eliminate fluid build up around tumors & shrink them
 - Used to normalize a-typical cells with the capability of becoming a cancer
 - Used internally to prevent & treat a variety of cancers, malignancies & tumors such as in the stomach, colon, prostate, testicles, bladder, throat, thyroid, mouth, cervix, uterus, ovaries, pancreas, breasts, lungs, liver, kidney, skin, lymph nodes, extremities, blood, brain & bone & terminal cancer
 - Used internally to prevent & treat all types of viruses & virus infections such as colds, flu, strep throat, mouth & gum diseases, yeast infections, all types of herpes & hepatitis viruses, shingles and even things such as prevention & treatment of HIV, SARS, West Nile Virus & Avian Bird Flu
 - Used externally to treat skin cancer, carcinoma, melanoma, warts, moles & as a drawing salve
- ...
- Used to purify blood & induce oxygen into the system inhibiting carcinogen growth
- ...

Ingredients & Formula:

Blood root, galangal & zinc chloride in a base of blended synergistic herbs (+ calcium in the tablets). Extensive research into herbal and plant life properties has indicated substantial disease prevention and healing qualities in each as well as having a multiplying effect when combined together.

Cleansing Time Pro's products have a natural chemical which enhances an enzyme known to neutralize carcinogens prior to their stimulating tumor growth. This works directly on the immune system

Complaint

and, quite naturally, acts as a preventative in that capacity. Reference: National Academy of Science.

Several case histories have revealed that formulating the proper portions of various herbal, as well as mineral ingredients results in a wide variety of healing abilities. Improper portions of the ingredients will not result in a favorable outcome. Therefore, duplication of 'Original Formula' Cleansing Time Pro Black Salve should not & can not be achieved.

History of Black Salve:

In 1890 Tom McCreary was diagnosed as having incurable, cancerous tumors on his neck, by physicians. They refused to operate, not wanting to risk his jugular vein. Tom said he paid attention to a repeated dream that came to him about how to make a remedy to cure himself. He obtained the elements and herbs for the remedy from some gypsies traveling through Texas at the time. He mixed up a black salve and applied it to his tumors. In less than a month Tom was healed and went on to live another 70 years. Over his lifetime, he was a preacher, rancher, doctor, farmer and sheriff under Judge Parker. He lived with a strength that became legendary. Tom kept the formula for the black salve to himself except for sharing it with an old friend. After Tom's long life, his son Howard and grandson Mickey, sought out the old friend who taught them how to make the black salve. Howard McCreary, attempting to make the black salve available to everyone, started a company in the '60's. The company had some tests done in the early '70's at the University of Colorado to discover more about it. The Veterinarian College at Fort Collins tested it on all viruses known at the time. They discovered that it

Complaint

killed those known viruses on contact. They discovered that with one application, sarcoids on horses (similar to skin cancer) had an 80% cure. With two applications, they achieved 100% cure. For many years it had been used to cure cancer in cows, save herds of calves from early viral diseases and treat abnormal tissue growths in all kinds of pets. By word of mouth, ranchers, homesteaders and folks on the rodeo circuits used it on external cancers, tumors and growths on themselves. Some successfully treated gangrene and even leprosy, in situations far from towns and doctors. Tom's son, Howard McCreary, was the first to use it internally. He had been diagnosed as having stomach cancer in the '60's. After he checked himself in the hospital for surgery the night before, as they did in those days, he took the first dose in a capsule without telling his doctors. The next morning they postponed his surgery because he was running a fever which continued for several days. On the 5th day, Howard said he passed a large quantity of black, vile smelling feces - apparently the growth itself. When the doctors took x-rays, they discovered that the cancerous growth was gone. Howard went on to live another 25 years without recurring stomach cancer. . . ."

[Exhibit B, respondent's Black Salve & Tablet Information & Instruction Package]

**Deceptive Representations Regarding the
Efficacy of Cleansing Time Pro Black Salve & Tablets**

7. Through the means described in Paragraph 6, respondent has represented, expressly or by implication, that Cleansing Time Pro Black Salve & Tablets:

Complaint

A. are effective in preventing, treating and/or curing all cancers, malignancies and tumors, including, but not limited to, stomach cancer, colon cancer, prostate cancer, testicular cancer, bladder cancer, throat cancer, thyroid cancer, mouth cancer, cervical cancer, uterine cancer, ovarian cancer, pancreatic cancer, breast cancer, lung cancer, liver cancer, kidney cancer, brain cancer and brain tumors, lymphoma, blood diseases, and bone cancer;

B. are effective in treating inoperable cancers;

C. are effective in treating skin cancer, including melanoma;

D. are effective in reducing the size of, or eliminating, cancerous tumors;

E. are safer and more effective in the treatment of cancer than are conventional cancer therapies, such as surgery, radiation, chemotherapy, and other drug treatments; and

F. are effective in preventing, treating, and/or curing numerous viral infections, including hepatitis, HIV, SARS, West Nile Virus, and Avian Bird Flu.

8. Through the means described in Paragraph 6, respondent has represented, expressly or by implication, that she possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made.

9. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made. Therefore, the representation set forth in Paragraph 8 was, and is, false or misleading.

Complaint

**Deceptive Representation Regarding
Endorser of Cleansing Time Pro Black Salve & Tablets**

10. Through the means described in Paragraph 6, respondent has disseminated testimonials for Cleansing Time Pro Black Salve & Tablets from consumers who purportedly were treated or cured of cancer in the ordinary course of using the product. Respondent has failed to disclose adequately that one of the endorsers had a material connection with Cleansing Time Pro. Specifically, at the time of providing her endorsement, one of the consumers was Holly A. Bacon, the sole owner of Cleansing Time Pro. This fact would materially affect the weight and credibility given by consumers to the endorsement and would be material to consumers in their purchase or use of the products. Therefore, the failure to adequately disclose this fact, in light of the representation made, was, and is, a deceptive practice.

11. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-second day of October, 2008, has issued this complaint against respondent.

By the Commission.

Complaint

EXHIBIT A

Black Salve & Wings Heartdrops



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Cleansing Time Pro

**CANCER, VIRUS & HEART DISEASE PRODUCTS
NATURAL - EASY TO USE**

**USE IN THE COMFORT OF YOUR OWN HOME
NO HEALTH INSURANCE REQUIRED**

We have many testimonials to support our products from people who have used them to avoid major operations, radiation, chemotherapy & other drugs! We invite you to read this entire page & click on the buttons to the left to learn more about these wonderful products.

Cleansing Time™ Pro Black Salve & Tablets:

All natural herbal cancer & virus treatment & preventative that is **the**

" ORIGINAL FORMULA " and
is the **Grandfather** of black salve used for
over **116 years!** This product has been used
successfully on **humans** , **pets** &
animals to prevent cancer, treat & overcome a wide
range of internal & external cancers, viruses and other illnesses. It starts
working in 5 seconds!

Known Uses for Cleansing Time™ Pro Black Salve & Tablets

- Used in place of radiation therapy treatments & chemotherapy treatments
- Used to attack all known forms of cancer in & on the human & animal
- Used to eliminate fluid build up around tumors & shrink them
- Used to normalize a-typical cells with the capability of becoming a cancer
- Used **internally** to treat & overcome a variety of cancers, malignancies & tumors. Used for stomach cancer, colon cancer, prostate cancer, testicular cancer, bladder cancer, throat cancer, thyroid cancer, mouth cancer, cervical cancer, uterine cancer, ovarian

EXHIBIT A-1

Complaint

Black Salve & Wings Heartdrops

cancer, pancreatic cancer, breast cancer, lung cancer, liver cancer, kidney cancer, brain cancer & brain tumors, lymphoma, blood diseases, bone cancer & all types of viruses

- Used **externally** as a skin cancer treatment, treating carcinoma, melanoma, warts, moles & as a drawing salve
- People with in-operable cancers sent home to die have used black salve with astonishing results
- People with virus infections sent home without a prescription by their doctor have used black salve with excellent results.
- Viruses have been repeatedly overcome such as colds, flu, strep throat, mouth diseases, herpes & yeast infections
- Used to treat all types of hepatitis viruses, HIV, SARS & West Nile Virus
- Used to repair & boost the immune system
- Highest of antioxidants
- Used to treat pets & animals with Parvo, Corona Virus, colds & flu
- Used to prevent cat cancer & dog cancer & treat bone cancer in large breed dogs

Ambrosia Skin & Scar Nectar

Massage Ambrosia emollient onto the skin to prevent & reduce the appearance of scars & sun spots - soothes & protects

Wings Heartdrops:

A Certified herbal formula used to treat & prevent heart disease, heart attacks, congestive heart failure & vascular plaque build up!

Known uses for Wings Heartdrops:

- Used to remove plaque build up in the heart & arteries
- Used to regulate the heart beat
- Used to relieve angina pain
- Used to normalize high blood pressure
- Used to lower cholesterol
- Used as a powerful anti-bacterial agent
- Used to boost the immune system

EXHIBIT A-2

Complaint

Black Salve & Wings Heartdrops

Russian Gold:

Anti-aging formula from Russia once classified and held top-secret.
It's youthening and energy capabilities are rewarding!

Known uses for Russian Gold:

- Used to increase mental function
- Used to increase energy
- Used to improve physical performance
- Used as a powerful anti-aging elixer

NOTE: This is not a scientific report or study. The above are what users have reported. These products are not endorsed by the FDA. No claims or guarantees are made & Cleansing Time Pro assumes no liability for the use of these products. This is a personal choice made solely by you. Pregnant women & people who have stomach ulcers should not use black salve or black salve tablets. Do not touch metal to black salve as it will render it useless - only use plastic or wooden utensils for application.



HOW TO PLACE YOUR ORDER: After clicking "catalog" button on the top left of the site or by clicking items found at the bottom of the site, make your selections by adding items to the shopping cart then click on the "view cart/checkout" button to add up and/or finalize your purchase.

SHIPPING: Most orders are only \$4.05 but your order will be adjusted to actual at time of transaction.

Priority Mail - Shipping Chart

Weight not over	USA 1-3 days	Int'l 4 -7 days
1 pound	4.05	6.00 - 15.00
2 pounds	4.05 - 6.00	9.00 - 19.00
3 pounds	6.00 - 8.10	12.00 - 26.00
4 pounds	8.10 Flat Rate	16.00 - 31.00

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EXHIBIT A-3

Complaint

Black Salve & Wags Heartdrops

Featured Products:









	<u>Ambrosia Skin & Scar Nectar - Emollient used to prevent & reduce the appearance of scars & sun spots</u> - 24.95 50 ml jar
	<u>Black Salve & Tablet Information & Instruction Package - For internal & external use & history of the product</u> - 3.00 Included FREE with a Salve or Tablet purchase!
	<u>Black Salve - Used externally or internally to prevent & treat cancer & viruses in & on the human & animal bodies</u> - 49.95 1 Oz Jar
	<u>Black Salve Pet & Animal Formula - Used internally to prevent & treat cancer & viruses - for small breed animals under 50 lbs.</u> - 22.00 30 Capsules
	<u>Black Salve Tablets-Used internally to prevent & treat cancer & viruses in the human, pet & animal body in a convenient tablet</u> - 34.95 60 Tablets
	<u>Empty Gelatin Capsules - Pkq of 100 - Required for internal use of black salve</u> - 4.00 Empty Gelatin Capsules
	<u>Heartdrops - 2 Fluid Oz - Certified herbal formula used to prevent & treat heart & vascular diseases</u> - 34.95 2 Fluid Oz
	<u>Heartdrops - 4 Fluid Oz - Certified herbal formula used to prevent & treat heart & vascular diseases</u> - 59.95 4 Fluid Oz
	<u>Russian Gold - Adaptogens used for deep immune support, anti-aging, energy & vitality</u> - 39.95 2 fl. oz. bottle

EXHIBIT A-4

Complaint

Testimonials on Black Salve & Wings Heartdrops


[Cleansing Time Pro](#)
[Testimonials](#)
[View Catalog](#)
[About Us](#)
[Feel Good Tips](#)
[Contact Us](#)
[FAQ's](#)
[History](#)
[Privacy Policy](#)
[Useful Links](#)
[View Cart /](#)
[Checkout](#)
Testimonials and classic examples:

Unfortunately there is not enough room on this site to cover all the testimonials from people who have used these products to treat minor conditions to very serious conditions by both humans and their pets & animals. You are always welcome to use the products first hand to discern their value and/or pass the information along to those who may benefit.

I had lymphoma B cancer & used this herbal **Black Salve** internally & **Black Salve Tablets** instead of a doctors prescribed **68 radiation treatments** with excellent results! I avoided all the unwanted long term side effects of radiation by using black salve. I have chosen to share my experience with others so that they may benefit from it as I have. My cancer is gone and as an added bonus I have a lot more energy. My oncologist told me near the middle of my black salve treatment I had "the blood of a child" but he didn't know why. I had serious reservations about having radiation because of all I've heard & seen from people who have had it. After all these years of humans being subjected to radiation and all the testing they've done with it, people are still dying from it! In my opinion, black salve is the safest and most effective alternative to radiation. Holly B.

I have been plagued for 20 years with malignant basil cell carcinoma. My face & forehead have seven scars from the doctor's knife. Recently my daughter, who used black salve for her horse's melanoma, gave me a little dab of black salve. I used it on what I was sure was another malignant cancer. I made 1 application & about 10 days the tumor came off in the bandaid. There was a hole about 1/8 of an inch deep. It has now filled in & I don't believe there will be much of a scar, if any. I have the salve on another & hopefully the last, cancer & it's working just like the first. To me this is a miracle salve. Bill P., TX

On January 1, 2001 my litter of 8 Rottweiler pups was vomiting & defacating with blood in the stools at 11pm. By 4:00 a.m. all were so ill that I called my daughter in St. Louis because she has worked extensively in veterinary care & is currently working at the university there in the Dept. of Research. She told me it sounded like **Parvo or Corona**, both of which can be fatal. I put all the pups on **Cleansing Time (black salve products)** & within 72 hours they were all drinking & eating on their own & all the above symptoms were over! Karen C.

My friend used **Wings Heart Drops** so he would not have to undergo **surgery for heart disease** that caused his heart to beat irregular & for high blood pressure. He didn't have insurance & was affaid he might not come out of the operation. I gave him a bottle of Wings & less than a week later he told me I was an 'angel' but I only supplied him with 'Wings'. He looked & felt great! Lin Gardnerville, NV

[Main Page](#) [Testimonials](#) [Catalog](#) [About Us](#)

[Feel Good Tips](#) [Contact Us](#) [FAQ's](#) [History](#) [Privacy](#)

EXHIBIT A-5

Complaint

Treatments on Black Salve & Wingo Herbs/ops

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EXHIBIT A-6

<http://www.cleansingtimepro.com/black>?pageid=6&catref=0&printstr=0 (2 of 2) [2/8/2008 10:38:55 AM]

Complaint

Catalog for Black Salve & Wings Heartdrops products



Cleansing Time Pro
Testimonials
View Catalog
About Us
Feel Good Tips
Contact Us
FAQ's
History
Privacy Policy
Useful Links
View Cart / Checkout

Shopping

Category: Top

Categories:

Catalog Search:

Jump to: 1
On page 1 of 1

[Ambrosia Skin & Scar Nectar](#) [Black Salve & Tablets](#) [Russian Gold - Anti-aging](#)

[Wings Heartdrops](#)

EXHIBIT A-7

Complaint

About Cleansing Time Pro



- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

About Cleansing Time Pro

Cleansing Time Pro was established to meet the concerns and problems faced by cancer, virus, heart & vascular diseased victims who are seeking treatment for their conditions.

We began on the frontiers and over 116 years later are on the cutting edge of protecting people from such deadly diseases as the Bird Flu, SARS and the West Nile Virus worldwide! It was only months ago we first heard of these and they spread quickly to the U.S. It is common knowledge there is little that can be done once infected, according to health professionals. Medical facilities have even tried to hide the number of people infected! This is because they are not knowledgeable about and did not use our herbal treatment that is effective against viruses but instead relied on traditional medical paths. They soon discovered they were faced with full blown epidemics and most recently of SARS and the West Nile Virus. Cleansing Time Pro is all about revealing the facts. With Cleansing Time Pro's Black Salve Tablets, why not protect or treat yourself? It starts working within 5 seconds!

We stand firm in our knowledge & belief that the traditional medical based treatments are doing little to relieve pain their patients feel while undergoing invasive operations, chemotherapy and other drug treatments along with radiation treatments that has proven harmful by the United States government. Feel free to take a look at what the National Council for Radiation Protection (NCRP) has to say at www.ncrponline.org. And see what virtually every site advocating radiation has to say about their side effects. Yet hundreds of thousands of cancer victims are being directed by medical professionals to have radiation treatments. Again, Cleansing Time Pro is all about revealing the facts. We are knowledgeable on the effects of radiation on humans and hope that you also take a serious look into this subject.

While traditional medical paths have helped many they have also made many, many people sick. In contrast, Cleansing Time Pro is here to make people aware there is an alternative & there is something you can do right now even if you have no insurance! Our alternative treatment products have over 116 years of history behind them with many, many testimonials to prove their weight for treating & overcoming a long list of conditions unrelated & related to viruses & cancer in & on the human body as well as most pets & animals. Do you have heart or vascular problems? We have helped thousands with that too!

We believe our products are key to treatment of cancer, viruses, heart & vascular disease and prevention can be attained here in the U.S. as well as abroad.

Focus Group:

Meets to discuss & categorize individual cancer, virus, heart & vascular conditions & documents individual progress & testimonials.

EXHIBIT A-8

Complaint

About Cleansing Time Pro

Great News:

Our own Ms. Holly Bacon attended the American Cancer Society's Relay For Life - Hunters for the cure (Southwest division), a 2 day & night team event to help fight cancer and remember those who lost the battle. She along with hundreds of other cancer survivors and other participants ran & walked several miles around a track, lit candles and placed donated quarters along the track. She helped raise money for the American Cancer Society by making & selling Smores (yum), sunglasses & other items. She participated in a Pajama Parade at midnight & won 1st place! She was honored with a tiara, sash & wand then made one last trip around the track in her PJ's! Way to go Holly!

Special Thanks:

Thanks go to Cleansing Time Pro Advisory Board Committee members including Research & Cleansing Consultants who so generously volunteer their time for a very good cause! Good Job!

CLEANSING TIME™ PRO**YOUR ALTERNATIVE FOR LIFE**

[Main Page](#) [Testimonials](#) [Catalog](#) [About Us](#)

[Feel Good Tips](#) [Contact Us](#) [FAQ's](#) [History](#) [Privacy](#)

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Hours of Operation
24 Hours Online !

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Discover Card
Checks & money orders by mail

EXHIBIT A-9

Complaint

Feel Good Tips from Cleansing Time Pro



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Here at Cleansing Time Pro we are committed to those who suffer from cancer, heart & vascular related illnesses. We want you to feel good! We hope these tips can help. Please feel free to share any others with us!

Feel Good Tips:

If you are undergoing ct (cat) scans and the thick white contrast/dye you are asked to drink does not agree with you or makes you sick then ask them to let you drink the lemonade drink instead. It's just like drinking lemonade and has a watery consistency.

Most people lose their hair with chemotherapy drugs and this is a trauma all by itself. However, with Black Salve products you will not lose your hair.

Most people with cancer have become 'dis'-eased due to some personal trauma or tragedy, over work, over stress and not eating right. They tend to further compound the issue with negative thinking. Therefore, it is of utmost importance that you try to think positive and 'ease' yourself! Please, let your condition just leave your mind for a minute and focus instead on all the positive things in your life right now. Do this on a regular basis several times per day & feel what a difference this makes The body often follows what the mind is thinking. Remember, you are special so be kind to yourself! Also, treat yourself to something special as often as possible.

Cancer, viruses, infections - "let's just throw the bums out!" So says Dr. Susan Lark, Founder of the Menopause & PMS Self Help Center & graduate of N.W. University School of Medicine & 3 time winner Am. Med. Asso. Dr.'s Recognition award. From cervical cancer to sniffles, from chronic fatigue to a flattened immune system she tells us she wants us to "tune in" to our body.

While undergoing any of your treatment mostly try to stay away from spicy foods.

It's important that you get your vitamins & minerals daily to strengthen your immune system. One way to do this is to get some good tasting chewable vitamins. You probably don't need mega vitamins because your system won't absorb them unless you're taking Cleansing Time Pro's "Original" formula black salve or black salve Tablets. But with the chewable vitamins you will be able to keep them on your person & take them whenever you remember even if you don't have water. Come on, you can do it. Just think of them as breath fresheners!

EXHIBIT A-10

Complaint

Feel Good Tips from Cleansing Time Pro

[Main Page](#) [Testimonials](#) [Catalog](#) [About Us](#)

[Feel Good Tips](#) [Contact Us](#) [FAQ's](#) [History](#) [Privacy](#)

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EXHIBIT A-11

Complaint

Cleansing Time Pro answers your questions about Black Salve & Wings Heartdrops



- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

Contacting Cleansing Time Pro

Our Address

Cleansing Time Pro
9732 State Rt. 445, #114
Sparks, NV 89436
USA

Phone Contact Information:

Call Toll Free! : (866) 330-3667

:

Internet Contact Information:

Customer Service: cleansingtimepro@msn.com
Website Address: www.CleansingTimePro.com

Contact Us

Name:
Company:
Email Address:
Phone:

Comments

Complaint

FAQ's about Black Salve & Wings Heartdrops



- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

FAQ's about Black Salve & Wings Heartdrops

If Cleansing Time Pro's products work on cancer, viruses, heart & vascular diseases, why don't most traditional medical doctors use them?

Because the products are herbal in nature & grown out of the ground they are not endorsed by the American Medical Association. It is soon discovered that medical facilities do not make much money with these types of "remedies" due to their effectiveness & the fact that people can & do use them in their own homes. Doctors will always use the scientific (drug) approach. Drug companies will always be advertising through the medical journals & to doctors. Please read our 'History' page to learn more about why the American Medical Association does not recognize herbal treatments.

Are there any side effects from these products?

Black salve products taken internally should be taken with food and on a full stomach to avoid an upset stomach. Side effects are usually mild & go away during or after treatment. This may include loose stools, sinus headache, stiffness in joints or fever. Black salve used externally as a poultice could cause a burning sensation and/or pain that will go away during or after treatment & may cause some degree of scarring. However, we have worked to reduce the chances of this by defining dermatological practices for your use before, during & after treatment. However, every effort should be made to let the cancerous material come to the surface of the skin naturally, leave it alone & not pick it off. Picking it off could cause unnecessary scarring & prevent the full mass from coming out. Usually this process is completed when it falls off by itself. External treatment can last days or months from start to finish depending on the severity of the condition. Wings Heartdrops will leave a garlic taste in the mouth for a few minutes after use.

Can I take these products with other medications?

It depends but there should not be any problems with most over the counter meds. The choice is ultimately solely up to you. Cleansing Time Pro is held harmless from any action you may take arising out of your condition. It is best if you either contact us or your physician or both and give it some thought about what you're trying to achieve. However, please be aware that regular physicians do not know about herbal treatments. So in most cases, if asked or told about these products it may interfere in your treatment by that physician.

EXHIBIT A-13

Complaint

FAQ's about Black Salve & Wings Heartdrops

Due to the complex human, animal & pet nature & various conditions, we will be happy to try to help you with any specific questions you may have. Simply click on the 'Contact Us' button on the left of this page & fill in the form with your question. It will be e-mailed to us at cleansingtimepro@msn.com or telephone us toll free at 1-866-330-3667.

How long will it take to get my order?

We always ship U.S. Priority mail & usually takes 2 - 3 days (United States) or 4 - 7 days (Internationally) not including holidays or weekends.

EXHIBIT A-14

<http://www.cleansingtimepro.com/faq%20about%20black%20salve%20and%20wings%20heartdrops.html> (7 of 7) (1/18/2008 10:59:04 AM)

Complaint

History of herbs & black salve



- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

A piece of history of particular interest dates back to 1825. This is an excerpt from a book authored by John S. Haller published in 1994 by the Southern Illinois University Press called Medical Protestants - the eclectics in American medicine.

With the practice of French physicians using minerals (gold, silver & copper to name a few) to treat their patients came many unsuccessful attempts. But with the few people they were able to miraculously heal with the use of metals they received much attention. The news spread to America, the practice continued and they went on to form an association of physicians. Over a period of time, some physicians incorporated the use of plant life to heal people.

After many years about 50% of the doctors left the association to form a new association of medical protestants built entirely on the use of remedies made from plant life or herbs.

However, since the original mineral association was much older it received more attention from those who would finance their endeavors. So while the mineralists struggled with many disappointing setbacks in their treatments the new protestants were slowly healing people in one small town after another. They remained healing people in this fashion ever since while the old association of metalists continued to grow with the new scientific discoveries being made throughout the century and later became known as the American Medical Association.

So there you have it folks. We can send people to the moon & mars, have a lot of fancy medical machinery to peer deeper into our beings but still can't eradicate deadly diseases. The mark (herbal treatment) was missed by a long shot as explained here but Cleansing Time Pro is turning the tide on this!

The history of black salve started when Tom McCreary was diagnosed with incurable, cancerous tumors on his neck in 1890. He used black salve and went on to live another 70 years!

So please celebrate with us as Cleansing Time Pro salutes 116 years of black salve and the history of the natural healing process!

[Main Page](#) [Testimonials](#) [Catalog](#) [About Us](#)

[Feel Good Tips](#) [Contact Us](#) [FAQ's](#) [History](#) [Privacy](#)

EXHIBIT A-15

Complaint

History of births & black sabb

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EXHIBIT A-16

<http://www.cleansingtimepro.com/bank?pageid=4&catref=0&printstr=0> (2 of 2) [2/8/2008 10:39:05 AM]

Complaint

Privacy Policy of Cleansing Time Pro



Cleansing Time Pro

Privacy Policy

Testimonials

Protecting Your Privacy

View Catalog

About Us

Feel Good Tips

The privacy & security of personal information about our customers is important to us. Our Privacy Policy governs customer information which means personally identifiable information. The policy covers individuals who obtain products from us for personal, family or household uses.

Contact Us

Security & Confidentiality

FAQ's

History

Privacy Policy

We only use a state of the art SSL (secure) system on our website for the purpose of conducting a sales transaction using the buyers information. This information is not shared by us with anyone and not retained once the transaction is complete.

Useful Links

View Cart /

Checkout

We do not retain, hold or share with any outside source any personally identifiable information regarding our customers.

Information Sharing

Cleansing Time Pro may retain information on the actual condition treated and the outcome of the treatment.

Cleansing Time Pro may retain the name, address and e-mail address of any customer for the purpose of questioniers, notification of any new treatments, products or promotional sales.

The above information is not shared with any outside source. However, you may opt out of Cleansing Time & Cleansing Time Pro's internal information sharing by requesting to opt out by clicking on our "contact us" button located on the left side of our website, calling toll free at 1-866-330-3667 or e-mailing us at cleansingtimepro@msn.com

Federal & State Laws

The practices stated above are in accordance with federal and state law.

[Main Page](#) [Testimonials](#) [Catalog](#) [About Us](#)

[Feel Good Tips](#) [Contact Us](#) [FAQ's](#) [History](#) [Privacy](#)

EXHIBIT A-17

Complaint


Privacy Policy of Cleaning Time Pro

EXHIBIT A-18

<http://www.cleaningtimepro.com/blank?pageno=5&cat=0&print=0> (2 of 2) [2/8/2008 10:39:06 AM]

Complaint

Useful Links



Useful Links

- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

[Pet Health Aromatherapy & Discount Specialist - KNN Corporation](#)
[Meet the Scala's - Your Success Is Their Business](#)
[Combat acne! A guide to the causes & various home remedies.](#)

EXHIBIT A-19

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=1055249



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Ambrosia Skin & Scar Nectar - Emollient used to prevent & reduce the appearance of scars & sun spots

50 ml jar Emollient used to prevent & reduce the appearance of scars & sun spots, hydrates tissues & restores elasticity

24.95

Qty:

EXHIBIT A-20

http://www.cleansingtimepro.com/proddetail?prodid=1055249 [2/6/2008 10:39:20 AM]

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=744149



- [Cleansing Time Pro](#)
- [Testimonials](#)
- [View Catalog](#)
- [About Us](#)
- [Feel Good Tips](#)
- [Contact Us](#)
- [FAQ's](#)
- [History](#)
- [Privacy Policy](#)
- [Useful Links](#)
- [View Cart / Checkout](#)

Shopping

[Top](#)



Black Salve & Tablet Information & Instruction Package -
For internal & external use & history of the product.

Includes instructions for internal and external use for both humans and animals and history of the product. Included FREE with a Salve or Tablet purchase.

3.00

Qty:

EXHIBIT A-21

http://www.cleansingtimepro.com/proddetail?prodid=744149 [2/6/2008 10:39:22 AM]

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=744147



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Black Salve - Used externally or internally to prevent & treat cancer & viruses in & on the human & animal bodies

49.95

Qty:

http://www.cleansingtimepro.com/proddetail?prodid=744147 [2/6/2008 10:39:23 AM]

EXHIBIT A-22

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=1034888



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Black Salve Pet & Animal Formula - Used internally to prevent & treat cancer & viruses - for small breed animals under 50 lbs.

Powdered, beef flavored pet & animal black salve formula used internally to prevent & treat cancer & viruses. For use with smaller breed animals under 50 lbs.

22.00

Qty:

EXHIBIT A-23

http://www.cleansingtimepro.com/proddetail?prodid=1034888 [2/6/2008 10:39:27 AM]

Complaint

<http://www.cleansingtimepro.com/proddetail?prodid=744148>



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Black Salve Tablets-Used internally to prevent & treat cancer & viruses in the human, pet & animal body in a convenient tablet

34.95

Qty:

EXHIBIT A-24

<http://www.cleansingtimepro.com/proddetail?prodid=744148> [2/6/2008 10:39:29 AM]

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=488190



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Empty Gelatin Capsules - Pkg of 100 - Required for
internal use of black salve

Used for internal ingestion of black salve

-4.00

Qty:

http://www.cleansingtimepro.com/proddetail?prodid=488190 [2/6/2008 10:39:30 AM]

EXHIBIT A-25

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=744855



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Heartdrops - 2 Fluid Oz - Certified herbal formula used to prevent & treat heart & vascular diseases

34.95

Qty:

EXHIBIT A-26

http://www.cleansingtimepro.com/proddetail?prodid=744855 [2/6/2008 10:39:32 AM]

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=744856



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Heartdrops - 4 Fluid Oz - Certified herbal formula used to prevent & treat heart & vascular diseases

59.95

Qty:

EXHIBIT A-27

http://www.cleansingtimepro.com/proddetail?prodid=744856 [2/6/2008 10:39:33 AM]

Complaint

http://www.cleansingtimepro.com/proddetail?prodid=1055250



- Cleansing Time Pro
- Testimonials
- View Catalog
- About Us
- Feel Good Tips
- Contact Us
- FAQ's
- History
- Privacy Policy
- Useful Links
- View Cart / Checkout

Shopping

[Top](#)



Russian Gold - Adaptogens used for deep immune support, anti-aging, energy & vitality

Anti-aging herbal extract contains adaptogens used for deep immune support, to slow the aging process & increase energy, vitality & endurance.

39.95

Qty:

EXHIBIT A-28

http://www.cleansingtimepro.com/proddetail?prodid=1055250 [2/6/2008 10:39:35 AM]

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EXHIBIT B

Cleansing Time Pro
9732 State Rt. 445, #114
Sparks, NV 89441
Toll Free: 866-330-3667
www.CleansingTimePro.com
e-mail: cleansingtimepro@msn.com

Please read this informational package more than once. We are here to help. Please allow us to do so. For more information please visit us on the world wide web or e-mail us at the addresses above.

DIRECTIONS FOR HUMAN USE:**Black Salve Tablets - Used Internally**

Virus Related Disorders: After a full meal, oral ingestion of one Cleansing Time Pro Black Salve Tablet daily for four days will usually suffice. This procedure may take several more days for more severe cases and fortify the immune system - take for a period of up to 27 days - once daily for seven days, then abstain for two days, then repeat the process for two additional weeks.

Internal Growths/Cysts: After a full meal, oral ingestion of one Cleansing Time Pro Black Salve Tablet daily for seven days, then abstain for two days, then repeat the process for three additional weeks. This should produce results of non activity. Large growths with lengthy history may take longer.

Cancer Tumors: After a full meal, oral ingestion of two Cleansing Time Pro Black Salve tablets in the morning, then two more tablets after a full meal in the evening. Do this for seven days, then abstain for two days, then repeat this process for three additional weeks. At this time you may want to perform diagnostic tests to monitor progress, if any. Another 4 week process may be necessary and then follow up with tablets periodically as you see fit to maintain non activity.

Black Salve - Used Internally

Internal Tumors: After a full meal, prepare an empty small size gelatin capsule by using a plastic or wooden instrument or toothpick. Never use metal objects as it will render the product useless. Fill the gel cap with a dab of Cleansing Time Pro Black Salve the size of a small pea - size = () in the smaller portion of the gel cap, join the gel cap back together and drink down with a large glass of water. Always prepare these daily/as needed because the moisture from the salve will cause the gel cap to melt. Take for a period of up to 28 days - once daily for seven days, then abstaining for two days, then repeating the process for three additional weeks.

A beneficial option is to begin drinking a catalyst water several days ahead such as Willard Water, Colloidal Silver Water or Lifeline is best. Check your health food stores. It is used for the distribution of the active ingredients of Black Salve to the tissue and organs but it is not necessary.

Black Salve - Used Externally (Read carefully - starts working within 5 seconds)

Black Salve has been used to draw out all kinds of foreign material from the body such as glass, wood, shrapnel as well as cancer tumors and abnormal cells and tissue.

Apply a sufficient amount of Cleansing Time Pro Black Salve to cover the irritated area (usually a thin layer but still maintaining the black color). Apply Vaseline to the gauze portion of a bandage. This is very important to prevent the bandage from sticking to the affected area. Cover the treated area with the bandage for 8 to 24 hours. Then, soak a cotton ball in Hydrogen Peroxide, remove the bandage and wash the excess salve from the area applied.

Normally a red and greyish coloring will have appeared with a degree of swelling, indicating favorable penetration. If only a

Complaint

small area in the treated area is red and greyish in color you may wish to reapply an additional amount of salve for another 24 hour period, repeating the same cleaning process. Change the Vaseline coated bandage each day after cleaning the perimeter of the area with Hydrogen Peroxide to eliminate excess excretion. Usually, the more excretion that appears the better. The salve is drawing the abnormal tissue, cells and mass to the surface for elimination. This is usually accomplished without any noticeable bleeding. Often at this stage the growth will become twice or more its normal size and the area around the growth may swell. The growth may lighten in color becoming 'dead white' after the first day and may then re-darken slightly. Pus may form under and around the growth as the body pushes the growth out.

You may shower or wash the area every day. It is essential to keep it covered with new daily applications of Vaseline and clean bandages. This is based on experience.

A scab will appear and remove itself usually within ten days to three weeks. More favorable results will occur if the scab is not lifted or pried from the area. Normally, the skin will return to a smooth surface shortly after either by filling in with new tissue or scar tissue. Effects of scarring can be eliminated or minimized by taking vitamin E orally before and during use and rubbing vitamin E on the area after the scab falls off.

The salve used externally can cause a burning sensation. This should be kept in mind when applying to very large areas. The effects of this can be lessened by taking over the counter pain medication prior to and during its use. If severe pain develops only leave the salve on for 8 hours, wash the salve off the skin and apply plain Vaseline to another clean bandage and cover the affected area.

If dealing with a skin cancer, it is recommended to treat one area at a time but not more than five areas, waiting for the hole to fill in with new skin before treating the second or consecutive area(s). You may want to start in a place where you can hide the bandage easily such as just under your shirt sleeve, etc. The salve will draw from the surrounding circumference of the treated area.

These recommendations describe the absolute minimum doses that people have found to be effective. It cannot be stressed enough that Black Salve is very potent. Do not assume that if a little works, more will be better. Use the smallest doses possible and increase only if it truly seems necessary to you. Otherwise you will engender far more pain than necessary and extend the healing period.

What Everyone Needs to Know:

The tablets are all you need if you are just doing a regular detoxification. But if you're dealing with a very serious problem you should have both tablets and salve. For instance, you might want to take up to two salve capsules per day then follow up your treatment with the tablets at a later date to maintain non activity. Do not exceed 4 tablets or 2 capsules per day. If using the salve externally, you may want to take a tablet orally as well.

There is no set dosage and the amount taken will depend on each person and the way they feel after taking it. You may want to increase or decrease the dosage. Always take with a meal to avoid stomach upset.

Due to the ingredients used to hold the tablets together to form the pill it has less active ingredients than the salve. A single tablet is 1/2 the potency of a pea size portion of salve in a gelatin capsule.

You might feel 'pain', a 'pulling', 'drawing' or 'tingling' sensation as the tumor or cancer starts to break down and come away or dissolve. You may notice a lessening of the above feelings as your treatment progresses & this is a good sign!

'Original Formula' Cleansing Time Pro Black Salve products have been called 'the relentless healer' tracking down cancer cells and abnormalities throughout the body when used internally and flushing them from your system via your waste. Some people have reported loose bowels, foul breath and feces due to the elimination process. And when used externally, deposits them to the surface of the skin in varied appearances (usually the uglier the excretion the better). Pain, swelling and sometimes fever is associated during its use but in almost all reported cases, it eliminates abnormal tissue and stimulates regrowth of either healthy tissue or scar tissue.

If you are in the process of using chemotherapy, do not use Black Salve. The chemical action that occurs with the herbs could clash with the substances in chemotherapy drugs. Also, Black Salve may destroy or rid your body of the chemotherapy drugs. Waiting a sufficient amount of time after chemotherapy is your best bet.

Complaint

The medical approach is successful in some peoples lives. However, some people who use Black Salve do not have medical operations, chemotherapy or radiation treatments with reported results. Some people have had all operations, chemotherapy and radiation either in whole or in part and have taken Black Salve with reported results. Some people with inoperable cancer/tumors have taken Black Salve with reported results. So it doesn't matter where you are in your treatment, just that you are doing something, because time is of the essence. Most people like the fact that Black Salve, a natural holistic folk remedy, can be taken in the comfort of their own home without insurance.

It is particularly important to take daily vitamins & minerals and to try to eat fresh fruits & vegetables during and after treatment with Black Salve Tablets or Capsules to help fortify your immune system and give you strength and energy. Vitamin E tablets or vitamin E cream is also recommended for use.

Refuse to indulge in self doubt or in feeling like a victim. Rather, (on a daily basis as often as possible) fan in yourself the ferocious feeling of YES to the life-force, to preservation and to becoming greater than you were yesterday. This triggers the body's release of hormones and enzymes that literally instruct the body to become whole and stay well! Please understand that each of us can do anything and that miraculous change is the result of a mind and a feeling that will accept nothing less.

IMPORTANT WARNING NOTES: Pregnant women or people with stomach ulcers should not use black salve or black salve tablets. Always take black salve on a full stomach. Do not touch anything metal to black salve, use only wooden or plastic utensils. People applying salve topically should use extreme caution. People treating late stage liver cancer should use black salve or tablets sparingly. Do not take black salve if you are currently on chemotherapy, wait at least 2 weeks. Keep out of the reach of other people, children, pets & animals.

Cleansing Time Pro recommends diagnostics (blood tests, MRI's, CT scans or PET scans) be performed to gauge your condition, progress or size of your tumor, your blood levels, etc.

Black salve can cause swelling. Because of this, people with brain tumors should not take black salve. However, if treating a brain tumor(s) with black salve you may need a qualified surgeon to insert a small hole(s) in the skull to relieve pressure. Do not think this is odd in any way. Many brain tumors are inoperable. However, a small hole is far superior to the sort of treatment one would receive from the full blown standard medical procedures.

While we have had great success in treating cancer and viruses with these products, they may not be for everyone. This informational package has been prepared as a narration of what users have reported and what to be the most effective way to use Black Salve products. No claims or guarantees can be made by Cleansing Time™ Pro as to the use of Black Salve products. By virtue of its use it must be understood that the choice and process used in the various forms of application or ingestion of these products is the sole responsibility of the user and does so at their own risk and accept full responsibility for any effects. Use remains at your sole discretion and Cleansing Time Pro is held harmless from any and all claims.

Known Uses For Cleansing Time™ Pro Black Salve & Tablets:

- Used in place of radiation therapy treatments & chemotherapy treatments
- Used to attack all known forms of cancer in & on the human & animal bodies
- Used to eliminate fluid build up around tumors & shrink them
- Used to normalize atypical cells with the capability of becoming a cancer
- Used internally to prevent & treat a variety of cancers, malignancies & tumors such as in the stomach, colon, prostate, testicles, bladder, throat, thyroid, mouth, cervix, uterus, ovaries, pancreas, breasts, lungs, liver, kidney, skin, lymph nodes, extremities, blood, brain & bone & terminal cancer
- Used internally to prevent & treat all types of viruses & virus infections such as colds, flu, strep throat, mouth & gum diseases, yeast infections, all types of herpes & hepatitis viruses, shingles and even things such as prevention & treatment of HIV, SARS, West Nile Virus & Avian Bird Flu
- Used externally to treat skin cancer, carcinoma, melanoma, warts, moles & as a drawing salve
- Used to treat pets & animals with colds, flu, Parvo, Corona Virus, cancer, tumors & prevention/treatment of bone cancer in large breed dogs
- Used to purify blood & induce oxygen into the system inhibiting carcinogen growth
- Used to repair & boost the immune system & enhance overall assimilation of nutrients
- Used as the highest of antioxidants
- Used to remove plaque from teeth and disease from gums by applying a match head size portion of Cleansing Time Pro Salve to the toothpaste used once daily for 7 to 10 days

Complaint

- Used to alleviate yeast infection in human females with use of one pea size portion of salve per quart of warm water as a douche. Used to alleviate infections on male human & animal gender parts (including horses) by washing with the above douche.

DIRECTIONS FOR PET & ANIMAL USE:

Black salve works in/on animals in very much the same way as humans! Please read the animal & history sections that follow for more information.

Black Salve - external use: The same directions for salve used on humans apply to animals & can be found on page 2. Exception: Do Not use salve on areas of the animal where it can be licked off such as on the paws or legs unless a cone collar is used and the animal proves not to be able to access the treated area with the collar on. Do not remove the cone collar until the full treatment is over and the salve is washed off completely or the hole has filled in with new skin.

The doses for tablets & salve are different for animals than they are for humans. Be sure to feed the animal plenty of food before each dose and have plenty of water available. Open the jaws/mouth and slip the tablet to the back of the throat so it can be swallowed. Keep an eye on the pet for any unusual signs such as vomiting and discontinue use if necessary or cut back on the dose. The pet may have loose stools - be prepared in advance for this. Diagnostics such as x-rays, & blood tests are recommended to gauge the animals progress.

Black Salve Tablets - internal use: General illnesses - Animals 2 to 15 pounds - 1/4 of a tablet per day. Animals 15 to 30 pounds - 1/2 of a tablet per day. Animals 30+ pounds - 1 full tablet per day. Administer for 5 days then abstain for 2 days. Depending on the effectiveness of the first treatment, a second treatment may be given and follow up with subsequent treatments as you see fit. Severe illnesses - double the dose by administering once in the morning and once in the evening.

Black Salve using empty gelatin capsules - internal use: More severe illnesses or cancer - animals 50 pounds or more - prepare an empty gel cap with 1/2 of a dried pea size portion of salve. Administer for 7 days then abstain for 2 days. Repeat this process for an additional 2 weeks or up to 27 days. Animals 80 to 150 pounds (and when trying to prevent/treat bone cancer in large breed dogs) - prepare an empty gel cap with 1 dried pea size portion of salve. See found on page 1 of this informational packet. Administer for 7 days then abstain for 2 days. Repeat this process for an additional 2 weeks. A second course up to 27 days may be administered.

Horses, cattle & large animals: General illnesses: prepare 1 or 2 gel caps with a dried pea size portion of salve. Administer for 7 days then abstain for 2 days then repeating this process if needed. For more severe illnesses: prepare up to 3+ gel caps in the morning after the animal has been fed & another 3+ gel caps in the evening after its meal with a dried pea size portion of salve. Administer for 7 days, then abstain for 2 days. Repeat this process for an additional 2 weeks or up to 27 days. A second course up to 27 days may be administered. For ease in treating very large animals, the same stated portions of salve may be blended up with a liquid such as water and squirted down the throat taking care not to let the liquid splash out onto yourself, the animal or surrounding areas.

Small breed pets & animals (Under 50 lbs.) - We carry a specially designed powdered, beef flavored gelatin capsule specifically for use on small breed animals under 50 pounds. Separate directions & dosage comes printed on the product bottle. This product may be stirred in the pets food or the capsule may be inserted to the back of the pets throat.

Ingredients & Formula:

Blood root, galangal & zinc chloride in a base of blended synergistic herbs (+ calcium in the tablets). Extensive research into herbal and plant life properties has indicated substantial disease prevention and healing qualities in each as well as having a multiplying effect when combined together.

Cleansing Time Pro's products have a natural chemical which enhances an enzyme known to neutralize carcinogens prior to their stimulating tumor growth. This works directly on the immune system and, quite naturally, acts as a preventative in that capacity. Reference: National Academy of Science.

Several case histories have revealed that formulating the proper portions of various herbal, as well as mineral ingredients results in a wide variety of healing abilities. Improper portions of the ingredients will not result in a favorable outcome. Therefore, duplication of 'Original Formula' Cleansing Time Pro Black Salve should not & can not be achieved.

Complaint

History of Black Salve:

In 1890 Tom Mc Creary was diagnosed as having incurable, cancerous tumors on his neck, by physicians. They refused to operate, not wanting to risk his jugular vein. Tom said he paid attention to a repeated dream that came to him about how to make a remedy to cure himself. He obtained the elements and herbs for the remedy from some gypsies travelling through Texas at the time. He mixed up a black salve and applied it to his tumors. In less than a month Tom was healed and went on to live another 70 years. Over his lifetime, he was a preacher, rancher, doctor, farmer and sheriff under Judge Parker. He lived with a strength that became legendary. Tom kept the formula for the black salve to himself except for sharing it with an old friend. After Tom's long life, his son Howard and grandson Micky, sought out the old friend who taught them how to make the black salve. Howard Mc Creary, attempting to make the salve available to everyone, started a company in the '60's. The company had some tests done in the early '70's at the University of Colorado to discover more about it. The Veterinarian College at Fort Collins tested it on all viruses known at the time. They discovered that it killed those known viruses on contact. They discovered that with one application, sarcoids on horses (similar to skin cancer) had an 80% cure. With two applications, they achieved 100% cure. For many years it had been used to cure cancer in cows, save herds of calves from early viral diseases and treat abnormal tissue growths in all kinds of pets. By word of mouth, ranchers, homesteaders and folks on the rodeo circuits used it on external cancers, tumors and growths on themselves. Some successfully treated gangrene and even leprosy, in situations far from towns and doctors. Tom's son, Howard Mc Creary, was the first to use it internally. He had been diagnosed as having stomach cancer in the '60's. After he checked himself in the hospital for surgery the night before, as they did in those days, he took the first dose in a capsule without telling his doctors. The next morning they postponed his surgery because he was running a fever which continued for several days. On the 5th day, Howard said he passed a large quantity of black, vile smelling feces - apparently the growth itself. When the doctors took x-rays, they discovered that the cancerous growth was gone. Howard went on to live another 25 years without recurring stomach cancer.

Another piece of history of particular interest dates back to 1825 in America. This is an excerpt from a book authored by John S. Haller published in 1994 by the Southern Illinois University Press called Medical Protestants - the eclectics in American medicine. With the practice of French physicians using metals (gold, silver & copper to name a few) to treat their patients came many unsuccessful attempts. But with the few people they were able to miraculously heal with the use of metals they received much attention. The news spread to America, the practice continued and they went on to form an association of physicians. Over a period of time, some physicians incorporated the use of plant life to heal people. After many years about 50% of the doctors left the association to form a new association of medical protestants built entirely on the use of remedies made from plant life or herbs. However, since the original association was much older it received more attention from those who would finance their endeavors. So while the metalists struggled with many disappointing setbacks in their treatments the new protestants were slowly healing people in one small town after another. They remained healing people in this fashion ever since while the old association of metalists continued to grow with the new scientific discoveries being made throughout the century and later became known as the American Medical Association. So there you have it folks, the reason why we have a lot of fancy medical machinery to peer deeper into our beings but can't seem to eradicate deadly diseases.

Please celebrate with us as Cleansing Time Pro salutes 117 years of "Original Formula" Black Salve, the grandfather of cancer and virus treatment and the history of the natural prevention and healing process!

TABLETS**SALVE**

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Western Region proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Holly A. Bacon is the sole proprietor of Cleansing Time Pro, a Nevada company with its principal office or place of business at 9732 State Rt. 445, #114, Sparks, Nevada 89436.

Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “respondent” means Holly A. Bacon, individually and doing business as Cleansing Time Pro, her successors and assigns, and her officers, agents, representatives and employees.
2. “Commerce” means as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. “Competent and reliable scientific evidence” means tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
4. “Food” and “drug” mean “food” and “drug” as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
5. “Covered product or service” means any food, dietary supplement, or drug, including, but not limited to, Cleansing Time Pro Black Salve & Tablets, or any other health-related product, service, or program.

Decision and Order

6. “Endorsement” means as defined in 16 C.F.R. § 255.0(b).
7. “Clearly and prominently” means as follows:
 - a. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. *Provided, however,* that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the ad is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.
 - b. In a print advertisement, promotional material (including, but not limited to a rebate coupon or form), or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.
 - c. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

Decision and Order

The disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

8. The term “including” in this order means “without limitation.”
9. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of Cleansing Time Pro Black Salve & Tablets, or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

- A. that such product is effective in the prevention, treatment, or cure, or assists in the prevention, treatment, or cure, of cancer;
- B. that such product is effective in the treatment of inoperable cancers;
- C. that such product is effective in the treatment of skin cancer, including melanoma;
- D. that such product reduces the size of, or eliminates, cancerous tumors;

Decision and Order

- E. that such product is safer and more effective in the treatment of cancer than are conventional cancer therapies, such as surgery, radiation, chemotherapy, and other drug treatments; or
- F. that such product is effective in the prevention, treatment, or cure, or assists in the prevention, treatment, or cure, of hepatitis, HIV, SARS, West Nile Virus, or Avian Bird Flu,

unless the representation is true, non-misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name or endorsement, about the absolute or comparative benefits, performance, efficacy, safety, or side effects of such covered product or service, unless the representation is true, non-misleading, and, at the time it is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising, labeling, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about any user or endorser of such product or service unless she discloses, clearly and

Decision and Order

prominently, a material connection, when one exists, between such user or endorser and the respondent or any other individual or entity manufacturing, advertising, promoting, offering for sale, selling, or distributing such product or service. For purposes of this Part, “material connection” means any relationship that materially affects the weight or credibility of the user testimonial or endorsement and that would not reasonably be expected by consumers.

IV.**IT IS FURTHER ORDERED** that:

- A. Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.**IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days of the date of entry of this order, respondent shall compile a list containing the full name and mailing address, the product(s) purchased, and, if available, the consumer’s telephone number and email address, of every person who has purchased Cleansing

Decision and Order

Time Pro Black Salve & Tablets from the respondent since July 1, 2005; and

- B. Within forty-five (45) days after the date of entry of this order, respondent shall send by first class mail, postage prepaid, an exact copy of the notice attached as Attachment A to all persons identified in Subparagraph A of this Paragraph. The mailing shall not include any other documents.

VI.

IT IS FURTHER ORDERED that respondent shall not sell, rent, lease, transfer, or otherwise disclose the name, address, telephone number, credit card number, bank account number, e-mail address, or other identifying information of any person who paid any money to respondent, at any time prior to entry of this order, in connection with the purchase of Cleansing Time Pro Black Salve & Tablets. *Provided, however;* that respondent shall disclose to the FTC, upon request, the list compiled pursuant to Paragraph V.A of this order; and respondent may disclose such identifying information to a law enforcement agency or as required by any law, regulation, or court order.

VII.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. A specimen copy of all advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and

Decision and Order

- C. All tests, reports, studies, surveys, demonstrations, or other evidence in her possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondent shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying a copy of each signed statement acknowledging receipt of the order.

IX.

IT IS FURTHER ORDERED that respondent, for a period of three (3) years after the date of issuance of this order, shall notify the Commission of the discontinuance of her current business or employment, or of her affiliation with any new health-related business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and her duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

Decision and Order

X.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which she has complied with this order.

XI.

This order will terminate on October 22, 2028, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

FEDERAL TRADE COMMISSION DECISIONS
VOLUME 146

Decision and Order

ATTACHMENT A**ATTACHMENT A**
LETTER TO BE SENT BY FIRST CLASS MAIL
[To be printed on letterhead of Cleansing Time Pro]

[Name and address of recipient] [Date]

Dear [Recipient]:

Our records show that you bought Cleansing Time Pro Black Salve & Tablets. These products were sold on our website www.cleansingtimepro.com. We are writing to tell you that the Federal Trade Commission ("FTC") has alleged that our advertising claims for these products were false or unsubstantiated. To resolve these charges, we have entered into a settlement with the FTC that prohibits us from making misleading claims about these products or any other health-related product. The settlement with the FTC does not constitute an admission that we have violated the law. As part of the settlement, however, we agreed to send you the following information about the scientific evidence on Cleansing Time Pro Black Salve & Tablets.

Very little scientific research has been done concerning Cleansing Time Pro Black Salve & Tablets as a treatment or cure for cancer in humans. The scientific studies that have been done do not demonstrate that Cleansing Time Pro Black Salve & Tablets, or the ingredients in these products, are effective when used as treatments for cancer. In addition, according to the American Cancer Society, there have been numerous reports of severe burns and permanent scarring from some of these salves.

It is very important that you talk to your doctor or health care provider before using *any* alternative or herbal product, including Cleansing Time Pro Black Salve & Tablets. Speaking with your doctor is important to make sure that all aspects of your medical treatment work together. Things that seem safe, such as certain foods, herbs, or pills, may interfere or affect your cancer or other medical treatment, or other medicines you might be taking. Some herbs or other complementary or alternative treatments may keep your medicines from doing what they are supposed to do, or could be harmful when taken with other medicines or in high doses. It also is very important that you talk to your doctor or health care provider before you decide to take any alternative or herbal product, including Cleansing Time Pro Black Salve & Tablets, instead of taking conventional cancer treatments that have been scientifically proven to be safe and effective in humans.

If you would like further information about complementary and alternative treatments for cancer, the following Internet web sites may be helpful:

1. The National Cancer Institute: www.cancer.gov/cancertopics/pdq; or
2. The National Center for Complementary and Alternative Medicines: www.nccam.nih.gov

You also can contact the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER or 1-800-422-6237.

Sincerely,

Analysis to Aid Public Comment

ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Holly A. Bacon, doing business as Cleansing Time Pro (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter concerns the advertising and promotion of products known as Cleansing Time Pro Black Salve & Tablets. According to their labels, these products contain “blood root, galangal & zinc chloride in a base of blended synergistic herbs (+ calcium in the tablets).” Cleansing Time Pro Black Salve is an ointment that respondent recommends for external use. Alternatively, respondent recommends that consumers take the product internally by purchasing Black Salve Tablets or by placing an amount of the Black Salve ointment into a gelatin capsule.

The Commission’s complaint charges that respondent claimed that Cleansing Time Pro Black Salve & Tablets were effective to treat, prevent, or cure numerous forms of cancer and various viral infections, including hepatitis, HIV, SARS, West Nile Virus, and Avian Bird Flu. The complaint alleges that respondent did not have a reasonable basis for these claims. The Commission’s complaint also challenges respondent’s testimonial advertising. The complaint alleges that respondent failed to disclose adequately that one of the endorsers was respondent Holly A. Bacon herself. The complaint alleges that this was a deceptive act or practice, because the fact that one of the endorsers had a

Analysis to Aid Public Comment

material connection with Cleansing Time Pro would materially affect the weight and credibility given by consumers to the endorsement and would be material to consumers in their purchase or use of the products.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I requires respondent to have competent and reliable scientific evidence substantiating any claim that Cleansing Time Pro Black Salve & Tablets, or any other covered product or service, is effective in the prevention, treatment or cure of cancer, cancer, hepatitis, HIV, SARS, West Nile Virus, or Avian Bird Flu. A “covered product or service” is defined as any food, dietary supplement, or drug, including, but not limited to, Cleansing Time Pro Black Salve & Tablets, or any other health-related product, service, or program. Part II requires that any future claim about the absolute or comparative benefits, performance, efficacy, safety or side effects of any covered product or service be truthful and supported by competent and reliable scientific evidence.

Part III of the proposed order addresses the deceptive endorsement claim by requiring that respondent disclose any material connection between an endorser and respondent, if such a connection exists. “Material connection” is defined as any relationship that materially affects the weight or credibility of the user testimonial or endorsement and that would not reasonably be expected by consumers.

Part IV of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative or final Food and Drug Administration (“FDA”) standard or under any new drug application approved by the FDA; and representations for any product that are specifically permitted in labeling for that

Analysis to Aid Public Comment

product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires respondent to compile a list of all consumers who purchased Cleansing Time Pro Black Salve & Tablets from respondent since July 1, 2005, and to mail a letter (Attached to the proposed order as Attachment A) to each purchaser describing the scientific evidence related to these products. Part VI prohibits respondent from providing any identifying information about her purchasers to anyone other than the Commission, another law enforcement agency, or as required by law.

Parts VII through X of the proposed order require respondent to keep copies of relevant advertisements and materials that substantiate claims made in the advertisements; to provide copies of the order to certain of her employees; to notify the Commission of her affiliation with any new health-related business or employment; and to file compliance reports with the Commission. Part XI of the proposed order is a “sunset” provision, dictating that the order will terminate twenty years from the date it is issued or twenty years after a complaint is filed in federal court, by either the United States or the FTC, alleging any violation of the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.