UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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In the Matter of))
DOCKET NO. 9267
METAGENICS, INC.,)
a corporation, doing business as) AGREEMENT CONTAINING
Ethical Nutrients, and) CONSENT ORDER TO
) CEASE AND DESIST
JEFFREY KATKE,)
individually and as an officer)
of said corporation.)
_____)

The agreement herein, by and between Metagenics, Inc., a corporation, by its duly authorized officer, and Jeffrey Katke, individually and as an officer of said corporation, hereafter sometimes referred to as respondents, and their attorneys, and counsel for the Federal Trade Commission, is entered into in accordance with the Commission's Rules governing consent order
procedures. In accordance therewith the parties hereby agree that:

1. Respondent Metagenics, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of California, with its office and principal place of business located at 971 Calle Negocio, San Clemente, California 92672. Respondent Jeffrey Katke is an officer of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation, and his address is the same as that of said corporation.

2. Respondents have been served with a copy of the complaint and the amended complaint issued by the Federal Trade Commission charging them with violation of Section 5(a) and 12 of the Federal Trade Commission Act, and have filed an answer to said complaint denying
said charges. After a hearing, the Administrative Law Judge issued an Initial Decision in this matter. Both respondents and counsel supporting the complaint filed notices of appeal from the Initial Decision. In lieu of pursuing cross-appeals, respondents and counsel supporting the complaint have agreed to the entry of this Agreement Containing Consent Order to Cease and Desist based upon the amended complaint.

3. Respondents admit all jurisdictional facts set forth in the Commission's complaint and amended complaint in this proceeding.

4. Respondents waive:

(a) Any further procedural steps;
(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
(d) Any claim under the Equal Access to Justice Act.

5. This agreement shall not become part of the public record of the proceeding unless

and until it is accepted by the Commission. If the agreement is accepted by the Commission, it will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the respondents, in which event it will take such action as it may consider
appropriate, or issue and serve its decision, in disposition of the proceeding.
6. This agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in the complaint and amended complaint, or that the facts as alleged in the complaint and amended complaint, other than jurisdictional facts, are true.
7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 3.25(f) of the Commission's Rules, the Commission may without further notice to respondents, (1) issue its decision containing the following order to cease and desist in disposition
of the proceeding, and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall
become final upon service. Delivery by the U.S. Postal Service of the decision containing the agreed-to order to respondents' address as stated in this agreement shall constitute service. Respondents waive any right they might have to any other manner of service. The complaint and the amended complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or to contradict the terms of the order.
8. Respondents have read the complaint, the amended complaint, and the order contemplated hereby. They understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. Respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

I

IT IS ORDERED that respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey
Katke, individually and as an officer of said corporation, and respondents' agents, representatives,
and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce,
as "commerce" is defined in the Federal Trade Commission Act, shall not represent, in any manner, directly or by implication, that:
1. post-menopausal women who have lost bone and who use such product will

experience no additional bone loss or bone thinning or will achieve a growth of new bone or increased bone thickness greater than the amount of bone lost;
2. users of such product will not experience bone loss or bone thinning;
3. such product restores bone strength;
4. such product reduces or eliminates pain associated with bone ailments; or
5. such product is more bioavailable, more absorbable, or more effectively utilized by the body than other forms of calcium, or is superior to or more effective than other forms of calcium in the prevention or treatment of bone ailments,

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "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.

II

IT IS FURTHER ORDERED that respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers,

and Jeffrey Katke, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food"

and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

III

IT IS ORDERED that respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey

Katke, individually and as an officer of said corporation, and respondents' agents, representatives,

and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce,

as "commerce" is defined in the Federal Trade Commission Act, insofar as said respondents make

any representation, in any manner, directly or by implication, regarding the relationship between calcium and osteoporosis:

A. shall limit any such representation to the health claims authorized by the Food and Drug Administration for calcium and osteoporosis as set forth in Section 101.72 of Title 21 of the Code of Federal Regulations, 58 Fed. Reg. 2665 (1993), and any

amendments thereto; or
B. at the time of making such representation, shall possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV

IT IS FURTHER ORDERED that respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey Katke, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of:
A. Bone Builder or any food or dietary supplement, food, or drug containing calcium, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not make any representation, in any manner, directly or by implication, that any such product will treat, cure, alleviate the symptoms of, prevent, or reduce the risk of developing any disease, disorder, or condition; or

B. any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not make any representation, in any manner, directly or by implication, that any such product is more effective than any other product in treating, curing, alleviating the symptoms of, preventing, or reducing the risk of developing any disease, disorder, or condition,
unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V

Nothing in this Order shall prohibit respondents from making any representation that is specifically permitted in labeling for any such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI

Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VII

IT IS FURTHER ORDERED that for five (5) years after the last date of dissemination of any representation covered by this Order, respondents, or their successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:
A. Any advertisement making any representation covered by this Order;
B. All materials that were relied upon in disseminating such representation; and
C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers, and complaints or inquiries from governmental

organizations.

VIII

IT IS FURTHER ORDERED that respondent Metagenics, Inc., or its successors and assigns, shall:

A. Within thirty (30) days after the date of issuance of this Order, provide a copy of this Order to each of its operating divisions, subsidiaries, principals, officers, directors, managers and distributors, and to each of its employees, agents, and representatives engaged in the preparation, placement, or dissemination of advertisements, promotional materials, product labels, or other such sales materials covered by this Order; and

B. For a period of five (5) years from the date of issuance of this Order, provide a copy of this Order to each of its principals, officers, directors, managers and distributors, and to all employees, agents, and representatives engaged in the preparation, placement, or dissemination of advertisements, promotional materials, product labels, or other such sales materials covered by this Order within three (3) days after the person commences his or her responsibilities.

IX

IT IS FURTHER ORDERED that respondent Metagenics, Inc., 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 a 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 the acts or practices subject to this order; the proposed 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 the respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as 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, Washington, D.C. 20580.

X

IT IS FURTHER ORDERED that for a period of five (5) years from the date of issuance of this Order, respondent Jeffrey Katke shall provide written notice to the Federal Trade Commission within thirty (30) days of:

A. Any change in his business or employment that may affect compliance obligations arising out of this Order;

B. The discontinuance of his business or employment; and

C. His affiliation with any new business or employment; each such notice to include his business address and telephone number, home address, and a statement describing the nature of the business or employment and his duties and responsibilities.

XI

This order will terminate twenty years from the date of its issuance, or twenty 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 paragraph in this order that terminates in less than twenty 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 paragraph.

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 paragraph as though the complaint was never 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.

XII

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after service upon them of this Order, and at such other times as the 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.

SIGNED this ___ day of _____, 1996.

Metagenics, Inc.

BY: _____

Jeffrey Katke

President

_____

Jeffrey Katke

Individually and as an officer of Metagenics, Inc.

_____

Robert Ullman, Esq.

Marc Ullman, Esq.

Bass & Ullman, P.C.

Counsel for Metagenics, Inc. and Jeffrey Katke

_____

Lesley Anne Fair

Counsel Supporting the Complaint

APPROVED:

_____

C. Lee Peeler

Associate Director for Advertising Practices

_____

Joan Z. Bernstein

Director

Bureau of Consumer Protection

UNITED STATES OF AMERICA

BEFORE FEDERAL TRADE COMMISSION

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In the Matter of))
METAGENICS, INC.,)
a corporation doing business as) DOCKET NO. 9267
Ethical Nutrients)
and)
JEFFREY KATKE,)
individually and as an officer)
of said corporation.)
_____)

AMENDED COMPLAINT

The Federal Trade Commission, having reason to believe that Metagenics, Inc., a corporation, doing business as Ethical Nutrients, and Jeffrey Katke, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: Respondent Metagenics, Inc., doing business as Ethical Nutrients, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its principal office or place of business at 971 Calle Negocio, San Clemente, California 92672.

Respondent Jeffrey Katke is an officer of Metagenics, Inc. Individually or in concert with others, he formulates, directs and controls the acts and practices of the said corporation, including
the acts and practices alleged in this complaint. His business address is 971 Calle Negocio, San Clemente, California 92672.

PARAGRAPH TWO: Respondents have manufactured, advertised, offered for sale, sold and distributed an orally-ingested product containing microcrystalline hydroxyapatite ("MCHC"),
minerals and protein, under the name Bone Builder (hereinafter "MCHC" or "Bone Builder"). Respondents also offer for sale and sell the MCHC product to other parties who market the product under their own brand names. Bone Builder is a food and/or drug, as the terms "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act.

PARAGRAPH THREE: 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.

PARAGRAPH FOUR: Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Bone Builder, including but not necessarily limited to the attached Exhibits A through D. These advertisements and promotional materials contain the following statements:

1. **The superior form of calcium proven to build bone.** The latest research shows "microcrystalline hydroxyapatite" is the superior form of calcium that can build bone. We call this exciting **Ethical Nutrient's** [sic] product: **BONE BUILDER**. (Exhibit A).

2. Some calcium supplements can be worse than not taking anything at all. At best, others may slow bone loss, occasionally stopping it. But, **BONE BUILDER** can

restore lost bone *and* has the clinical evidence to prove it! (Exhibit A).
3. **A significant statement recurs in a number of reports: MCHC either reduces or totally eliminated bone pain, which was not found true of any other substance.** (Exhibit A).
4. Only MCHC provides calcium in an "extremely bioavailable form" and the **studies on it have "also indicated the superiority of the substance over traditional soluble calcium supplements."** Of the substances used for experimentation to halt the progress of osteoporosis, only microcrystalline hydroxyapatite was considered to be totally free of "major potential hazard [sic]," which indicated its use for both "the treatment and prevention of osteoporosis." (Exhibit A).
5. These are just a few of the controlled clinical trials to be found in medical literature. The consensus of which is that microcrystalline hydroxyapatite halted bone loss, decreased pain and increased bone thickness when taken in adequate amounts over long periods of time, a record no calcium supplement could achieve. (Exhibit B).
6. **Contains most absorbable kind of calcium.** (Exhibit C).
3
7. BONE BUILDER is pure microcrystalline hydroxyapatite compound (MCHC), a substance which has been scientifically demonstrated to be **the** most effectively utilized source of calcium known. (Exhibit C).
8. Most importantly, **no other product in the United States is as effective at preventing bone loss.** (Exhibit C).
9. [R]esearch of the many common forms of calcium used in the trials demonstrated effectively that only one form of calcium was capable of preventing bone thinning and actually restoring bone strength, and that was "whole bone extract (microcrystalline hydroxyapatite concentrate) . . . ." (Exhibit D).
10. Where there is evidence that osteoporosis "runs in the family," and where there is evidence that calcium loss is already taking place, i.e. muscle spasms, receding gums, or loss of height, the ability of microcrystal-line hydroxyapatie [sic] (bone) concentrate places prevention as a matter of the individual sufferer's choice. This safe, reliable, inexpensive, scientifically-tested preventive is his/hers to take as they choose . . . . (Exhibit D).
PARAGRAPH FIVE: Through the use of the statements contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that:
1. post-menopausal women who have lost bone and who use Bone Builder or MCHC will experience no additional bone loss or bone thinning and will achieve a growth of new bone and increased bone thickness greater than the amount of bone lost;
2. users of Bone Builder or MCHC will not experience bone loss, bone thinning, or osteoporosis;
3. Bone Builder or MCHC restores bone strength;
4. Bone Builder or MCHC reduces or eliminates pain associated with bone ailments; and
5. Bone Builder or MCHC is more bioavailable, more absorbable, or more effectively utilized by the body than other forms of calcium or is more effective than other

forms of calcium in the prevention or treatment of bone ailments.
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PARAGRAPH SIX: Through the use of statements contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that at the time they made the representations set forth in PARAGRAPH FIVE, respondents possessed and relied upon a reasonable basis that substantiated such representations.
PARAGRAPH SEVEN: In truth and in fact, at the time respondents made the representations set forth in PARAGRAPH FIVE, respondents possessed and relied upon a reasonable basis to substantiate that: adequate calcium intake has many benefits and is one of the essential factors in the body's ongoing process of removal of old bone and replacement by new bone; in conjunction with other factors, adequate calcium intake can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength; and individuals who do not consume adequate calcium are at greater risk of experiencing bone fractures than those who do. However, respondents did not possess and rely upon a reasonable basis that substantiated the representations in PARAGRAPH FIVE. Therefore, the representation set forth in PARAGRAPH SIX was, and is, false and misleading.
PARAGRAPH EIGHT: Through the use of the statements contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that scientific research, including clinical tests, scientific papers and/or scientific studies, proves that:
1. post-menopausal women who have lost bone and who use Bone Builder or MCHC will experience no additional bone loss or bone thinning and will achieve a growth of new bone and increased bone thickness greater than the amount of bone lost;
2. users of Bone Builder or MCHC will not experience bone loss, bone thinning, or osteoporosis;
3. Bone Builder or MCHC restores bone strength;
4. Bone Builder or MCHC reduces or eliminates pain associated with bone ailments; or
5. Bone Builder or MCHC is more effectively utilized by the body than other forms of calcium or is superior to or more effective than other forms of calcium in the prevention or treatment of bone ailments.
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PARAGRAPH NINE: In truth and in fact, the representations set forth in PARAGRAPH EIGHT have not been proven by scientific research, including clinical tests, scientific papers and/or scientific studies. Therefore, the representations set forth in PARAGRAPH EIGHT were, and are, false and misleading.
PARAGRAPH TEN: 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 _____ day of _____, 1997, has issued this amended complaint against respondents.
By the Commission.
Donald S. Clark

Secretary
[Exhibits A-D attached to paper copies of amended complaint, but not available in electronic form.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed consent order from Metagenics, Inc. and its officer and director, Jeffrey Katke.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) 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.

On August 16, 1994, the Commission issued a complaint against respondents, alleging that they made deceptive claims in advertisements for Bone Builder, a calcium supplement. After an administrative trial, the Administrative Law Judge issued an Initial Decision on October 22, 1996, from which both complaint counsel and respondents filed notices of appeal. On January 7, 1997, the Commission granted a Joint Motion to Withdraw from Adjudication to consider the proposed consent agreement in this case.

The Commission has issued an amended complaint, clarifying some of the allegations in the August 16, 1994, complaint. The amended complaint alleges that respondents represented without substantiation that post-menopausal women who have already lost bone and who use Bone Builder will experience no additional bone loss and will achieve a growth of new bone greater than the amount of bone lost; that users of Bone Builder will not experience bone loss or osteoporosis; that Bone Builder restores bone strength; that Bone Builder reduces or eliminates pain associated with bone ailments; and that Bone Builder is more bioavailable, more absorbable,
or more effectively utilized by the body than other forms of calcium or is more effective than other forms of calcium in the prevention or treatment of bone ailments. The amended complaint also states that respondents relied upon a reasonable basis to substantiate that adequate calcium intake has many benefits and is one of the essential factors in the body's ongoing process of removal of old bone and replacement by new bone; in conjunction with other factors, adequate calcium intake can play a significant role in reducing the rate of bone loss or bone thinning and in
protecting bone strength; and individuals who do not consume adequate calcium are at greater risk of experiencing bone fractures than those who do.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent respondents from engaging in similar acts and practices in the future. In advertising or selling any food, drug, or supplement, Part I of the order requires respondents to rely on competent and reliable scientific evidence to support any claim that post-menopausal women who have lost bone and who use the product will experience no additional bone loss or will achieve a growth of new bone greater than the amount of bone loss or that users of the product will not experience bone loss. Part I requires the same level of substantiation for any claim that a food, drug, or supplement restores bone strength, reduces or eliminates pain associated with bone ailments, or is superior to any other form of calcium in bioavailability, absorbability, utilization by the body, or treatment or prevention of bone ailments.

In advertising or selling any food drug, or supplement, Part II forbids respondents from

misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test
or study. In making claims regarding the relationship between calcium and osteoporosis, Part III requires respondents to limit themselves to the health claims authorized by the Food and Drug Administration, as set forth in 58 Fed. Reg. 2665 (1993), or to have competent and reliable scientific evidence to support the claims.

Part IV requires respondents to possess competent and reliable scientific evidence to support health-related claims for products containing calcium, and to have scientific substantiation
for health-related superiority claims for any food, drug, or supplement.

Part V allow respondents to make representations that are specifically permitted by FDA regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990. Part VI allows respondents to make any claim for a drug that is permitted in labeling for that drug under any tentative or final FDA standard or under any FDA-approved new drug application

Parts VII through X relate to respondents' obligations to make available to the Commission materials substantiating claims covered by the order; to notify the Commission of changes in Metagenics's corporate structure; to notify the Commission of changes in Mr. Katke's employment or business affiliations; and to provide copies of the orders to certain Metagenics personnel. Part XI provides that the order will terminate after twenty years under certain circumstances. Part XII requires respondents to file periodic compliance reports with the Commission.

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.