

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of

**HEALTH SCIENCE
INTERNATIONAL, INC.,
a corporation, and**

**DAVID MARTIN,
individually and as an officer of
Health Science International, Inc.**

)
)
)
) **FILE NO. 072-3145**

) **AGREEMENT CONTAINING
CONSENT ORDER**

The Federal Trade Commission has conducted an investigation of certain acts and practices of Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International, Inc. (“proposed respondents”). Proposed respondents are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Health Science International, Inc., by its duly authorized officers, and David Martin, individually and as an officer of Health Science International, Inc., and counsel for the Federal Trade Commission that:

1. Proposed respondent Health Science International, Inc. is a Florida corporation with its principal office or place of business is at 1648 Taylor Road, Suite 118, Port Orange, Florida 32128.

2. Proposed respondent David Martin is an officer of Health Science International, Inc. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Health Science International, Inc. His principal office or place of business is the same as that of Health Science International, Inc.

3. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.

4. Proposed 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; and
- (c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

5. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the 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 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order 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 of the complaint and the decision and order to proposed respondents' address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

8. Proposed respondents have read the draft complaint and consent order. Proposed respondents understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

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

1. Unless otherwise specified, “Respondents” shall mean:
 - a. Health Science International, Inc., a corporation, and its successors and assigns and its officers; and
 - b. David Martin, individually and as an officer of Health Science International, Inc.
2. “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.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Serenity for Women Natural Progesterone Cream.
4. “Food,” shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. “Drug” shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. “Device” shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical

action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.

8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.

9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product 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 or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user’s risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user’s risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or

- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not 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 person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

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 final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration;

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 Nutrition Labeling and Education Act of 1990; and

C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents 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.

V.

IT IS FURTHER ORDERED that Respondents shall delivery 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. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to Health Science International, Inc. or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. **Provided, however,** that, with respect to any proposed change about which Respondents learn less than thirty (30) days prior to the date 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.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, 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.

VIII.

IT IS FURTHER ORDERED that Respondents 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.

IX.

This order will terminate twenty (20) years from the date of its issuance, 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 Respondent 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 this 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.

Signed this _____ day of _____, 2007.

RESPONDENTS

HEALTH SCIENCE INTERNATIONAL, INC., a
corporation

DAVID MARTIN, individually and as an officer of Health
Science International, Inc.

FEDERAL TRADE COMMISSION

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