**072-3145**

**UNITED STATES OF AMERICA**
**FEDERAL TRADE COMMISSION**

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

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| **In the Matter of** | ) | |
| **HEALTH SCIENCE INTERNATIONAL, INC., a corporation, and** | ) | **DOCKET NO. C-4205** |
| **DAVID MARTIN, individually and as an officer of Health Science International, Inc.** | ) | |

## DECISION AND ORDER

The Federal Trade 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 the 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 by the Respondents that the law has been violated as alleged in such complaint, or that any of 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 Act, and that a 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 for the

receipt and consideration of public comments, 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 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. 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. 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. 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 contain69.7600 sS0 TD030.0000 TDu, a corpocto

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 o

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.

By the Commission.

Donald S. Clark
Secretary

SEAL
ISSUED: November 13, 2007