#### UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS:	Deborah Platt Majoras, Chairman
	Pamela Jones Harbour
	Jon Leibowitz
	William E. Kovacic
	J. Thomas Rosch
	<b>5.</b> 1 Holling 1050H

In the Matter of	) )	
HERBS NUTRITION CORPORATION a corporation, and	N, ) ) DOCKET NO	. 9325
SYED M. JAFRY,	)	
individually and as an officer of Herbs Nutrition Corporation	)	

#### **COMPLAINT**

The Federal Trade Commission, having reason to believe that Herbs Nutrition Corporation, a corporation, and Syed M. Jafry, individually and as an officer of Herbs Nutrition 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 Herbs Nutrition Corporation is a California corporation with its principal office or place of business at 21712 Hawthorne Blvd #276, Torrance, California 90503.

2. Respondent Syed M. Jafry is an officer of Herbs Nutrition Corporation. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Herbs Nutrition Corporation, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Herbs Nutrition Corporation.

3. 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.

4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have

not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Eternal Woman Progesterone Cream and Pro-Gest Body Cream. Respondents advertise and offer the products for sale through the Internet site <u>www.progesterone-cream.net</u>.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Eternal Woman Progesterone Cream and Pro-Gest Body Cream are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Eternal Woman Progesterone Cream is a drug labeled as containing Natural Progesterone USP from soy (500 mg per ounce) and other ingredients. A four ounce jar costs \$18.93 plus shipping and handling, and a two ounce tube costs \$9.50 plus shipping and handling. Pro-Gest Body Cream is a drug labeled as containing USP Progesterone. A 2 ounce tube costs \$18.13 plus shipping and handling. Eternal Woman Progesterone Cream and Pro-Gest Body Cream are applied transdermally.

8. To induce consumers to purchase Eternal Woman Progesterone Cream and Pro-Gest Body Cream, Respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on Respondents' website:

- A. Progesterone Cream contains NO synthetic hormones and thus can help you balance your hormones. Progesterone cream eliminates estrogen dominance and relieve your symptoms without dangerous side effects. (Exhibit A at 1.)
- B. Medical experts believe the out of balance hormones are due to the lack of progesterone in women. Clinical studies show that PMS, menopausal problems, breast cancer and fibrocystic breast have a direct relationship with estrogen dominance. Progesterone is needed for the proper function of the adrenal glands. Stress on the adrenal glands may lead to progesterone deficiency, often causing symptoms of nervous disorders, depression, irritability, fatigue and mood swings. Medical practitioners reports many of these issues are helped through the use of a high quality natural progesterone cream, as Wild Yam & Progesterone+ or Ultra Harmony -a plant estrogen cream. Our creams do not contain estrogen but plant estrogens, which have no side effects.

\* \* \*

Millions of women use natural progesterone to reduce monthly PMS symptoms, ease the transitions of menopausal hot flashes, night sweats, mood swings, while others use it as to maintain healthy bones.

#### **Benefits of Progesterone**

\* \* \*

Protects against endometrial cancer Helps protect against breast cancer

\* \* \*

Natural progesterone is naturally produced in the body. Synthetic progestins can cause side effects.

(Exhibit A at 4.)

C. Natural Progesterone cream is a safe, natural alternative to HRT because it's produced by a woman's body during the second half of each monthly cycle, from ovulation until menses, and is the dominant hormone during this phase.

\* \* \*

Natural Progesterone cream also stimulates bone-building and thus helps protect against osteoporosis.

(Exhibit A at 6.)

D. Your body needs natural progesterone. . .For women, who suffer from hysterectomy symptoms, menstrual conditions, female health conditions, hormone deficiencies, menopause hot flashes, osteoporosis or thinning bones, pms. Reduces breast cancer risk, hair loss, fat gain from estrogen dominance, menopause acne, migraine headaches, and much more. . .

\* \* \*

In the right amount, progesterone can:

\* \* \*

Decrease risk of endometrial cancer Help protect against breast cancer, fibrocystic breasts, and osteoporosis (Exhibit A at 12-13.) 9. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that:

- A. Eternal Woman Progesterone Cream and Pro-Gest Body Cream are effective in preventing, treating, or curing osteoporosis;
- B. Eternal Woman Progesterone Cream and Pro-Gest Body Cream are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and
- C. Eternal Woman Progesterone Cream and Pro-Gest Body Cream do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, Respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. The acts and practices 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.

# NOTICE

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth  $(20^{th})$  day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the ALJ shall file an initial decision containing

appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the ALJ, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 7 days after the last answer is filed by any party named as a respondent in the complaint. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

Notice is hereby given to each of the respondents named in this complaint that a hearing before the ALJ on the charges set forth in this complaint will begin on January 3, 2008, at 10 a.m., or such other date and time as determined by the ALJ, in Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. At the hearing, you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

### ORDER

# DEFINITIONS

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

- 1. Unless otherwise specified, "Respondents" shall mean:
- a. Herbs Nutrition Corporation, a corporation, and its successors and assigns and its officers; and
- b. Syed M. Jafry, individually and as an officer of Herbs Nutrition Corporation.

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 Eternal Woman Progesterone Cream and Pro-Gest Body 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 Pharmacopeia, 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.

**IT IS FURTHER ORDERED** that Respondents 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. 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 Herbs Nutrition Corporation 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.

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.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, D.C., this twenty-eighth day of September, 2007.

By the Commission.

Donald S. Clark Secretary