



1. Respondent Merilou Barnekow is an individual trading and doing business as Women's Menopause Health Center with her principal office or place of business at 1026 Blue Water Highway, Surfside Beach, Texas 77541. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Women's Menopause Health Center.

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" shall mean Merilou Barnekow, individually and trading and doing business as Women's Menopause Health Center.

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 Preserve Progesterone Cream and Return to Eden 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 Respondent, 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, Respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

**II.**

**IT IS FURTHER ORDERED**

- 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.

**V.**

**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

## VIII.

**IT IS FURTHER ORDERED** that Respondent 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 she has complied with this order.

## IX.

This order will terminate on November 19, 2027, 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.

By the Commission.

Donald S. Clark  
Secretary

SEAL

ISSUED: November 19, 2007