

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of

**MERILOU BARNEKOW,
an individual trading and doing business
as WOMEN’S MENOPAUSE HEALTH
CENTER**

FILE NO. 072-3143

**AGREEMENT CONTAINING
CONSENT ORDER**

The Federal Trade Commission has conducted an investigation of certain acts and practices of Merilou Barnekow, an individual trading and doing business as Women’s Menopause Health Center (“proposed respondent”). Proposed respondent is 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 Merilou Barnekow, an individual trading and doing business as Women’s Menopause Health Center, and counsel for the Federal Trade Commission that:

1. Proposed 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. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
 - (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.
4. 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 acce

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 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 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 Respondent 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 Respondent 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 Respondent 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 Respondent sha

VI.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change with regard to Women's Menopause Health Center or any business entity that 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 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 is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, DivnRw000eyht

- 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.

RESPONDENT

MERILOU BARNEKOW, individually and trading and
doing business as Women's Menopause Health Center

FEDERAL TRADE COMMISSION

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APPROVED:

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