

during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of ProBalance and ProBalance Plus, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that ProBalance and ProBalance Plus: (1) Are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) 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. The complaint alleges that respondents failed to have substantiation for these claims. The complaint also alleges that respondents misrepresented that clinical testing proved that ProBalance and ProBalance Plus are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations

for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

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## FEDERAL TRADE COMMISSION

[File No. 072 3143]

### **Merilou Barnekow, an individual trading and doing business as Women's Menopause Health Center; Analysis of Proposed Consent Order to Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed Consent Agreement.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before November 7, 2007.

**ADDRESSES:** Interested parties are invited to submit written comments. Comments should refer to "Women's Menopause Health Center, File No. 071 3143," to facilitate the organization of comments. A comment filed in paper form should include this reference both

in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/Office of the Secretary, Room 135-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

Comments containing confidential material must be filed in paper form, must be clearly labeled "Confidential," and must comply with Commission Rule 4.9(c). 16 CFR 4.9(c) (2005).<sup>1</sup> The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments that do not contain any nonpublic information may instead be filed in electronic form as part of or as an attachment to email messages directed to the following email box: [consentagreement@ftc.gov](mailto:consentagreement@ftc.gov).

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC website, to the extent practicable, at [www.ftc.gov](http://www.ftc.gov). As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy.htm>.

**FOR FURTHER INFORMATION CONTACT:**  
Laura DeMartino (202) 326-3030,  
Bureau of Consumer Protection, Room NJ-2122, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following

<sup>1</sup> The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for October 5, 2007), on the World Wide Web, at <http://www.ftc.gov/os/2007/10/index.htm>. A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

#### **Analysis of Agreement Containing Consent Order to Aid Public Comment**

The Federal Trade Commission ("FTC" or "Commission") has accepted, subject to final approval, an agreement containing a consent order from Merilou Barnekow, an individual trading and doing business as Women's Menopause Health Center ("respondent").

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of Preserve Progesterone Cream and Return to Eden Progesterone Cream, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC complaint, respondent represented that Preserve Progesterone Cream and Return to Eden Progesterone Cream: (1) are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) 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. The complaint alleges that respondent failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and

reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of her personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

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## **GENERAL SERVICES ADMINISTRATION**

[OMB Control No. 3090-0250]

### **General Services Administration Acquisition Regulation; Information Collection; Zero Burden Information Collection Reports**

**AGENCY:** Office of the Chief Acquisition Officer, GSA.

**ACTION:** Notice of request for comments regarding a renewal to an existing OMB clearance.

**SUMMARY:** Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement regarding zero burden information collection reports. The clearance currently expires on August 31, 2007.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

**DATES:** Submit comments on or before: December 14, 2007.

**FOR FURTHER INFORMATION CONTACT:** William Clark, Procurement Analyst, Contract Policy Division, at telephone (202) 219-1813 or via e-mail to [william.clark@gsa.gov](mailto:william.clark@gsa.gov).

**ADDRESSES:** Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory Secretariat (VIR), General Services Administration, Room 4035, 1800 F Street, NW., Washington, DC 20405. Please cite OMB Control No. 3090-0250, Zero Burden Information Collection Reports, in all correspondence.

#### **SUPPLEMENTARY INFORMATION:**

##### **A. Purpose**

This information requirement consists of reports that do not impose collection burdens upon the public. These collections require information which is already available to the public at large or that is routinely exchanged by firms during the normal course of business. A general control number for these collections decreases the amount of paperwork generated by the approval process.