
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.

4. Respondent has advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Preserve Progesterone Cream and Return to Eden Progesterone Cream. Respondent primarily advertises and offers the products for sale through the Internet site www.womens-menopause-health.com.

5. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Preserve Progesterone Cream and Return to Eden Progesterone Cream are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

6. Preserve Progesterone Cream is a drug labeled as containing USP Natural Progesterone and other ingredients. A 3.5 ounce bottle costs \$34.95 plus shipping and handling. Return to Eden Progesterone Cream is a drug labeled as containing USP Progesterone. A 2 ounce jar costs \$19.95 plus shipping and handling. Preserve Progesterone Cream and Return to Eden Progesterone Cream are applied transdermally.

7. Until on or about August 1, 2007, to induce consumers to purchase Preserve

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A natural course of action makes a lot more sense with progesterone cream's proven safety. Researchers have conducted clinical tests proving progesterone

* * *

Progesterone works to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

* * *

Research shows that osteoporosis prevention measures of a healthy calcium-rich diet, exercise and progesterone work better than using hormone replacement therapy.

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Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone mass while progesterone aids the body in building new bone.

* * *

This is the good news. Even if bones have lost density, there is opportunity to

* * *

If you have not already kicked the hormone replacement therapy [sic], now is as good a time as any. Order a bottle of Preserve and a pump container of Preserve Natural Progesterone Cream and experience healthy menopause for yourself.
(Exhibit A at 27-28.)

- H. The next step in the osteoporosis prevention plan is to begin using a high quality progesterone cream like Preserve to give the body the hormonal building block components for new bone growth. Progesterone serves a dual purpose. While providing positive effects on osteoporosis by promoting the building of new bone mass, progesterone also decreases menopause symptoms typical in the age group of women at risk for osteoporosis.
(Exhibit A at 29.)

8. From on or about August 1, 2007, to induce consumers to purchase Return to Eden Progesterone Cream, Respondent has disseminated or has caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit B. These advertisements contain the following statements and depictions, among others, on Respondent's website:

- A. Women today armed with educated health information, know there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned what women in Great Britain and Europe have known for decades - the benefits of natural progesterone like that found in Return to Eden natural progesterone cream. These women believe, from decades of use, that it can actually rebuild bone tissue with no known side effects.

With large studies* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead.

* * *

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast

cancers. Dr. Lee calls this “estrogen dominance.” Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Return to Eden all-natural progesterone cream.

* * *

Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone may provide many benefits and combats estrogen dominance.

(Exhibit B at 5, 7.)

- B. The benefits of natural diosgenin (nicknamed progesterone) cream are said to be many:

* * *

Balances estrogen dominance.

(Exhibit B at 9.)

- C. Given the positive benefits of progesterone cream and the low incidence of progesterone side effects, many women choose this natural alternative to achieve normal progesterone levels.

* * *

To achieve the optimal benefits of progesterone cream without progesterone side effects to achieve normal progesterone levels, use the natural progesterone cream 500 mg/oz Return to Eden formula.

(Exhibit B at 12.)

- D. The Federal Drug Administration recently mandated a new boxed warning on the danger of estrogen therapy and estrogen/progestin products such as Premarin and Prempro. This is the highest FDA warning level for drug labeling. The FDA estrogen information warning states an increased risk for heart disease, heart attacks, strokes, and breast cancer and also emphasizes that estrogen products are not approved for heart disease prevention.

* * *

The government report cites data from human epidemiology studies that show a connection between estrogen therapy and an increase in endometrial cancer and breast cancer.

* * *

Stopping hormone replacement therapy would be a difficult choice without effective alternatives to hormone replacement therapy. Fortunately, there are effective alternatives for women who no longer wish to take hormone replacement therapy.

A quality progesterone cream like Return to Eden natural progesterone cream, may gently alleviate menopause symptoms as well as hormone replacement therapy.

* * *

Balances estrogen dominance.
(Exhibit B at 14-15.)

- E. Women in Great Britain and Europe have found that progesterone is a natural alternative to traditional osteoporosis treatment. This natural alternative to traditional osteoporosis treatment is believed by them to build bone mass, and help decrease menopause symptoms without side effects associated with synthetic hormone replacement therapy or drugs [sic] used for the treatment of osteoporosis.

* * *

For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone may be the perfect natural alternative. The lack of progesterone is thought to cause a decrease in new bone formation.

Progesterone balances estrogen dominance. . .

* * *

For a natural alternative to osteoporosis treatment, postmenopausal women may use up to one teaspoon of high quality progesterone cream daily for three weeks each month. The week off progesterone maintains the sensitivity of the

progesterone receptors. We recommend Return to Eden natural USP progesterone cream.

* * *

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone loss while progesterone aids the body in building bone.

* * *

This is the good news. Even if bones have lost density, there is opportunity to

The above symptoms of menopause are successfully relieved for the majority of women when using Return to Eden as directed.

(Exhibit B at 24.)

- H. The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

* * *

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites

C. Preserve Progesterone Cream and Return to Eden Progesterone 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 6 through 8, Respondent has represented, expressly or by implication, that she 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, Respondent 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.

THEREFORE, the Federal Trade Commission, on this nineteenth day of November, 2007, has issued this complaint against respondent.

By the Commission.

Donald S. Clark
Secretary

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