DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 21, 2005

WARNING LETTER

VIA FEDEX

Ms. Kim Puffenbarger
Ms. Jana Brabec, Founder
One Life USA
2749 Exchange Court
West Palm Beach, FL 33409

Dear Ms. Puffenbarger and Ms. Barbec:

This letter refers to your firm's marketing and distributing of "Barbec Basics Natural Progesterone Cream," topical hormone cream offered for sale on your website, www.onelifeusa.com.

Violations of the Federal Food, Drug, and Cosmetic Act

As reviewed on October 12, 2005, the claims that appear on your website establish the intended use of this product as a drug, as defined by section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 321(g)(1). Furthermore, your product is a new drug under section 201(p) of the FDCA, 21 U.S.C. § 321(p), because it is not generally recognized by qualified scientific experts as safe and effective for its labeled uses. Statements documenting that your product is intended to cure, mitigate, treat, or prevent disease, or to affect the structure or function of the body, include, but are not limited to, the following:

- "Safe Natural Alternative to HRT"

- "This product has been scientifically proven to be safer for women than prescription hormone replacement therapy (HRT) . . . ."

- "Benefits

    - Stimulates osteoblast bone building
    - Restores sex drive
    - Protects against fibrocystic breasts
    - Natural antidepressant

- Facilitates thyroid hormone action
- Normalizes blood sugar levels
- Normalizes zinc and copper levels
- Helps prevent breast cancer . . .
- Normalizes blood clotting . . .
- Restores proper oxygen cell levels . . .
- Elimination of depression after childbirth"

OTC topical hormone containing products promoted for use as a drug are subject to the final rule under 21 CFR § 310.530(b). This rule states that any OTC drug product other than hydrocortisone that is labeled as a topically applied hormone-containing product for drug use is regarded as a new drug. Your product falls within this rule because it is labeled as a topical hormone product for drug use.

Moreover, OTC topical hormone creams are new drugs because there is no evidence that they are generally recognized by qualified scientific experts as safe and effective for their labeled uses. 21 U.S.C. § 321(p).

Furthermore, Barbec Basics Natural Progesterone Cream is misbranded under section 502(f)(1) of the FDCA because the directions for use are inadequate for the intended uses of your product.

Under section 301(d) and 505(a) of the FDCA, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. There are no approved applications for OTC topical hormone products. Therefore, your product is an unapproved new drug and your distribution of it in interstate commerce violates sections 301(d) and 505(a) of the FDCA.

Further, you should be aware that laws enforced by the Federal Trade Commission (FTC) govern claims made in advertising, including print, broadcast, websites, and other electronic media. The FTC Act, 15 U.S.C. § 41 et seq., prohibits unfair or deceptive acts and practices, including false and unsubstantiated advertising claims. It is against the law to make health claims without substantiation or to overstate the health benefits of the products you promote. Please be aware that product claims can be communicated to consumers in a variety of ways, including product name, website name, product testimonials, endorsements, or use of metatags.

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that the drug products you manufacture or distribute meet all of the requirements of the FDCA and FTC Act and their implementing regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the awarding of contracts.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to FDA enforcement action without further notice. The FDCA

provides for seizure of illegal products and for an injunction against the manufacturers and distributors of illegal products.

You must notify FDA in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations of the FDCA and its implementing regulations, and the steps taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Further, if your firm does not manufacture the product identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Your response regarding the FDA violations should be directed to Virginia Meeks, Compliance Officer, Food and Drug Administration, Florida District, 555 Winderley Place, Suite 200, Maitland, FL 32751 phone (407) 475-4700.

Sincerely,

Mandee Rosler Rosenberg
Acting Director
Division of New Drugs and Labeling Compliance

cc:

Paul Puffenbarger
Administrative Contact
One Life USA, Inc.
2nd Floor
West Palm Beach, FL 33409