DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 9, 2005

WARNING LETTER

VIA FEDEX

President/Owner
Bio-Health
A Division of Zlabs LLC
70 S Val Vista Drive
Suite A3
PMB 442
Gilbert, AZ 85296

Dear President/Owner:

This letter refers to your firm's marketing and distributing of "Z-LABS Progesterone Cream," a topical hormone cream offered for sale on your website, www.Zlabs.us.

Violations of the Federal Food, Drug, and Cosmetic Act

As reviewed on October 11, 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 intended 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:

- "Benefits of Natural Progesterone include:
    - Protects against breast fibrocysts
    - Helps protect against endometrial, breast, ovarian, and prostate cancer
    - Normalizes blood clotting
    - Helps prevent hypertension
    - Acts as a natural diuretic
    - Acts as a natural antidepressant
    - Helps relieve anxiety
    - Helps normalize blood sugar levels
    - Helps thyroid hormone function . . .
    - Increases new bone formulation . . .
    - Reduces incidence of autoimmune disorders . . .
    - Prevents yeast (candida) infections . . .

- Stops ovulation by the other ovary. . . ."

• "Why Transdermal Application? . . . Oral doses of progesterone must be greater than transdermal doses in order to have the same biological effects . . . Transdermal progesterone is absorbed through the skin and into the layer of fat that lies beneath the surface, known as the subcutaneous fat . . . Natural progesterone is biologically active and when taken transdermally has an immediate effect on the body . . . ."

Irrespective of the disclaimer on your website stating that your company does not claim any of it products will cure or prevent any disease, the claims made for your product on your website clearly demonstrate that Z-Labs Progesterone Cream is a drug as defined by section 201(g)(1) because it is intended for the treatment, mitigation, and/or prevention of disease, and/or to affect the structure or any function of the body of man.

OTC topical hormone containing products promoted for drug use 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).

Additionally, FDA's regulations state that a drug may be considered a new drug because of the newness of its dosage form or the method or duration of administration or application suggested in its labeling. 21 CFR § 310.3(h)(5). A transdermal delivery system for a drug is not generally recognized by experts to be safe and effective for its intended uses as found in its labeling. Accordingly, FDA considers all transdermal drug delivery products to be new drugs under § 201(p) of the act and under 21 C.F.R. § 310.3. Your product is labeled as having a transdermal delivery system; accordingly, it is a new drug under the FDCA and its implementing regulations.

Furthermore, Z-LABS Progesterone Cream is misbranded under section 502(f)(1) of the FDCA because the directions for use are inadequate for the intended uses of this 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 Pamela Schweikert, Director, Compliance Branch, Food and Drug Administration, Los Angeles District, 19701 Fairchild, Irvine, CA 92612, phone (949) 608-4426.

Sincerely,

Kathleen R. Anderson

Kathleen R. Anderson
Acting Director
Division of New Drugs and Labeling Compliance