DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 9, 2005

WARNING LETTER

VIA FEDEX

Ms Susan Turner, Owner
HMS Crown, Inc.
332 Kit Carson Road
6457 NDCBU
Taos, NM 87571

Ms Susan Turner, Webmaster
HMS Crown
550 Vista Drive
Ridgeway, CO 81432

Dear Ms Turner:

This letter refers to your firm's marketing and distribution of "HMS Queen's Progesterone" and "HMS King's Progesterone," topical hormone creams offered for sale on your website, www.hmscrown.com.

Violations of the Federal Food, Drug, and Cosmetic Act

As reviewed on October 14, 2005, the claims that appear on your website establish the intended use of these products as drugs, 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 products are new drugs under section 201(p) of the FDCA, 21 U.S.C. § 321(p) because they are not generally recognized by qualified scientific experts as safe and effective for their labeled uses. Statements documenting that your products are 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:

HMS Queen's Progesterone

- "Where to apply **HMS** Progesterone Crème: Natural progesterone . . . in a moisturizing cream can be applied . . . in cases of osteoporosis, to the entire trabecular spine."

- ". . . news on progesterone -- . . . to help reverse bone loss, prevent some cancers, ease and prevent arthritis . . . ."

- "HMS Queen's Progesterone for
    - Menopause Relief
    - Prevent Osteoporosis
    - Ease PMS
    - Prevent Cancers . . .
    - Relieve Depression
    - Endometriosis or Fibrocystic Breast?"

- "Endometriosis or Fibrocystic Breast? One common factor in both of these conditions is a higher level of circulating estrogen, indicating a hormonal imbalance. Progesterone – which helps normalize all other endocrine and hormonal activity in the body – may help clear these conditions by helping to lower the level of estrogen."

- "Women over 50 years of age should use natural progesterone crème to help prevent osteoporosis."

HMS King's Progesterone

- "*Older men with rheumatoid arthritis have reported relief from pain and swelling after rubbing natural progesterone crème on their joints.*"

- "Where to apply **HMS** Progesterone Crème: Natural progesterone . . . in a moisturizing creame can be applied . . . in cases of osteoporosis, to the entire trabecular spine."

- ". . . news on progesterone -- . . . to help reverse bone loss, prevent some cancers, ease and prevent arthritis . . ."

- "The most effective method of restoring physiologic progesterone levels (equivalent to normal body function) is with the proper supplementation of topically applied transdermal natural progesterone crème, that can be absorbed through the skin. Transdermal creams are much more effective than oral progesterone, because if taken orally, most of the progesterone is burned away by stomach acids during the digestive process. On the other hand, a transdermal crème goes directly to the blood stream and begins work immediately."

Irrespective of the disclaimer on your website stating that your products are not a cure for any condition, the claims made for your products on your website clearly demonstrate that your products are drugs as defined by section 201(g)(1) because they are 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 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).

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 any 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 CFR § 310.3(h)(5). Your product is labeled as having a transdermal delivery system. Therefore it is a new drug under the FDCA and its implementing regulations.

Furthermore, HMS Queen's Progesterone and HMS King's Progesterone are misbranded under section 502(f)(1) of the FDCA because the directions for use are inadequate for the intended uses of these products.

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 Shelly Maifarth, Compliance Officer, Food and Drug Administration, Denver District, 6th Ave & Kipling Street, Denver Federal Center, Denver, CO 80225-0087, phone (303) 236-3046.

Sincerely,

Kathleen R. Anderson

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