DEPARTMENT OF HEALTH & HUMAN SERVICES

FOI

Food and Drug Administration
Rockville MD 20857

MAY 20 1999

TRANSMITTED VIA FACSIMILE

Kay Mary Harrell
Manager, Regulatory Affairs
Healthpoint
307 E. Josephine Street
San Antonio, TX 78215

Re: ANDA 75-325
Embeline E (clobetasol propionate cream- emollient) Emollient, 0.05%
MACMIS ID #7575

Dear Ms. Harrell:

As part of our routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed promotional materials for Embeline E (clobetasol propionate cream-emollient) Emollient, 0.05%. These materials include brochures with identification numbers: 136186-0199, 136187-0199, 136188-0199, 136189-0199 and 136190-0199. We have determined that they are in violation of the Federal Food, Drug, and Cosmetic Act and the implementing regulations. Specifically, these materials lack fair balance and contain misleading comparisons as explained below.

Lack of Fair Balance of Risk Information

Your promotional materials are false or misleading, lacking in fair balance, or otherwise misleading because they fail to present the information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. In the brochures, Healthpoint presents large-type, bolded, colorful bullets and charts emphasizing Embeline E's efficacy claims. In contrast, brochures 136186-0199, 136188-0199, 136189-0199 and 136190-0199 do not disclose *any* risk information associated with the drug. Brochure 136187-0199 only presents a short asterisked statement in small print at the bottom right corner of the third page that "treatment beyond 2 weeks is not recommended."

Healthpoint fails to include important risk information presented in the precaution section of the approved product labeling such as the bolded information:

- Clobetasol propionate is a highly potent topical corticosteroid that has been shown to suppress the HPA axis at doses as low as 2g/day.

- Embeline E Emollient should not be used in the treatment of rosacea or perioral dermatitis, and should not be used on the face, groin or axillae.

Also, Healthpoint fails to include adverse reactions that have been reported such as burning/stinging, pruritis, irritation and erythema.

Misleading Comparisons and Unsubstantiated Superiority Claims

Healthpoint presents unsubstantiated superiority claims and misleading comparisions regarding class rank and formulation differences. Specifically, Healthpoint compares its product, Embeline E (a class I ranking topical steroid cream) to another product, Diprolene AF (a class II ranking topical steroid cream). This comparison implies that Embeline E is superior to the other product. However, Healthpoint does not explain that there are differences in efficacy and safety with class I and class II products. In addition, Healthpoint compares Embeline E (which contains dimethicone) to Psorcon (which does not contain dimethicone). This comparison is misleading because it implies that Embeline E is superior to the other product based on formulation differences of inactive ingredients without substantiating evidence for support.

Healthpoint also claims that Embeline E is "the new drug of choice" and that "dry, scaly dermatoses need both..." a class I steroid potency and a formulation that contains dimethicone and emollients. These claims imply that Embeline E is superior to all other products, including other class I ranking steroid products, or products that do not contain the same inactive ingredient without substantiating evidence. Further, as a generic product of the innovator, Temovate E, Embeline E would not be considered a "new drug."

In the materials, Healthpoint compares the prices of products and references a survey conducted in 1/99. This survey reference is misleading without identifying the source of the reference since there are many price sources available.

Requested Actions

Healthpoint should immediately cease distribution of this and other similar promotional materials for Embeline E that contain the same or similar claims or presentations. Healthpoint should submit a written response to DDMAC on or before June 3, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Healthpoint should list the materials to be discontinued, and include the date on which this and other similarly violative materials were discontinued.

Healthpoint should direct its response to the undersigned by facsimile at (301) 594-6771, or in writing to DDMAC, 5600 Fishers Lane, HFD-40, Room 17B-20, Rockville, MD 20857. DDMAC reminds Healthpoint that only written communications are considered official. In all correspondence related to this matter, please refer to MACMIS ID # 7575 in addition to the ANDA number.

Sincerely,

Cheryl Y. Roberts, M.S., J.D.
Regulatory Review Officer,
Division of Drug Marketing,
Advertising and Communications