



NDA 17-765/S-024

Healthpoint, Ltd.
Attn.: Kay Mary Harrell
Director, Regulatory Affairs
307 E. Josephine Street
San Antonio, TX 78215

Dear Ms. Harrell:

Please refer to your supplemental new drug application dated June 10, 2003, received June 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CLODERM™ Cream, (clorcotolone pivalate), 0.1%.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a new 90 gram package size of CLODERM™ Cream, 0.1%.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert, immediate container label and carton label) attached to this letter.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-765/S-024." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kalyani Bhatt, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader for the
Division of Dermatologic & Dental Drug Products,
(HFD-540)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Encl.: Draft labeling (4 pages)

**This is a representation of an electronic record that was signed electronically and
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/s/

Wilson H. DeCamp
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approved