DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-076

Ferndale Laboratories, Inc.
Attention: Richard Hamer, Vice President, Regulatory Affairs
780 West Eight Mile Road
Ferndale, Michigan 48220

Dear Mr. Hamer:

Please refer to your new drug application (NDA) dated June 26, 2006, received July 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Locoid (hydrocortisone butyrate) Lotion, 0.1%.

We acknowledge receipt of your submissions dated July 20 (2), August 18, September 12, November 2, and December 21, 2006 and January 31, February 1, March 5, 13, 14 (2), 15, 16 (2), and 23, and May 8, 2007.

This new drug application provides for the use of Locoid (hydrocortisone butyrate) Lotion, 0.1% for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application for ages 3 months to less than 18 years. We are waiving the pediatric study requirement for ages 3 months and below.

We remind you of your postmarketing study commitment in your submission dated March 23, 2007. This commitment is listed below.

1. A 2-year dermal carcinogenicity study with Locoid (hydrocortisone butyrate) Lotion, 0.1% with the following schedule:

   90-day Dose Ranging Study by June 1, 2008
   Study Protocol Submission: by December 1, 2008
   Study Start: by September 1, 2009
   Final Report Submission: by March 1, 2013

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Melinda Bauerlien, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Division Director
Division of Dermatology & Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich
5/18/2007 12:05:37 PM
Sign off for Dr. Susan Walker, Division Director