



NDA 20-769/S-009

Ferndale Laboratories, Inc.
Attn.: Shari Whaley,
Regulatory Affairs Manager
780 West Eight Mile Road
Ferndale, MI 48220

Dear Ms. Whaley:

Please refer to your supplemental new drug application dated December 20, 2005, received December 21, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Locoid Lipocream® (hydrocortisone butyrate) Cream, 0.1%.

This supplemental new drug application provides for a new 60 gram package size of Locoid Lipocream® (hydrocortisone butyrate) Cream, 0.1%.

We completed our review of this application. This application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling (package insert, immediate container and carton labels) submitted December 20, 2005.

Please submit an electronic version of the FPL reflecting the addition of the new 60g package size 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-769/S-009.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit an updated version of the content of labeling [21 CFR 314.50(l)] in Structured Product Labeling (SPL) format as described at the following website:

<http://www.fda.gov/oc/datacouncil/spl.html>.

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 Valerie Jimenez, Regulatory Project Manager, at (301) 796-1345.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

Hasmukh Patel

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