DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-514/S-009

Ferndale Laboratories, Inc.
Attention: Khaled Mohamed
Regulator Affairs Coordinator
780 West Eight Mile Rd.
Ferndale, MI 48220

Dear Mr. Mohamed:

Please refer to your supplemental new drug application dated August 22, 2005, received August 23, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Locoid (hydrocortisone butyrate) Cream, 0.1%.

This CBE-30 supplemental new drug application provides for the discontinuation of release testing of the Locoid ® Cream bulk product prior to filling into finished product.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maria Anderson, Project Management, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, Ph.D.
Chief, Branch III
Division of Premarketing Assessment II
Office of New Drug Quality Assessment
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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/s/

Moo-Jhong Rhee

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