DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-769/S-003

Ferndale Laboratories, Inc.
Attn.: Khaled Mohamed
Regulatory Affairs Coordinator
780 West Eight Mile Road
Ferndale, MI 48220

Dear Mr. Mohamed:

Please refer to your supplemental new drug application dated October 2, 2003, received October 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Locoid® Lipocream® (hydrocortisone butyrate cream) Cream, 0.1%.

We acknowledge receipt of your submission dated April 21, 2004.

Your submission of April 21, 2004 constituted a complete response to our February 2, 2004, action letter.

This supplemental new drug application provide for a manufacturing site change from the approved facility in Meppel, Netherlands, to Ferndale's facility in Ferndale, MI, including new packaging, a new excipient, new acceptance tests and acceptance criteria, and(b)(4)----------
(b)(4)----------

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter.

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 Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Ramesh Sood, 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

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/s/

Ramesh Sood

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