DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-612

MAR 19 1999

Hind Health Care, Inc.
Attention: Larry Caldwell, Ph.D.
Consultant to Hind Health Care, Inc.
3707 Williams Road Suite 101
San Jose, CA 95117-2017

Dear Dr. Caldwell:

Please refer to your new drug application (NDA) dated May 31, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lidoderm Patch (lidocaine patch) 5% w/w. Please refer to our not approvable letter dated April 17, 1997, and our approvable letter dated December 2, 1998.

We acknowledge receipt of your submission dated January 15, 1999. This submission, together with your submissions of August 30, October 30, and December 1, 1997; February 9, 1999, and March 4, 1999, and correspondence via facsimile transmission dated March 15 and 18(two), 1999, constituted a complete response to our December 2, 1998, action letter.

This new drug application provides for the use of Lidoderm Patch (lidocaine patch) 5% w/w for the treatment of pain in post-herpatic neuralgia.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted March 4 and 18, 1999, immediate container and carton labels submitted March 15, 1999). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-612." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, contact Victoria Lutwak, Project Manager, at (301) 827-2090.

Sincerely,

John E. Hyde Ph.D., M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research