DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-806/S028

Watson Laboratories, Inc.
Attention: Randy A. Aquipel
Associate, Regulatory Liaison
Research Park
417 Wakara Way
Salt Lake City, UT 84108

Dear Mr. Aquipel:

Please refer to your supplemental new drug application dated January 8, 2002, received January 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordran (flurandrenolide) SP Cream, 0.025% and 0.05%.

We acknowledge receipt of your submission dated June 25, 2002.

This supplemental new drug application provides for a new drug product manufacturing site, an improved analytical method for the flurandrenolide assay, and editorial changes in the label to reflect the corporate name and identified manufacturing site.

We have completed the review of this supplemental 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 with the minor editorial labeling revision listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

The corporate name change and manufacturing site is listed at the end of the label as:

Manufactured for Oclassen Dermatologics
A Division of Watson Pharma, Inc.
Corona, CA 92880 by
(b)(4)----------

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.

If you have any questions, call Mary Jean Kozma-Fornaro, Supervisor, Project Management Staff, at (301) 827-2020.

Sincerely,

Wilson H. DeCamp, 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

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

/s/

Wilson H. DeCamp
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approved