DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-790/S-018

Watson Laboratories, Inc.
Attn.: Randy A. Aquipel,
Associate regulatory Liaison,
U.S. Proprietary Products
417 Wakara Way
Salt Lake City, UT 84108

Dear Mr. Aquipel:

Please refer to your supplemental new drug application dated June 27, 2003, received June 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cordran® Lotion (flurandrenolide lotion), 0.05%.

This supplemental new drug application provides for (1) an alternate finished drug product manufacturing site (b)(4)---------- ----------, (2) alternate analytical and testing sites for drug substance at (b)(4)----------and at Watson Laboratories, Inc. - Utah, 417 Wakara Way, Salt Lake City, UT 84108, (3) a new regulatory analytical procedure, and (4) manufacturing process and equipment changes. Draft labeling, in the form of annotated package insert, carton and container labels, was also submitted.

We have completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter.

Revised labeling (package insert, carton and container labels), following exactly the annotations submitted in the supplement, should be submitted to your next annual report. Any other changes should be submitted as a separate labeling supplement.

We have not completed validation of the regulatory method submitted in the supplemental application. However, we expect your continued cooperation to resolve any problems that may be identified. Please submit two copies of the method validation package for method 73.5270.00, which should also contain a list of reserved samples and contact information for the person responsible for these samples.

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 Ginny Giroux, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

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

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/s/

Wilson H. DeCamp
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approved