DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-967/S-004

Westwood-Squibb Pharmaceuticals, Inc.
Attention: David L. Silberstein
Associate Director, Regulatory Science
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated May 4, 1992, received May 11, 1992, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ultravate®(halobetasol propionate cream) Cream, 0.05%.

Your submission of February 19, 1996 constituted a complete response to our September 7, 1995 action letter.

This supplemental new drug application provides for revised labeling in accordance with the Division of Topical Drug Products' labeling recommendations for topical corticosteroid drug products and includes the results of the hypothalamic-pituitary-adrenal (HPA) axis suppression study as requested by the Agency at the time of the NDA approval.

We completed our review of this supplemental new drug application as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on February 19, 1996. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

We request the following revisions to be made to the labeling as soon as possible and no later than 6 months after the date of this letter:

- In the INDICATIONS AND USAGE section, add "Use in children under 12 years of age is not recommended." as the last sentence to the first paragraph.
- In the INDICATIONS AND USAGE section, add the second paragraph to read "As with other highly active corticosteroid, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary."
- In the PRECAUTIONS, Information for Patients section, delete "5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressing."
- In the DOSAGE AND ADMINISTRATION section, the first sentence of the second paragraph should read "Ultravate (halobetasol propionate cream) Cream is a super-high potency topical corticosteroid;…"

These revisions are consistent with the conditions of the September 7, 1995 Approvable Letter. Report the changes in the Annual Report.

If a letter communicating important information about this drug product (i.e. a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be necessary.

If you have any questions, call Margo Owens, Regulatory Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}
Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
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/

John Kelsey
4/2/03 03:50:06 PM
for Dr. Wilkin