



NDA 17-950/S021

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: David L. Silberstein
Associate Director, Dossier Planning and Liason Support
Regulatory Dossier Planning and Management
P.O. Box 4000
Princeton, New Jersey 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated August 27, 2001, received August 30, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Westcort® (hydrocortisone valerate cream) Cream, 0.2%.

We acknowledge receipt of your submission dated November 11, 2002.

This supplemental new drug application, S021, provides for the addition of the "Geriatric Use" subsection of the label, as reflected in 21 CFR 201.57 (f)(10).

In addition, the label was reviewed and revised in the following areas: PRECAUTIONS: General, Information for Patients, Carcinogenesis, Mutagenesis, and Impairment of Fertility, Pregnancy Category C, and Pediatric Use Subsections, and the ADVERSE REACTIONS section.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text (package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper 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 supplement NDA 17-950/S-021."

Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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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 and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

**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
3/24/03 11:01:12 AM
for Dr. Wilkin