DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-726/S009
NDA 18-726/S012

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: David L. Silberstein
Associate Director, Dossier Planning and Liaison 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 S009, dated February 20, 1996, received February 27, 1996, and supplemental new drug application S012, 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 ointment) Ointment, 0.2%.

Supplemental new drug application S009 provides for final printed labeling for an approvable action dated August 30, 1995. Supplemental new drug application S012 provides for 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, Pregnancy: Teratogenic Effects, Pregnancy Category C, and Pediatric Use subsections, and the ADVERSE REACTIONS section.

We have completed the review of these supplemental applications, 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 enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling text (package insert). Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Provide Regulatory Submissions in Electronic Format – NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 supplements NDA 18-726/S009 and S012".

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

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

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, call Victoria Lutwak, 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/

Jonathan Wilkin

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