DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-526/S-010

Bristol-Myers Squibb
Attention: David L. Silberstein
Associate Director, Dossier Planning and Liaison Support
Regulatory Dossier Planning and Management
PO Box 4000
Princeton, NJ 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 **Staticin (erythromycin) Solution, 1.5%.**

This supplemental new drug application provides for a revision to add a **Geriatrics Use** subsection to the **PRECAUTIONS** Section of the package insert to comply with the final rule 21 CFR 201.57(f)(10).

We have completed the review of this supplemental application, 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 submitted labeling dated August 27, 2001. Accordingly, this supplemental application is approved effective on the date of this letter.

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 Frank Cross, 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/

Jonathan Wilkin

12/15/02 03:44:32 PM