DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-898/S-054

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Jerry Gennaro, Ph.D.
Director, Regulatory Science
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Gennaro:

Please refer to your supplemental new drug application dated April 1, 2003, received April 2, 2003, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Pravachol (pravastatin sodium) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **PRECAUTIONS,** *Pediatric Use* subsection of the package insert to include the following sentence:

> *Children and adolescent females of child-bearing potential should be counseled on appropriate contraceptive methods while on pravastatin therapy (see* ***CONTRAINDICATIONS*** *and* ***PRECAUTIONS****:* ***Pregnancy****).*

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 1, 2003.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

> Division of Drug Marketing, Advertising, and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857

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, HFD-410
> 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 Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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