DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-915/S-032

Bristol-Myers Squibb Company
Attention: Ms. Grace D. Heckman
Box 5400
Princeton, NJ 08543-4000

Dear Ms. Heckman:

Please refer to your supplemental new drug application dated August 25, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monopril (fosinopril soidum) 10, 20, and 40 mg Tablets.

We acknowledge receipt of your submissions dated July 21, 2000 and April 16, 2002 that constituted a complete response to our July 11, 2001 action letter.

This supplemental new drug application provides for final printed labeling revised as follows:

1. The following section has been added to the **PRECAUTIONS** section:

   Geriatric Use
   Clinical studies of MONOPRIL did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

2. The following revision is noted in the **STORAGE** section:

   Change from:
   " Store between 15° C (59° F) and 30° C (86° F). Avoid prolonged exposure to temperature above 30° C (86° F). Keep bottles tightly closed (protect from moisture)."

   Revised to:
   " Store at 25° C (77° F); excursions permitted to 15° C - 30° C (59° F - 86° F) [see USP Controlled Room temperature]. Protect from moisture by keeping bottle tightly closed."

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 product is safe and effective for use as recommended in the final printed labeling included in your April 16, 2002 submission. Accordingly, this supplemental application is approved effective on the date of this letter.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Alisea Sermon, Pharm.D.
Regulatory Health Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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/

Doug Throckmorton

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