



NDA 19-915/S-038

NDA 20-286/S-006

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

Dear Ms. Heckman:

Please refer to your supplemental new drug applications dated July 2, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Monopril (fosinopril sodium) 10, 20 and 40 mg Tablets (NDA 19-915) and Monopril-HCT (fosinopril sodium/hydrochloride) 20/12.5 mg and 10/12.5 mg Tablets (NDA 20-286).

These "Changes Being Effected" supplemental new drug applications provide for changes to the **WARNINGS** section of labeling as follows:

1. Under **WARNINGS**, the **Angioedema** subsection was re-title "**Head and Neck Angioedema**".
2. Following the **Head and Neck Angioedema** subsection and before the paragraph entitled "In large U.S. postmarketing study..." the following text has been added:

Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. The angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor. Intestinal angioedema should be included in the differential diagnosis of patients on ACE inhibitors presenting with abdominal pain.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 9, 2003.

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

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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 contact:

Alisea Sermon, Pharm.D.
Regulatory 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

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/s/

Doug Throckmorton
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