DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-915/S-042
20-286/S-008

Bristol-Myers Squibb
Attention: Mr. David Silberstein
PO Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug applications dated August 12, 2008 submitted under section 505(b)(1) 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/hydrochlorothiazide) 20/12.5mg and 10/12.5mg Tablets (20-286).

These "changes-being-effected" supplemental applications provide for additional information in the **PRECAUTIONS**/**Drug Interactions** section of the package insert as requested in our letter dated March 3, 2008.

These supplemental new drug applications provide for electronic labeling with the following revisions:

NDA 19-915

1. Under the **PRECAUTIONS**/***Drug Interactions*** subsection, the following interaction has been added:

   Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including MONOPRIL.

2. We also note several editorial revisions throughout the label.

NDA 20-286

1. Under the **PRECAUTIONS**/**Drug Interactions** subsection, the following interaction has been added:

   Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including MONOPRIL-HCT.

2. We also note several editorial revisions throughout the label.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the electronic (SPL) labeling text submitted on August 12, 2008. 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Alisea Crowley, Pharm.D., RAC
Senior Regulatory Project Manager
(301) 796-1144

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and 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/

Norman Stockbridge

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