DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-377/S-063

Mutual Pharmaceutical Company, Inc.
Attention: Andria Werynski
Assistant Manager, Regulatory Affairs
1100 Orthodox Street
Philadelphia, PA 19124

Dear Ms. Werynski:

Please refer to your supplemental new drug application dated December 21, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactrim (sulfamethoxazole and trimethoprim) Tablets and Double Strength Tablets, 400mg/80mg and 800mg/160mg.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Bactrim package insert, in the WARNINGS section as well as the PRECAUTIONS/Information for Patients subsection. These revisions were requested by the Agency in a letter to you dated October 27, 2006, and are associated with the potential risks of contracting *Clostridium difficile* associated disease (CDAD) as a result of antimicrobial therapy.

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and with the editorial revisions included in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted labeling dated December 21, 2006. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 17-377/S-063**." Approval of this submission by FDA is not required before the labeling is used.

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, call J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Labeling submitted December 21, 2007

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth

6/5/2007 08:50:47 AM