DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17-377/S-067

SUPPLEMENT APPROVAL

Mutual Pharmaceutical Company, Inc.
Attention: Robert Dettery
Vice President, Regulatory Affairs
1100 Orthodox Street
Philadelphia, PA 19124

Dear Mr. Dettrey:

Please refer to your Supplemental New Drug Application (sNDA) dated October 5, 2009, received, October 5, 2009 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bactrim™ Tablets, USP and Bactrim™ DS (Double Strength) Tablets, 400mg/80mg and 800mg/160mg.

We also acknowledge receipt of your amendments dated June 14, 2010, and July 8, 2010. The June 14, 2010, amendment constitutes a complete response to our May 14, 2010, action letter.

This "Changes Being Effected" supplemental new drug application provides for changes to the **WARNINGS, PRECAUTIONS, ADVERSE REACTIONS** and **REFERENCES** sections of the product labeling.

We have completed our review of this supplemental application, as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. The enclosed label also includes a change approved by the Agency on June 28, 2010, revising the Quality Control parameter for *Escherichia coli* (ATCC 25922) in the **Clinical Pharmacology, Microbiology** subsection.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-17377	SUPPL-67	MUTUAL PHARMACEUTICAL CO INC	BACTRIM (SULFAMETHOXAZOLE/TRIMETHOP) TAB

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

/s/

SUMATHI NAMBIAR
07/27/2010