DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17-377/S-068
NDA 17-377/S-073

SUPPLEMENT APPROVAL

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

Dear Mr. Dettery:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 30, 2010 (S-068) and October 26, 2012 (S-073), received April 30, 2010 and October 26, 2012, respectively. These supplements were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BACTRIM Tablets, USP (400mg/80mg) and BACTRIM DS (double strength) Tablets, 800mg/160mg.

We acknowledge receipt of your amendments dated December 15, 2010, August 24 and October 21, 2011, September 21, 2012, and July 1, 2013, to S-068 and July 1, 2013, to S-073.

The August 24, 2011, submission constituted a complete response to our August 24, 2010 action letter for S-068.

These "Prior Approval" supplemental new drug applications provide for the following:

- **NDA 17-377/S-068:** Revisions to the **CONTRAINDICATIONS, WARNINGS** and **PRECAUTIONS** sections, *Carcinogenesis, Mutagenesis, Impairment of Fertility and Teratogenic Effects* subsections, of the package insert.

- **NDA 17-377/S-073:** Revisions to the following sections of the package insert:

    - **CLINICAL PHARMACOLOGY**
    - **PRECAUTIONS:** *Electrolyte Abnormalities and Drug Interactions* subsections
    - **ADVERSE REACTIONS:** *Metabolic and Nutritional* and *Postmarketing Experience* subsections

We have completed our review of these supplemental applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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
07/12/2013