DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 17-377/S-066 **SUPPLEMENT APPROVAL**

United Research Laboratories, Inc.
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 application (NDA) dated April 3, 2009, received April 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Bactrim (sulfamethoxazole and trimethoprim) Tablets, USP and Bactrim (sulfamethoxazole and trimethoprim) DS (Double Strength) Tablets.

We also acknowledge receipt of your correspondence dated February 1, 2008.

This supplemental new drug application provides for a response to our letter of January 6, 2008, requesting updates to the *in vitro* susceptibility test interpretive criteria (breakpoints) and the quality control parameters for *in vitro* susceptibility testing listed in the package insert as applicable.

We have completed our review of this application and find the data submitted to support changing the Quality Control (QC) parameter for *Escherichia coli* ATCC 25922 from (b) (4) to (b) (4) in the **CLINICAL PHARMACOLOGY, *Microbiology Subsection*** acceptable. Additionally, we agree that no other revisions to the *in vitro* susceptibility test interpretive criteria or the *in vitro* susceptibility test QC parameters are required at this time. Therefore, this supplement is approved, effective on the date of this letter.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the labeling submitted April 3, 2009. For administrative purposes, please designate this submission, "SPL for approved NDA 17-377/S-066.

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 regarding this specific supplement, call Maureen Dillon-Parker, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Acting Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-17377	SUPPL-66	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/

WILEY A CHAMBERS
06/28/2010