DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22352/S-013
NDA 22352/S-014

RELEASE REMS REQUIREMENT SUPPLEMENT APPROVAL

United Research Laboratories, Inc.
Mutual Pharmaceutical Company, Inc.
1100 Orthodox Street
Philadelphia, PA 19124

Attention: Robert Dettery
Vive President, Regulatory Affairs

Dear Mr. Dettery:

Please refer to your Supplemental New Drug Application (sNDA) dated June 24, 2011, received June 24, 2011, (S-014), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Colcrys (colchicine) Tablets.

We also acknowledge receipt of your amendment dated July 12, 2011, and your March 29, 2011, assessment of the Colcrys (colchicine) risk evaluation and mitigation strategy (REMS).

This sNDA provides for revisions to the labeling for Colcrys (colchicine) in response to our safety labeling change notification letter dated May 27, 2011, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Colcrys (colchicine). This information pertains to patients not understanding the risk of drug-drug interactions and risks associated with patients who have liver or kidney problems. This sNDA also proposes to eliminate the requirement for the approved Colcrys (colchicine) REMS.

We have completed our review of this supplemental application, as amended. It is 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, text for the Medication Guide), 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 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 this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Colcrys (colchicine) Tablets was originally approved on July 29, 2009, and the most recent REMS modification was approved on April 29, 2010. The REMS consists of a Medication Guide, and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Colcrys (colchicine).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Colcrys (Colchicine) Tablets outweigh its risks.

Therefore, a REMS is no longer required for Colcrys (colchicine) Tablets.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

PROMOTIONAL MATERIALS

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 Ladan Jafari, Safety Regulatory Project Manager, at (301) 796-1231.

Sincerely,

{See appended electronic signature page}

Sally Seymour, M.D.
Deputy Director for Safety
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
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/

SALLY M SEYMOUR
07/20/2011