DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-352/S-004 SUPPLEMENT APPROVAL

AR Holding Company, Inc.
c/o Mutual Pharmaceutical Company, Inc.
1100 Orthodox Street
Philadelphia, PA 19124

Attention: Robert Dettery
Vice President, Regulatory Affairs

Dear Mr. Dettery:

Please refer to your supplemental new drug application (sNDA) dated October 19, 2009, received October 20, 2009, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Colcrys (colchicine) Tablets 0.6 mg.

We acknowledge receipt of your submission dated March 30, 2010.

This Prior Approval supplemental drug application, S-004, provides for changes to the company name on the approved risk evaluation and mitigation strategy (REMS) and Medication Guide to reflect the Transfer of Ownership of NDA 22-352, which was effective on August 3, 2009.

We have completed our review of this 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, 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 (text for the package insert, submitted October 19, 2009, and Medication Guided submitted March 30, 2010) 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.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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.

We request that the revised 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) was originally approved on July 29, 2009. The REMS consists of a Medication Guide and timetable for the submission of assessments of the REMS. The proposed modifications to the REMS are the change in company name on the REMS document and in the Medication Guide and revision to the timetable for submission of assessments.

Your proposed modified REMS, submitted on October 19, 2009, and appended to this letter, is approved. The REMS consists of a Medication Guide and timetable for submission of assessments of the REMS. The REMS assessment plan and the dates in the timetable for submission of assessments will remain the same as that approved on July 29, 2009.

Prominently identify submissions containing REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022352
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022352-PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022352
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Ramani Sista, Regulatory Project Manager, at (301) 796-1236.

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(S):
Content of Labeling
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22352	SUPPL-4	AR HOLDING CO INC	COLCRYS TABLETS 0.6 MG

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
04/29/2010