DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021799/ S-022

SUPPLEMENT APPROVAL
REMS ASSESSMENT ACKNOWLEDGEMENT
RELEASE REMS REQUIREMENT

AR Holding Company, Inc.
c/o Mutual Pharmaceuticals 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 (sNDA) dated and received April 25, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Qualaquin (quinine sulfate) capsules, 324 mg.

We acknowledge your assessment of the risk evaluation and mitigation strategy (REMS) for Qualaquin (quinine sulfate) capsules, 324 mg, dated December 15, 2011. In accordance with Section 505-1(h)(2) of the FDCA, we notified you that we were initiating discussions of your REMS assessment through an email on February 13, 2012. This letter is a follow-up to that email. After consultation between the Office of Surveillance and Epidemiology and the Office of New Drugs, we found the REMS assessment to be complete.

This Prior Approval supplement proposes to eliminate the requirement for the approved REMS for Qualaquin (quinine sulfate) capsules, 324 mg.

We have completed our review of this supplemental application and it is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Qualaquin (quinine sulfate) capsules, 324 mg, was originally approved on June 15, 2010. The REMS consists of a Medication Guide, a communication plan, and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS consists of eliminating the requirement for the REMS for Qualaquin (quinine sulfate) capsules, 324 mg.

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 Qualaquin (quinine sulfate) capsules, 324 mg, outweigh its risks.

The REMS assessment received on December 15, 2011 demonstrated that the components of the communication plan have been completed, with the exception of distributing the final Dear Health Care Provider (DHCP) letter. Although the assessment suggested that understanding of the benefits and risks of the use of Qualaquin (quinine sulfate) capsules, 324 mg, as a treatment for leg cramps is not optimal, we have determined that the risk of serious hematologic reactions is likely to be low due to declining drug use, and we have further determined that it is no longer necessary to include the communication plan as an element of the approved REMS to ensure that the benefits of the drug outweigh the risks. Therefore, we agree with your proposal, and a REMS is no longer required for Qualaquin (quinine sulfate) capsules, 324 mg.

We remind you that the Medication Guide will continue to be part of the approved labeling for Qualaquin (quinine sulfate) capsules, 324 mg in accordance with 21 CFR 208. Additionally, we recommend that the DHCP letter be distributed in August 2012, as originally planned.

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 Gregory DiBernardo, Regulatory Project Manager, at (301) 796-4063.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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
05/22/2012