DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19591/S-030

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Hoffmann-La Roche Inc.
Attention: Ms. Lynn DeVenezia-Tobias
Senior Program Manager, Diversified Products
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your Supplemental New Drug Application (sNDA) dated March 31, 2011, received April 1, 2011, under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lariam® (mefloquine hydrochloride) Tablets, 250 mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 20, 2011.

This supplemental new drug application proposes that the requirement for the Lariam REMS be eliminated.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Lariam® (mefloquine hydrochloride) was originally approved on August 20, 2009. 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 Lariam® (mefloquine hydrochloride).

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of the Lariam® (mefloquine hydrochloride) outweigh its risks. Therefore, we agree with your proposal and a REMS for Lariam® (mefloquine hydrochloride) is no longer required. We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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}

Ozlem Belen, MD, MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant 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/

OZLEM A BELEN
04/29/2011