DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019384/S-058

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Merck Sharp & Dohme Corp.
Attention: Daniel J. Larkins
Manager, Worldwide Regulatory Affairs
P.O. Box 1000, UG2CD-50
North Wales, PA 19454-2505

Dear Mr. Larkins:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 14, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NOROXIN® (norfloxacin) Tablets.

We acknowledge receipt of your amendment dated May 3, 2011.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 27, 2011.

This sNDA, as amended, proposes to eliminate the requirement for the approved NOROXIN® (norfloxacin) Tablets REMS.

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

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for NOROXIN® (norfloxacin) Tablets was originally approved on April 27, 2009, and the most recent REMS modification was approved on February 25, 2011. 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 NOROXIN® (norfloxacin) Tablets.

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 NOROXIN® (norfloxacin) Tablets outweigh its risks.

Therefore, we agree with your proposal and a REMS for NOROXIN® (norfloxacin) Tablets 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.

REPORTING REQUIREMENTS

We also 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
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
09/08/2011