DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-384/S-045

Merck & Co., Inc.
Attention: Mary Beth Wigley
Manager, Regulatory Affairs
P.O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486-0004

Dear Ms. Wigley:

Please refer to your supplemental new drug application, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NOROXIN™ (norfloxacin) Tablets, 400 mg.

We also acknowledge receipt of your amendment dated January 24, 2006, which included the requested WAES reports.

This supplement was submitted as Changes Being Effected (CBE) and provides for additional text in the **PRECAUTIONS/** *Drug Interactions* subsection regarding concomitant administration of a non-steroidal anti-inflammatory drug (NSAID) with a quinolone and adding the term "hypoesthesia" to the **ADVERSE REACTIONS/*Post Marketing/*** *Nervous System/Psychiatric* subsection.

The changes were made as follows (additions are <u>double underlined</u>):

1. The following text was added as the last paragraph under the **PRECAUTIONS/***Drug Interactions* subsection:

   <u>The concomitant administration of a non-steroidal anti-inflammatory drug (NSAID) with a quinolone, including norfloxacin, may increase the risk of CNS stimulation and convulsive seizures. Therefore, NOROXIN should be used with caution in individuals receiving NSAIDS concomitantly.</u>

2. The following adverse event was added under the **ADVERSE REACTIONS/*Post Marketing/****Nervous System/Psychiatric* subsection:

   - <u>hypoesthesia,</u>

We have completed the review of this labeling supplement, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 18, 2005.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Christine Lincoln, Labeling Reviewer, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
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/

Renata Albrecht

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