DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

NDA 021085/S-052
NDA 021277/S-049

Bayer Pharmaceuticals Corporation
Attention: Larry Winick
Deputy Director, Global Regulatory Affairs
P.O. Box 1000
Montville, New Jersey 07045-1000

Dear Mr. Winick:

Please refer to your supplemental New Drug Applications (sNDAs), dated and received June 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AVELOX® (moxifloxacin hydrochloride) Tablets (NDA 021085), and AVELOX® (moxifloxacin hydrochloride) Injection (NDA 021277).

We acknowledge receipt of your amendments, dated July 12, 2011, and your risk evaluation and mitigation strategy (REMS) assessment dated December 29, 2010.

These "Prior Approval" sNDAs provide for revisions to the Medication Guide.

We have completed our review of these supplemental applications, as amended. They are 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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

We request that the modifications approved today be available on your website within 10 days of receipt of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT

The REMS for AVELOX® (moxifloxacin hydrochloride) Tablets and Injection was originally approved on April 27, 2009, and the most recent REMS modification was approved on August 3, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

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 AVELOX® (moxifloxacin hydrochloride) Tablets and Injection outweigh its risks. We refer to the July 8, 2011 teleconference with Susmita Samanta, Safety Regulatory Project Manager, Division of Anti-Infective Products, where you agreed with this determination.

Therefore, a REMS for AVELOX® (moxifloxacin hydrochloride) Tablets and Injection 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 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, MD, 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

ENCLOSURE:
Approved Medication Guide

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
08/03/2011