DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-085/S-059
NDA 21-277/S-055

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Bradley Jones, MS, RAC
Associate Director, Global Regulatory Affairs
100 Bayer Boulevard
P.O. Box 0915
Whippany, NJ 07981-0915

Dear Mr. Jones:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 29, 2014, received May 29, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Name of Drug Product	NDA Number	Supplement Number
AVELOX (moxifloxacin hydrochloride) 400 mg Tablets	NDA 21-085	S-059
AVELOX (moxifloxacin hydrochloride in sodium chloride injection) IV	NDA 21-277	S-055

We acknowledge receipt of your amendment dated October 06, 2014.

These "Prior Approval" supplemental new drug applications provide for the inclusion of Blood Glucose Disturbances in the **WARNINGS AND PRECAUTIONS** section of the package insert and the addition of cyclosporine to the list of drugs that do not affect moxifloxacin concentration in the **CLINICAL PHARMACOLOGY** section, **Pharmacokinetics** subsection (12.3)**.**

The following sections of the package insert were revised with information concerning Blood Glucose Disturbances as follows: **HIGHLIGHTS OF PRESCRIBING INFORMATION**, **WARNINGS AND PRECAUTIONS**, **CLINICAL PHARMACOLOGY**, **PATIENT COUNSELING INFORMATION** and **MEDICATION GUIDE** under (What should I tell my healthcare provider before taking AVELOX?)

APPROVAL & LABELING

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.

We note that your October 06, 2014, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 package insert and 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.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Fariba Izadi, Pharm.D., Regulatory Health Project Manager, at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
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
11/20/2014