



NDA 021085/S-064  
NDA 021277/S-060

## SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.  
Attention: Joseph Marini, M.S., R.Ph.  
Associate Director  
Regulatory Affairs, Established Products  
100 Bayer Blvd  
Whippany, NJ 07981-0915

Dear Mr. Marini:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for AVELOX (moxifloxacin hydrochloride) Tablets, 400 mg (NDA 021085), and AVELOX (moxifloxacin hydrochloride in NaCl injection) IV, 400 mg (NDA 021277).

We also refer to our letter dated July 10, 2018, notifying you, under Section 505(o)(4) of the FDCA, of new safety information required to be included in the labeling for the systemic fluoroquinolone class of antibacterial drugs. This information pertains to the risk of psychiatric adverse reactions and hypoglycemic coma which are included in the **WARNINGS AND PRECAUTIONS** section.

These supplemental new drug applications provide for revisions to the **WARNINGS AND PRECAUTIONS** section (5) for AVELOX (moxifloxacin hydrochloride) Tablets, 400 mg and AVELOX (moxifloxacin hydrochloride in NaCl injection) IV, 400 mg, consistent with our July 10, 2018, safety labeling change notification letter.

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications. 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(1)] 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, Medication

NDA 021085/S-064

NDA 021277/S-060

Page 2

Guide), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 include labeling changes for these NDAs, 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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

*{See appended electronic signature page}*

Joseph G. Toerner, M.D., M.P.H.  
Deputy Director for Safety  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE:

Content of Labeling

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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JOSEPH G TOERNER  
10/18/2018