SUPPLEMENT APPROVAL

NDA 21277/S-062
NDA 21085/S-066

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Kaitlyn Orland, PharmD, RPh
Manager, Regulatory Affairs
100 Bayer Blvd. PO Box 0915
Whippany, NJ 07981-0915

Dear Dr. Orland:

Please refer to your supplemental new drug applications (sNDAs) dated and received November 08, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA #	Supplement	Drug Product	Dosage
21085	S-066	Avelox (moxifloxacin)Tablets	400 mg
21277	S-062	Avelox (moxifloxacin) Injection in 0.8% sodium chloride solution	400 mg in a 250 mL single-dose flexible bag

These Prior Approval supplemental new drug applications provide for the following revisions to the Prescribing Information (PI):

HIGHLIGHTS OF PRESCRIBING INFORMATION

DOSAGE AND ADMINISTRATION section **(2), Important Administration Instructions** subsection **(2.2)** was updated to add information regarding missed doses.

WARNINGS AND PRECAUTIONS section **(5), *Clostridioides difficile*-Associated Diarrhea** subsection **(5.10)** was updated to replace *Clostridium with Clostridioides.*

USE IN SPECIFIC POPULATIONS section **(8)**, **Pegnancy** subsection **(8.1)** was updated to be consistent with the Pregnancy and Lactation Labeling Rule (PLLR) and the **Lactation** subsection **(8.2),** was updated to revise the risk summary and data.

DESCRIPTION section **(11),** subsetions **AVELOX Tablets (11.1)** and **AVELOX Injection (11.2)** were revised to include an equivalency statement.

PATIENT COUNSELING INFORMATION section **(17)** has been updated to be in agreement with **Important Administration Instructions** subsection **(2.2).**

Furthermore, minor editorial revisions have been made throughout the PI.

Medication Guide has been updated to be in agreement with the revisions made to the prescribing information.

In addition, the carton and container labeling were revised to update the equivalency statement for both Avelox tablets and Avelox Injection.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 sNDAs, 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

We acknowledge your April 24 & 28, 2020, submission containing final printed carton and container labeling.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 21085/S-066** (Avelox tablet) **and for approved NDA 21277/S-62** (Avelox IV). Approval of this submission by FDA is not required before the labeling is used.

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, PharmD, Safety Regulatory Project Manager at (301) 796-0563.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation & Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Carton and Container Labeling

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.

/s/

DMITRI IARIKOV
05/06/2020 10:02:38 AM