



NDA 19537/S-093  
NDA 20780/S-049

## SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.  
Attention: Kaitlyn Orland, PharmD, RPh  
Senior Manager, Regulatory Affairs-Established Product  
100 Bayer Blvd, PO Box 915  
Whippany, NJ 07981-0915

Dear Dr. Orland:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 25, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 20780 CIPRO (ciprofloxacin) for Oral Suspension  
NDA 19537 CIPRO (ciprofloxacin hydrochloride) Tablets

These "Changes Being Effected" supplemental new drug applications propose to correct the Dosage and Administration in the **HIGHLIGHTS** of the Prescribing Information with the following wording to make it consistent with the text in the corresponding sections of the PI:

" Decreased CIPRO absorption. Take CIPRO 2 hours before or 6 hours after administration of multivalent cation containing drugs (7)"

### **APPROVAL & LABELING**

We have completed our review of these applications. They 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.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, with the addition of any labeling changes in pending "Changes

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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(I)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, 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 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 Sheel Shah, Regulatory Project Manager, at (240)402-3968.

Sincerely,

*{See appended electronic signature page}*

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

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

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<sup>2</sup> 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>.

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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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