



NDA 019537/S-091
NDA 020780/S-048

SUPPLEMENT APPROVAL

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 (sNDA) 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
19537	S-091	CIPRO (ciprofloxacin hydrochloride) Oral Tablets	250 mg, 500 mg
20780	S-048	CIPRO (ciprofloxacin) Oral Suspension	5% (250 mg/5 mL) 10% (500 mg/5 mL)

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.

CLINICAL PHARMACOLOGY section (12), **Pharmacokinetics** subsection (12.3) has been revised to update pharmacokinetic parameters.

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

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

In addition, minor editorial revisions have been made throughout the PI.

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 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).

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>.

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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

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
05/08/2020 04:32:06 PM