NDA 019537/S-090
NDA 020780/S-047

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals, Inc.
Attention: Kaitlyn Orland, Pharm.D. R.Ph
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 June 28, 2019, and your amendments, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for.

NDA #	Supplement	Name	Strength
019537	S-090	Cipro (ciprofloxacin hydrochloride) Tablets	250 mg, 500 mg
020780	S-047	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 changes to the Prescribing Information (PI):

HIGHLIGHTS OF PRESCRIBING INFORMATION, USE IN SPECIFIC POPULATIONS (8) section, **Pregnancy (8.1)** subsection and **Lactation (8.2)** subsection **and PATIENT COUNSELING INFORMATION (17)** section were revised to comply with the Pregnancy and Lactation Labeling Rule (PLLR).

DOSAGE AND ADMINISTRATION section**, Dosage in Pediatric Patients (2.2)** subsection was updated to revise the total duration of therapy for plague.

DESCRIPTION (11), section was revised to add equivalency statement and relist inactive ingredients.

NONCLINICAL TOXICOLOGY (13) section, **Carcinogenesis, Mutagenesis, Impairment of Fertility (13.1)** subsection was updated to include more detail on animal dosing information.

REFERENCES (15) section was updated and minor editorial changes and clarifications were made throughout the PI.

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

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

[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.

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).

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

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
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