



NDA 019537/S-092

SUPPLEMENT APPROVAL

Bayer HealthCare Pharmaceuticals Inc.
Attention: Walid Kassaoui, PharmD
Manager, Regulatory Affairs-Established Products
100 Bayer Blvd, PO Box 915
Whippany, NJ 07981-0915

Dear Dr. Kassaoui:

Please refer to your supplemental new drug application (sNDA) dated February 26, 2021 received February 26, 2021 and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for cipro (ciprofloxacin hydrochloride) 250mg and 500mg tablets.

This Prior Approval sNDA provides for changes to the following sections/subsections of the prescribing information (PI): **HIGHLIGHTS OF PRESCRIBING INFORMATION; DOSAGE AND ADMINISTRATION** section (2), **Important Administration Instructions (2.4)** subsection; **DOSAGE FORMS AND STRENGTHS (3)** section, **Tablets (3.1)** subsection; **HOW SUPPLIED/STORAGE AND HANDLING (16)** section; and the **PATIENT COUNSELING (17)** section. The **Medication Guide (MG)** was revised to include identification of scoring of the 250mg and 500mg tablets. Minor editorial revisions were also made throughout the PI and the MG.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is 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](http://www.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.

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

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 this NDA, 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 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 questions, call Sheel Shah, Pharm D, 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
 - Medication Guide

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>.

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
11/11/2021 07:07:09 AM