NDA 050406/S-014

SUPPLEMENT APPROVAL

Pragma Pharmaceuticals, LLC
Attention: Michelle Kim, PharmD
Senior Director, Regulatory Affairs
134 Birch Hill Road
Locust Valley, NY 11560

Dear Michelle Kim:

Please refer to your supplemental new drug application (sNDA) dated and received March 26, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Keflex (cephalexin) for oral suspension, 125 mg/5 mL and 250 mg/5mL.

This Prior Approval supplemental new drug application provides for updates to the prescribing information (PI) in order to comply with the requirements for the Pregnancy and Lactation Labeling Rule (PLLR) [Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements/or Pregnancy and Lactation Labeling, 79 FR 233, December 4, 2014].

More specifically, this supplemental application has been submitted in response to our January 27, 2025, Prior Approval Supplement Request Letter, requesting these revisions and includes modification to the **HIGHLIGHTS OF PRESCRIBING INFORMATION** section, **INDICATIONS AND USAGE (1)** section, **DOSAGE AND ADMINISTRATION (2)** section and the **USE IN SPECIFIC POPULATIONS** section, **Pregnancy (8.1)** and **Lactation (8.2)** subsections, as well as minor editorial revisions to the **Renal Impairment (8.6)** subsection. Minor editorial revisions were also made throughout the other sections of the PI.

APPROVAL & LABELING

We have completed our review of this application, as amended and 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.[1] 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 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 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).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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.

If you have any questions, contact J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702 or by electronic mail at christopher.davi@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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
03/05/2026 11:02:14 AM