DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-405/S-108

SUPPLEMENT APPROVAL

Pragma Pharmaceuticals, LLC
Attention: John D'Angelo, M.S., R.Ph.
Vice President, Regulatory Affairs
134 Birch Hill Road
Locust Valley, NY 11560

Dear Mr. D'Angelo:

Please refer to your Supplemental New Drug Application (sNDA) dated June 20, 2018, received, June 22, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Keflex (cephalexin) Capsules, USP, 250 mg, 333 mg, 500 mg, and 750 mg.

This Prior Approval supplemental application provides for revisions to the prescribing information to satisfy the requirements for 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, see 21 CFR 201.56 (a and d) and 201.57 (c)(9) (i, ii, and iii)].

Specifically, this supplemental application has been submitted in response to the Agency's April 27, 2018, letter requesting these revisions and includes modifications to the **HIGHLIGHTS OF PRESCRIBING** 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.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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:

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

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 titled "SPL Standard for Content of Labeling Technical Qs and As" at:

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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
12/19/2018