



NDA 50-406/S-013

SUPPLEMENT APPROVAL

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

Dear Mr. D'Angelo:

Please refer to your Supplemental New Drug Application (sNDA) dated May 22, 2018, received May 22, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Keflex (cephalexin) Powder for Oral Suspension, 125 mg/5 mL and 250 mg/5 mL.

This "Changes Being Effected" supplemental new drug application proposes labeling changes to remove the susceptibility test interpretive criteria information and related information from the approved labeling and replace it with a reference to the Interpretive Criteria web page in accordance with section 511A of the FD&C Act. Moreover, this supplemental application has been submitted in response to the Agency's February 8, 2018, letter, requesting these changes.

APPROVAL & LABELING

We have completed our review of this supplemental application 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(1)] 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
12/18/2018

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