



NDA 50-405/S-106

SUPPLEMENT APPROVAL

Shionogi, Inc.
Attention: Denise Flanagan, PhD
Senior Director, Regulatory Affairs, CMC
300 Campus Drive
Florham Park, NJ 07932

Dear Dr. Flanagan:

Please refer to your Supplemental New Drug Application (sNDA) dated November 6, 2014, received November 6, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Keflex (Cephalexin) Capsules, USP, 250, 500 and 750 mg.

We also acknowledge receipt of your amendments dated February 20, August 14, and October 22, 2015.

This "Prior Approval" supplemental application proposes revisions to your package insert to comply with the content and format requirements of labeling for human prescription drug and biological products under 21 CFR 201.56(d) and 201.57, Physician's Labeling Rule (PLR).

In addition, revisions have been made to the CLINICAL PHARMACOLOGY, Microbiology (12.4) subsection to update *in vitro* susceptibility test interpretive criteria, as well as to the REFERENCES (15) section. Additional minor editorial changes have also been made to the package insert.

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, 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 includes 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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}

Sumathi Nambiar, MD, MPH
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 and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
10/30/2015