



NDA 50-757/S-018

SUPPLEMENT APPROVAL

Takeda Development Center Americas, Inc.
Attention: Clint Johansen
Manager, Global Regulatory Affairs
One Takeda Parkway
Deerfield, IL 60015

Dear Mr. Johansen:

Please refer to your Supplemental New Drug Application (sNDA) dated November 13, 2014, received November 13, 2014, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PREVPAC (lansoprazole/amoxicillin/clarithromycin).

This Prior Approval supplemental new drug application proposes revisions to the **Drug Interactions** section to clarify the effect Proton Pump Inhibitors (PPIs) may have on drugs with pH-dependent absorption pharmacokinetics, to add the term "cutaneous lupus erythematosus (CLE)" to the **ADVERSE REACTIONS, Postmarketing** subsection, and to incorporate changes made to the clarithromycin label approved in of July 2014.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below. This revision was accepted by you on February 21, 2017.

Under **WARNINGS** in the section entitled *Concomitant Use of PREVPAC with Methotrexate* PPI was replaced with the word PREVPAC in the last sentence.

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, except with the revisions listed above, the enclosed labeling text for the package insert 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 via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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 with the revisions listed above 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). Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).

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 Carmen DeBellas, Chief, Project Management Staff, at (301) 796-1023.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Acting 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 and this page is the manifestation of the electronic signature.

/s/

DMITRI IARIKOV
03/01/2017