



NDA 21144/S-019

SUPPLEMENT APPROVAL

sanofi-aventis US, LLC
c/o Sanofi US Services, Inc.
Attention: Cristina Di Ramio, PharmD, RPh
Manager, North America & Global Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Dr. Di Ramio:

Please refer to your Supplemental New Drug Application (sNDA) dated April 2, 2015, received April 2, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ketek (telithromycin) Tablet.

We acknowledge receipt of your amendments dated July 1 and October 8, 2015.

This "Prior Approval" supplemental new drug application proposes changes to the following:

- Subsection **5.2 QTc Prolongation** of the **WARNINGS AND PRECAUTIONS** section of the labeling to add ventricular arrhythmias, ventricular tachycardia and torsade de pointes with fatal outcomes.
- Subsection **6.2 Postmarketing Experience** to include ventricular arrhythmias with fatal outcome, ischemic cardiac events in the context of hypersensitivity reactions, pseudomembranous colitis, chromaturia, convulsions and dyspnea.
- **HIGHLIGHTS, PATIENT COUNSELLING** and **MEDICATION GUIDE** to reflect the above changes.

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.

We note that your April 2, 2015, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 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 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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

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
11/04/2015