DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-144/S-015

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

sanofi-aventis, U.S., LLC
Attention: John Cook
US Regulatory Affairs Marketed Products
PO Box 6890. BX4-212A
200 Crossing Boulevard
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your Supplemental New Drug Application (sNDA) dated May 18, 2011, received May 18, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ketek® (telithromycin) Tablets, 400 mg and 300 mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated June 2, 2011, and the amendment dated June 17, 2011.

This sNDA proposes to eliminate the requirement for the approved Ketek® (telithromycin) Tablets REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Ketek® (telithromycin) Tablets was originally approved on December 8, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Ketek® (telithromycin) Tablets.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Ketek® (telithromycin) Tablets outweigh its risks.

Therefore, we agree with your proposal and a REMS for Ketek® (telithromycin) Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We also 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
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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
06/20/2011