DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-144/S-012

sanofi aventis
Attention: Kathleen O'Donnell
Assistant Director, Regulatory Development.
Anti-Infectives, Oncology, and Bone
Mail Code BX4-212A Box 6890
200 Crossing Boulevard
Bridgewater, NJ 08807

Dear Ms. O'Donnell :

Please refer to your supplemental new drug application dated February 9, 2007, received February 9, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Ketek (telithromycin) 400mg and 300 mg Tablets.

This supplemental new drug application provides for the addition of a boxed warning for myasthenia gravis patients, updates to the **Microbiology**, **INDICATIONS AND USAGE**, **CONDRAINDICATIONS, WARNINGS**, **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the label. It also provides for a Medication Guide for patients.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling and Medication Guide, dated February 9, 2007.

Submit content of labeling [21CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the submitted labeling text dated February 9, 2007. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-144/S-012**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure:

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Janice Soreth
2/12/2007 09:01:53 AM