DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-144/S-004

Aventis Pharmaceuticals
Attention: Helen K. Edelberg, MD, MPH
Regulatory Liaison
200 Crossing Boulevard
P. O. Box 6800
Bridgewater, NJ 08807-0800

Dear Dr. Edelberg:

Please refer to your supplemental new drug application dated November 12, 2004, received November 15, 2004 submitted under 505 (b) of the Federal Food, Drug, and Cosmetic Act for Ketek (telithromycin), 300 mg and 400 mg Tablets.

We acknowledge receipt of your submissions dated January 21 and 31, February 18 and October 25, 2005.

This supplemental application provides for changes to the **PRECAUTIONS** section of the labeling concerning the occurrence of syncope usually associated with vagal syndrome and the addition of palpitations, pancreatitis and syncope to the post-marketing reports in the **ADVERSE EVENTS** section.

We completed our review of this application, as amended. 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 (text for package insert) submitted October 25, 2005.

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-004**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Soreth, MD
Division 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

11/2/2005 03:52:24 PM