DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-144/S-005

Aventis Pharmaceuticals, Inc.
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 and received December 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ketek (telithromycin), 300mg and 400 mg Tablets.

This supplemental new drug application provides for revisions to the DESCRIPTION, and HOW SUPPLIED section of the package insert as well as to the **What is KETEK?** section in the patient package insert.

We completed our review of this application and it is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text. We remind you that the expiration dating for these products is 24 months.

The final printed labeling (FPL) must be identical to the package insert and patient package insert submitted on December 10, 2004.

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-005**." 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, please call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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