DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-144/S-001 and S-003

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 applications dated April 9, 2004, (NDA 21-144/S-001) and August 3, 2004, (NDA 21-144/S-003), received April 9, 2004, and August 4, 2004, respectively, submitted under section 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 June 3, 7, and 17, 2004, for NDA 21-144/S-001, and January 5, 2005, for NDA 21-144/S-003.

These supplemental new drug applications provide for a new formulation of Ketek (300 mg Tablets) for use in patients with severe renal impairment (S-001) and for changes to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the package insert describing interactions with oral anticoagulants (S-003).

We completed our review of these applications, as amended, and they are 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 the package insert and container label).

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 these submissions "**FPL for approved supplement NDA 21-144/S-001 and NDA 21-144/S-003**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, we request that you submit four copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 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

Enclosure: Patient Package Insert
Container Label

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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