**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-681/S-014

Aventis Pharmaceuticals, Inc.
Attention: Mr. Jay Kraker
Specialist, US Regulatory Affairs
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-0977

Dear Mr. Kraker:

Please refer to your supplemental new drug application dated May 25, 2005, received May 26, 2005 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for HIPREX® methenamime hippurate) oral tablets, 1g.

This "Changes Being Effected in 30 days" supplemental new drug application provides for changes in the product labeling consistent with the Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use [21 CFR Part 201, Docket No. 00N-1463].

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.

The final printed labeling (FPL) must be identical to the enclosed labeling, submitted May 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 17-681/S-014**." 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 J. Christopher Davi, Regulatory Project Manager, at (301) 796-0702.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Labeling submitted on May 25, 2005

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

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/s/

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Janice Soreth

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