DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-547/S-061

Aventis Pharmaceuticals Inc.
Attention: Jay Kraker
Associate Specialist, Regulatory Affairs
200 Crossing Boulevard
P.O. Box 6890
Bridgewater, NJ 08807-0890

Dear Mr. Kraker:

Please refer to your supplemental new drug application dated April 27, 2004, received April 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claforan® Sterile (Cefotaxime sodium, USP) in 500 mg, 1g, 2g, and 10g strengths. This application is subject to the exemption provisions in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions in the text of the product labeling for Claforan®. These revisions address the requirements of the Final Labeling Rule for Systemic Drug Products Intended for Human Use (68 FR 6062, February 6, 2003). In addition, editorial revisions to the package insert for Claforan® were provided.

We completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call J. Christopher Davi, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
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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