DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-547/S-060
NDA 50-596/S-030

Aventis Pharmaceuticals Inc.
Attention: Kerry Rothschild, J.D.
Director, Regulatory Affairs
200 Crossing Boulevard
Bridgewater, NJ 08807-0890

Dear Mr. Rothschild:

Please refer to your supplemental new drug applications dated February 3, 2004, received February 4, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claforan® (cefotaxime sodium, USP) Sterile (NDA 50-547/S-060) and Claforan® (cefotaxime sodium) Injection (NDA 50-596/S-030). We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated May 24, 2004.

These supplemental new drug applications provides for the addition of a ***Geriatric Use*** subsection in the **PRECAUTIONS** section.

We have completed our review of these supplemental new drug applications, as amended. These applications are approved, effective on the date of this letter for use as recommended with the following revised wording:

Geriatric Use

> "Of the 1409 subjects in clinical studies of cefotaxime, 632 (45%) were 65 and over, while 258 (18%) were 75 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
>
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function (see **PRECAUTIONS, General**)."

The final printed labeling (FPL) must be identical to the enclosed revised wording indicated to the Geriatric Use subsection (text for the package insert). These revisions are terms of the approval of these supplemental applications.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-547/S-060 and NDA 50-596/S-030." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 LT Raquel Peat, Regulatory Health 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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