DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-547/S-047
NDA 50-596/S-023

Aventis Pharmaceuticals
Attention: Kimberly Davis
Senior Regulatory Analyst
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-2854

Dear Ms. Davis:

Please refer to your supplemental new drug applications dated November 12, 2001, received November 15, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claforan® (cefotaxime sodium) Injection and Sterile Solution. 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 November 12, 2001. Your submission of November 12, 2001 constituted a complete response to our August 26, 1997 action letter.

These supplemental new drug applications provide for revised prescribing information (PI) for Claforan. Changes recommended by the Agency in the September 2, 1994 approval letter and the August 26, 1997 approvable letter have been incorporated into the revised PI. Changes were as follows:

- Revised the version date and added "Rx only".

- Deleted "flags" (formerly sterile cefotaxime sodium) and (formerly cefotaxime sodium injection) per Guidance for Industry on injectable product nomenclature.

- **PRECAUTIONS** (page 12-14 of revised.doc)
  Added in the original supplement subsection header, **General** and added **Drug/Laboratory Test Interactions** subsection as requested in FDA letter of September 2, 1994.

  Revised **Carcinogenesis**, **Mutagenesis** and **Pregnancy** subsections per FDA approvable letter dated August 26, 1997.

  Editorial clarifications to **Nonteratogenic Effects** subsection to agree with study description in **Pregnancy**.

- **ADVERSE REACTIONS** (14-14 of revised.doc)

  Added in original supplement a list of cutaneous adverse reactions (erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis).

  Added in original supplement a **Cephalosporin Class Labeling** subsection as requested in FDA Letter of September 2, 1994.

- **OVERDOSAGE** (page 15 of revised. doc)

  Added in original supplement as requested in FDA letter of September 2, 1994.

  Revised the first paragraph per FDA approvable letter dated August 26, 1997.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter. However, a minor editorial correction should be made at the time of final printed labeling:

- In the first paragraph of the **OVERDOSAGE** section of the label, the word “toxic” should be replaced with “tonic”.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 12, 2001).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the Guidance for Industry titled “Providing Regulatory Submissions in Electronic Format – NDA” (January 1999). 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. Please individually mount ten 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-047, 50-596/S-023". 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 LTJG Raquel Peat, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

{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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