DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-547/S-068
NDA 50-596/S-037

SUPPLEMENT APPROVALS

sanofi-aventis U.S., LLC
Attention: Katherine Ng, Pharm.D.
Specialist, Base Business Product Support
U.S. Regulatory Affairs Marketed Products
55 Corporate Drive, Mail Stop 55A-430A
Bridgewater, NJ 08807-0912

Dear Dr. Ng:

Please refer to your Supplemental New Drug Applications (sNDAs) dated December 4, 2008, received December 5, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Claforan (cefotaxime sodium) Sterile IM/IV (NDA 50-547/S-068) and Claforan (cefotaxime sodium) Injection (NDA 50-596/S-037).

We acknowledge receipt of your amendments dated May 5, 2011 and September 6, 2011.

The May 5, 2011, submissions constitute a complete response to our action letter of May 13, 2010.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **PRECAUTIONS section, Drug Interactions** and **Drug/Laboratory Test Interactions** subsections of the package insert.

We have completed our review of these supplemental applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text submitted September 6, 2011.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as clean Microsoft Word versions. The marked-up copies should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for approved NDAs (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling dated September 6, 2011

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

/s/

KATHERINE A LAESSIG
09/09/2011