DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-547/S-071
NDA 50-596/S-042

SUPPLEMENT APPROVAL

sanofi-aventis, U.S., LLC
Attention: John Cook
Director, U.S. Regulatory Affairs, Marketed Products
55 Corporate Drive, Mailstop 55C-205A
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your Supplemental New Drug Application (sNDAs) dated August 13, 2014, received August 13, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 50-547: Claforan (cefotaxime sodium) Sterile IM/IV
- NDA 50-596: Claforan (cefotaxime) Injection

We also acknowledge receipt of your amendments dated March 12, 2015.

These "Changes Being Effected" supplemental new drug applications provide for the following:

- Revisions to the **CLINICAL PHARMACOLOGY, Microbiology** subsection to update the susceptibility test interpretive criteria and quality control parameters.
- Revisions to the **PRECAUTIONS, Drug Interactions** subsection to provide updated information on aminoglycosides and NSAIDs with regard to nephrotoxic effects.
- Updates to the **REFERENCES** section
- Minor editorial revisions

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions listed below and incorporated into the enclosed labeling:

- The "Resistant" value for Anaerobic Bacteria (agar method) has been changed to ≥4.
- The following note has been added immediately following Table 1: "Susceptible breakpoints are based on a dose of 1 gram q 8h in patients with normal renal function".

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, except with the revisions listed, 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 via 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 action letters, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed 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}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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

/s/

SUMATHI NAMBIAR
03/23/2015