DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-547/S-067
NDA 50-596/S-036

Sanofi-Aventis U.S., L.L.C.
Attention: John Cook
US Regulatory Affairs, Marketed Products
55 Corporate Drive (Mailstop 55A-430A)
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your supplemental new drug applications dated February 29, 2008, received March 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Claforan® (cefotaxime sodium) Sterile IV/IM (EQ 500mg, EQ 1g, EQ 2g, and EQ 10g base/vial) (NDA 50-547/S-067) and Claforan® (cefotaxime sodium) Injection (EQ 20 mg and EQ 40mg base/vial) (NDA 50-596/S-036).

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 also acknowledge receipt of your submissions dated July 30, 2008, April 3, 2009 and May 15, 2009.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **CONTRAINDICATIONS** and **ADVERSE REACTIONS** sections of the package insert, so as to furnish adequate information for the safe and effective use of these drugs. However, per your submission dated May 15, 2009, no changes are being proposed to the **CONTRAINDICATIONS** section of the package insert.

We completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed label submitted May 15, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "SPL for approved supplements NDA 50-547/S-067 and NDA 50-596/S-036."

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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
Deputy Director for Safety
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Label submitted May 15, 2009

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

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