DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 08-316/S-017

sanofi-aventis U.S. LLC
Attention: Mr. John Cook
U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, New Jersey 08807-0890

Dear Mr. Cook:

Please refer to your supplemental new drug application dated January 28, 2008, received January 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primaquine (primaquine phosphate) Tablet, 26.3 mg.

This supplemental new drug application provides for an update on the population at risk of hemolytic anemia due to congenital deficiency of erythrocytic glucose-6-phosphate dehydrogenase.

The following revisions (~~strikethrough~~ = deleted and underlined = added) to the text for the package insert for Primaquine were proposed in this supplemental application:

> Hemolytic reactions (moderate to severe) may occur in individuals with glucose-6-phosphate dehydrogenase (G-6-PD) ~~deficient~~ deficiency ~~Caucasians (particularly in Sardinians~~ and in individuals with a family or personal history of favism~~)~~. Areas of high prevalence of G-6-PD deficiency are Africa, Southern Europe, Mediterranean region, Middle East, South-East Asia, and Oceania. ~~Dark-skinned persons (Negroes, for example)~~ People from these regions have a greater tendency to develop hemolytic anemia (due to a congenital deficiency of erythrocytic glucose-6-phosphate dehydrogenase) while receiving Primaquine and related drugs.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to, and include the revisions listed, the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted January 28, 2008), must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the

National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplement NDA 08-316/S-017**."

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

If you have any questions, please call Mr. Gregory DiBernardo, Regulatory Health Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Renata Albrecht

7/28/2008 06:28:18 PM