DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-768/S-041

Sanofi Aventis, US
300 Somerset Corporate Boulevard
P.O. Box 6977
Bridgewater, NJ 08807-0977

Attention: John Cook
U.S. Regulatory Affairs Marketed Products

Dear Mr. Cook:

Please refer to your supplemental new drug application dated December 12, 2006 received December 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plaquenil (hydroxychloroquine sulfate, USP) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the ADVERSE REACTIONS section of the package insert to include the addition of abnormal color vision, anemia, urticaria, angioedema and bronchospasm.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (submitted on December 12, 2006). We note that you have submitted content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format identical to the enclosed labeling.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Stradley, Chief, Project Management Staff, at (301) 796-1298.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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