DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-165/S-024

sanofi aventis U.S. LLC
Attention: Emmanuel Hamon
Regulatory Specialist
US Regulatory Affairs Marketed Products
300 Somerset Corporate Boulevard
Bridgewater, NJ 08807-0977

Dear Mr. Hamon:

Please refer to your supplemental new drug application dated November 8, 2006, received November 9, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NicoDerm CQ (7 mg, 14 mg, 21 mg nicotine transdermal patch).

This "Changes Being Effected" supplemental new drug application provides for the addition of the statement "to avoid possible burns, remove the patch before undergoing any MRI (magnetic resonance imaging) procedures" in the Drug Facts label for the opaque patches. This supplement also provides for this MRI statement to appear in the User's Guide of both the opaque patches and the clear patches in the "Some Important Warnings" and "How to Use NicoDerm CQ Patches" sections immediately followed by the statement "(for opaque NicoDerm CQ patch only)".

We have 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 the enclosed labeling (text for the Drug Facts label and the User's Guide submitted November 8, 2006). The FPL must be formatted in accordance with the requirements of 21 CFS 201.66, where applicable.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-165/S-024**." Approval of this submission by FDA is not required before the labeling is used.

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, call Mary Lewis, Regulatory Project Manager, at (301)796-0941.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription 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/

Andrea Segal

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