DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-165/S-023

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 March 28, 2006 received March 29, 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 system) transdermal patch.

We acknowledge receipt of your submission dated August 18, 2006.

This supplemental application proposes to eliminate the disposal tray from the current marketed package.

We have completed our review of this application, as amended. 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 (carton label and users guide submitted on August 18, 2006) and must be formatted in accordance with the requirements of 21 CFR 201.66.

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-023**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura E. Shay, Regulatory Project Manager, at (301) 796-0994.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Andrea Segal

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