DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20165/S-036

SUPPLEMENT APPROVAL

sanofi-aventis US, LLC
Attention: Doris Sincak
Manager, US Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Sincak:

Refer to your Supplemental New Drug Application (sNDA) dated April 10, 2015, received April 10, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicoderm CQ (nicotine transdermal system) 21 mg, 14 mg, and 7 mg.

We acknowledge receipt of your amendments dated June 18, June 22, and September 23, 2015.

This prior approval sNDA proposes to add new bulleted warnings statements (diabetes, history of seizures, symptoms of an allergic reaction), as listed under the following warnings subheadings, to the outer carton's Drug Facts label and to the consumer information leaflet:

Ask a doctor before use if you have

- heart disease, recent heart attack, or irregular heartbeat. Nicotine can increase your heart rate.
- high blood pressure not controlled with medication. Nicotine can increase your blood pressure
- an allergy to adhesive tape or have skin problems because you are more likely to get rashes
- diabetes
- history of seizures

Stop use and ask a doctor if

- skin redness caused by the patch does not go away after four days, or if your skin swells, or you get a rash
- irregular heartbeat or palpitations occur
- you get symptoms of nicotine overdose such as nausea, vomiting, dizziness, weakness, and rapid heartbeat
- you have symptoms of an allergic reaction (such as difficulty breathing or rash)

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

LABELING

Submit final printed labeling (FPL), as identified in the table below as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the approved labeling identified in the table below. Even though the following pieces of labeling were not revised as part of this supplement, submit the labeling with the FPL for S-036 to complete the set of approved labeling under NDA 20165: 1) immediate containers [1-ct clear patch pouch,(7-, 14-, 21-mg) and 2) 1-ct opaque patch pouch (21 mg). The FPL must be in the *Drug Facts* format (21 CFR 201.66), where applicable.

Submitted Labeling Description	Submission Date
CLEAR PATCH	
Outer Carton	
21 mg (STEP 1) 7-ct, 14-ct, 21-ct	June 22, 2015
14 mg (STEP 2) 14-ct, 21-ct	June 22, 2015
7 mg (STEP 3) 14-ct	June 22, 2015
Outer Carton- *Veteran's Administration (VA)*	
21 mg (STEP 1) 14-ct	June 22, 2015
14 mg (STEP 2) 14-ct	June 22, 2015
7 mg (STEP 3) 14-ct	June 22, 2015
Cartons Backercard (Front/Back) for clamshell-type carton	
21 mg (STEP 1) 21-ct	June 22, 2015
14 mg (STEP 2) 21-ct	June 22, 2015
OPAQUE PATCH	
Outer Carton	
21 mg (STEP 1) 14-ct	June 22, 2015
Consumer Information Leaflet (User's Guide) Universal label for all counts, strengths, carton type, patch type	April 10, 2015

Submit the FPL electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20165/S-036**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), submit the content of labeling (Drug Facts) in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, submit representative container or carton labeling, whichever includes Drug Facts (where differences exist only in the quantity of contents statement), as a JPG file.

REPORTING REQUIREMENTS

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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Acting Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

VALERIE S PRATT
10/07/2015