DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020165/S-034

SUPPLEMENT APPROVAL

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

Dear Ms. Sincak:

Please refer to your Supplemental New Drug Application (sNDA) dated and received August 4, 2014, 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 December 3 and 15 (via email), 2014.

This "Changes Being Effected" sNDA provides for the following:

- Addition of an actual size image of the patch
- Addition of the text "***ACTUAL SIZE***" next to the actual size image of the patch
- Reduction in prominence of the "**EXTENDED RELEASE**" statement and graphic
- Addition of the GSK brand logo to the front page of the User's Guide and the principal display panel.

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 soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labeling listed in the following table, and 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	August 4, 2014
14 mg (STEP 2) 14-ct, 21-ct	August 4, 2014
7 mg (STEP 3) 14-ct	August 4, 2014

Immediate Container, Pouch	
7 mg, 1-ct	August 4 and December 3, 2014
14 mg, 1-ct	December 3, 2014
21 mg, 1-ct	December 3 and December 15 (email)
Cartons Backercard (Front/Back) for clamshell-type carton	
21 mg (STEP 1) 21-ct	August 4 and December 15 (email)
14 mg (STEP 2) 21-ct	August 4 and December 15 (email)
OPAQUE PATCH	
Outer Carton	
21 mg (STEP 1) 14-ct	August 4, 2014
Immediate Container, Pouch	
21 mg, 1-ct	December 3, 2014
Consumer Information Leaflet (User's Guide) Universal label for all counts, strengths, carton type, patch type	August 4, 2014

The FPL should be submitted 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, you may 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 020165/S-034**." 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), the content of labeling (Drug Facts) should be submitted 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, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted 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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Theresa Michele, MD
Director
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/

THERESA M MICHELE
02/03/2015