DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020165/S-031

SUPPLEMENT APPROVAL

sanofi-aventis U.S. 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 May 1, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NicoDerm CQ® (nicotine transdermal system), extended release film "clear patch," 7 mg, 14 mg, and 21 mg.

We acknowledge receipt of your amendments dated August 2 and September 24, 2013.

This "Changes Being Effected" supplemental new drug application provides for a new package design for use by the Veterans Administration (VA) in their outpatient pharmacies and Department of Defense facilities and also consists of revised labeling submitted in response to FDA's Notice of Findings, as published in the Federal Register dated April 2, 2013; Docket No. FDA−2013−N−0341: Modifications to Labeling of Nicotine Replacement Therapy Products for Over-The-Counter Human Use (78 FR 19718).

The provided changes include the following:

1. revised labeling based on FDA's April 2, 2013 Notice of Findings
2. removal of graphics from the Principal Display Panel (PDP)
3. color change to the outer carton
4. addition of a "Not for Retail Sale" flag to the PDP
5. addition of an NDA barcode to the PDP
6. removal of the theft deterrent tag
7. addition of the product description on the right side panel
8. addition of an updated trademark statement.

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, with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling, listed in the following table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Date Submitted
Step 1: 21 mg 14 ct clear patch (outer carton)	September 24, 2013
Step 2: 14 mg, 14 ct clear patch (outer carton)	September 24, 2013
Step 3: 7 mg, 14 ct clear patch (outer carton)	September 24, 2013
Consumer Information Leaflet (User's Guide)	May 1, 2013

Even though no revisions were made to the immediate container (pouch) labeling for the 7 mg clear patch, the 14 mg clear patch, and the 21 mg clear patch, submit this labeling as part of the FPL for this supplement (S-031) in order to maintain a record of the complete labeling (count sizes and packaging configurations).

The final printed labeling 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-031**." 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.

PREA

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES: 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/

JOEL SCHIFFENBAUER
10/31/2013