DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20165/S-038

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
Attention: Doris Sincak, MS
Manager, North America and Global Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Sincak:

Please refer to your Supplemental New Drug Application (sNDA) dated November 6, 2015, received November 6, 2015, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NicoDerm CQ (nicotine transdermal system) patch, 7 mg, 14 mg, and 21 mg.

This "Changes Being Effected" (CBE) supplemental new drug application is submitted in response to a CBE supplement request letter issued by FDA on October 8, 2015, to update labeling to inform consumers of the risk of peptic ulcer formation and delayed wound healing associated with nicotine replacement therapies.

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 enclosed labeling, as delineated and in accordance with the dates submitted in the table below. The FPL must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Labeling Description	Submission Date
CLEAR PATCH	
Outer Carton	
21 mg (STEP 1) 7-ct, 14-ct, 21-ct	November 6, 2015
14 mg (STEP 2) 14-ct, 21-ct	November 6, 2015
7 mg (STEP 3) 14-ct	November 6, 2015
***Immediate Container - Pouch**	
7 mg, 1-ct	April 1, 2016
14 mg, 1-ct	April 1, 2016
21 mg, 1-ct	April 1, 2016
Cartons Backercard (Front/Back) for clamshell-type carton	
21 mg (STEP 1) 21-ct	November 6, 2015
14 mg (STEP 2) 21-ct	November 6, 2015
Outer Carton ***Veteran's Administration (VA)***	
21 mg (STEP 1) 14-ct	November 6, 2015
14 mg (STEP 2) 14-ct	November 6, 2015
7 mg (STEP 3) 14-ct	November 6, 2015
Outer Carton ***3-COUNT Professional Sample***	
21 mg (STEP 1) 3-ct	November 6, 2015
Immediate Container- Pouch	
Same as the 21 mg, 1-ct (Clear Patch)	April 1, 2016
OPAQUE PATCH	
Outer Carton	
21 mg (STEP 1) 14-ct	November 6, 2015
Consumer Information Leaflet (User's Guide-booklet and leaflet)	November 6, 2015

Even though no revisions were made to the immediate containers for the 1-count Opaque Patch Pouch, 21 mg, submit as part of the FPL to maintain a complete record of all labeling (SKUs and package configurations) approved as part of this supplement.

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 20165/S-038**." 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 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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Deputy Director for Safety
Division of Nonprescription Drug Products
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/

VALERIE S PRATT
05/04/2016