DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020165/S-029

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 on March 8, 2013, 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 July 15, August 1, and October 31, 2013; and February 14, and April 28, 2014.

The October 31, 2013, submission constituted a complete response to our September 5, 2013, action letter.

This "Prior Approval" labeling supplemental new drug application proposes a new packaging design which affects the carton, backer card, pouch and User's Guide for all counts and strengths of currently marketed products. Design changes include new images, graphics changes, and font changes. This supplement also consists of revisions to the Drug Facts Label in order to comply with the Agency's April 2, 2013 Notice of Findings regarding Modifications To Labeling of Nicotine Replacement Therapy Products for Over-the-Counter (OTC) Human Use (78 FR 19718).

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 by May 9, 2014. The final printed labeling (FPL) must be identical to the following and must be in the "Drugs Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling Description	Date Submitted	Represents
Cartons		
21 mg (STEP 1) 14-ct (Carton for Clear Patch)	04/28/14	Final version not submitted 7-, 21-ct (Carton for Clear Patch) with 04/28/14 commitment to revise and submit
		Final version not submitted 14-ct (Carton for Opaque Patch) with 04/28/14 commitment to revise and submit
14 mg (STEP 2) 14-ct (Carton for Clear Patch)	04/28/14	Final version not submitted 21-ct (Carton for Clear Patch) with 04/28/14 commitment to revise and submit
7 mg (STEP 3) 14-ct (Carton for Clear Patch)	04/28/14	None
Cartons (Clear Patch) Backercard (front/back) for clamshell-type carton		
14 mg (STEP 2) 21-ct	03/08/13 marked up with 04/28/14 commitment to revise and submit	None
21 mg (STEP 1) 21-ct	03/08/13 marked up with 04/28/14 commitment to revise and submit	None
Immediate Container, Pouch (Clear Patch)		
21 mg (STEP 1) 1-ct	03/08/13	None
14 mg (STEP 2) 1-ct	03/08/13	None
7 mg (STEP 3) 1-ct	03/08/13	None
Immediate Container, Pouch (Opaque Patch)		
21 mg (STEP 1) 1-ct immediate container, pouch	03/08/13	None
Other Information for the Consumer		
Universal Label for all counts, strengths, carton	03/08/13 marked up	None

type, patch type Consumer Information Leaflet (User's Guide)	with 04/28/14 commitment to revise and submit	

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-029**." 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 Clinical Evaluation
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
04/30/2014