NDA 020165/S-047

SUPPLEMENT APPROVAL

Sanofi-Aventis US LLC
Attention: Doris Sincak, MS
Director, US Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Sincak:

Please refer to your supplemental new drug application (sNDA) dated and received August 15, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nicoderm CQ (nicotine transdermal system 7 mg/24 hr, 14 mg/24 hr, 21 mg/24 hr) extended release film.

This "Prior Approval" supplemental new drug application provides for updates to the User's Guide related to the behavioral support program (change in reference from Committed Quitters to MyQuit) and other editorial changes to the outer container carton labeling.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

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

Submitted Labeling Description	Submission Date
7 mg, 14 ct Retail Carton	September 15, 2021
7 mg, 14 ct Non-Retail Carton	September 15, 2021
14 mg, 14 ct Retail Carton	November 17, 2021
14 mg, 14 ct Non-Retail Carton	November 17, 2021
14 mg, 21 ct Retail (Club) Carton	November 17, 2021
14 mg, 21 ct Retail (Club) Back Card	September 15, 2021
14 mg, 21 ct Retail (Club) Front Card	September 15, 2021
21 mg, 3 ct Sample Carton	February 18, 2021
21 mg, 7 ct Retail Carton	November 17, 2021

21 mg, 14 ct Retail Carton	November 17, 2021
21 mg, 14 ct Non-Retail Carton	November 17, 2021
21 mg, 21 ct Retail (Club) Carton	November 17, 2021
21 mg, 21 ct Retail (Club) Back Card	September 15, 2021
21 mg, 21 ct Retail (Club) Front Card	September 15, 2021
User Guide (leaflet)	November 17, 2021

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*[1]. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020165/S-047**." 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 FDA.gov[2]. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 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.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default htm

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 Cynthia Kim, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
03/04/2022 03:57:52 PM