



NDA 020165/S-028

SUPPLEMENT APPROVAL

Sanofi-Aventis U.S., LLC
Attention: Doris Sincak
US Regulatory Affairs
Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Pani:

Please refer to your Supplemental New Drug Application (sNDA) dated March 27, 2012, received March 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NicoDerm® CQ® (nicotine) transdermal system patch.

This “Prior Approval” supplemental new drug application proposes a smaller size carton for NicoDerm® CQ® (nicotine) transdermal system patch, 21 mg/24 hr; Step 1 -7 count stock keeping unit, changes to the principal display panel, and a coupon to be inserted in the carton.

We have completed our review of this application. 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 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 (21 mg clear patch Step 1-7 count carton label and coupon submitted March 27, 2012), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Also include the immediate container (pouch) and consumer information leaflet as part of the FPL for this supplement in order to maintain a record of the complete labeling for each stock keeping unit.

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 02165/S-028.**” 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 Phong Do, Regulatory Project Manager, at (301) 796-4795.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:

Carton Labeling & Coupon

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
09/20/2012