



NDA 21024/S-020

SUPPLEMENT APPROVAL

Sanofi US Services Inc.
On behalf of sanofi-aventis US, LLC
Attention: Praveena Deenumsetti
Manager, Global Regulatory Affairs
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Deenumsetti:

Please refer to your supplemental new drug application (sNDA) dated January 10, 2020, received January 10, 2020 and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Priftin (rifapentine) tablets.

This Prior Approval supplemental new drug application proposes a new logo for the tablet carton.

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.

CARTON LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling 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*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labeling for approved NDA21-024/S-020.**” Approval of this submission by FDA is not required before the labeling is used.

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 Carmen DeBellas, PharmD, RPh, Regulatory Project Manager, at 301-796-1203.

Sincerely,

{See appended electronic signature page}

Dmitri Iarkov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton 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/

DMITRI IARIKOV
06/09/2020 03:23:32 PM