NDA 020520/S-038

SUPPLEMENT APPROVAL

Sanofi US Services Inc.
Attention: Doris Sincak MS
Senior 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 April 23, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zantac 75 (ranitidine hydrochloride) tablet, 75 mg.

This "Prior Approval" supplemental new drug application provides for discontinuation of the Consumer Information Leaflet (CIL) and addition of the "Tips for managing heartburn" information to the outer carton for all stock-keeping units.

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.

We remind you of your commitment to increase the size of the statement of identity by May 2020.

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 table below. The final printed label must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Zantac 75 tablets

Submitted Labeling	Date Submitted
2-count "*On-The-Go Packs*" carton (pouch) – origin Mexico	June 21, 2019
2-count "*On-the-Go Packs*" carton (pouch) – origin Spain	June 21, 2019

10-count carton (blister) – origin Mexico	April 23, 2019
10-count carton (blister) – origin Spain	April 23, 2019
30-count carton (blister) – origin Mexico	April 23, 2019
30-count carton (blister) – origin Spain	April 23, 2019
40-count *Bonus! 10 Free Tablets* carton (blister) – origin Mexico	April 23, 2019
40-count *Bonus! 10 Free Tablets* carton (blister) – origin Spain	April 23, 2019
60-count carton (bottle) – origin Mexico	April 23, 2019
60-count carton (bottle) – origin Spain	April 23, 2019
80-count carton (bottle) – origin Mexico	April 23, 2019
80-count carton (bottle) – origin Spain	April 23, 2019
96-count *Bonus! 16 Free Tablets* carton (bottle) – origin Mexico	April 23, 2019
96-count *Bonus! 16 Free Tablets* carton (bottle) – origin Spain	April 23, 2019
100-count dispenser (pouch) – origin Mexico	April 23, 2019
100-count dispenser (pouch) – origin Spain	April 23, 2019

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 020520/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 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*.

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 Dr. Helen Lee, Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director, Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[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

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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/

VALERIE S PRATT
09/18/2019 04:35:47 PM