DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20520/S-037

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 and received October 9, 2018, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zantac® 75 (ranitidine) tablet, 75 mg.

This "changes being effected" supplemental new drug application provides for "**Ask a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact with certain prescription drugs." This supplemental new drug application also provides for "**Ask a doctor before use if you have**" subheading, add "[bullet] kidney disease" to the bottom of the list." These warnings are in response to the Agency's communications of June 29 and August 10, 2018.

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

Labels Submitted	**Date submitted**
1-count immediate container (pouch)-origin Mexico	October 5, 2018
1-count immediate container (pouch)-origin Spain	October 5, 2018
2-count "*On-The-Go Packs*" carton (pouch) – origin Mexico	October 5, 2018

2-count "*On-The-Go Packs*" carton (pouch) – origin Spain	October 5, 2018
4-count carton (blister) – origin Mexico	October 5, 2018
4-count carton (blister) – origin Spain	October 5, 2018
4-count immediate container (blister)	February 8, 2019
10-count carton (blister) – origin Mexico	October 5, 2018
10-count carton (blister) – origin Spain	October 5, 2018
10-count immediate container (blister)	February 8, 2019
30-count carton (blister) – origin Mexico	October 5, 2018
30-count carton (blister) – origin Spain	October 5, 2018
40-count *Bonus! 10 Free Tablets* carton (blister) – origin Mexico	October 5, 2018
60-count carton (bottle) – origin Mexico	October 5, 2018
60-count carton (bottle) – origin Spain	October 5, 2018
60-count immediate container (bottle)	October 5, 2018
80-count carton (bottle) – origin Mexico	October 5, 2018
80-count carton (bottle) – origin Spain	October 5, 2018
80-count immediate container (bottle)	October 5, 2018
96-count *Bonus! 16 Free Tablets* carton (bottle) – origin Mexico	October 5, 2018
96-count *Bonus! 16 Free Tablets* carton (bottle) – origin Spain	October 5, 2018
96-count immediate container (bottle)	October 5, 2018
100-count dispenser (pouch) with CIL – origin Mexico	October 5, 2018
100-count dispenser (pouch) with CIL – origin Spain	October 5, 2018
Consumer Information Leaflet (blister)	October 5, 2018
Consumer Information Leaflet (bottle)	October 5, 2018

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (April 2017, Revision 4)*. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20520/S-037**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that a supplement will be required to update the Drug Facts labeling if you plan to market the *Cool Mint* product line.

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 CAPT Janice Adams-King, Safety Regulatory Health Project Manager, at 301-796-3713.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
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/

VALERIE S PRATT
04/04/2019 04:25:26 PM