



NDA 21698/S-029

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[®] 150 (ranitidine) tablet, 150 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. 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.

MAXIMUM STRENGTH ZANTAC 150 TABLETS

Submitted Labeling	Date Submitted
1-count immediate container (pouch) - Mexico	October 9, 2018
1-count immediate container (pouch) - Spain	October 9, 2018
3-count carton (blister) - Mexico	October 9, 2018
3-count carton (blister) - Spain	October 9, 2018
3-count immediate container (blister)	January 22, 2019

8-count carton (blister) - <i>Mexico</i>	October 9, 2018
8-count carton (blister) - <i>Spain</i>	October 9, 2018
8-count immediate container (blister)	January 22, 2019
24-count carton (blister) - <i>Mexico</i>	October 9, 2018
24-count carton (blister) - <i>Spain</i>	October 9, 2018
32-count "BONUS! 8 FREE TABLETS" carton (blister) - <i>Mexico</i>	October 9, 2018
32-count "BONUS! 8 FREE TABLETS" carton (blister) - <i>Spain</i>	October 9, 2018
40-count carton (bottle) - <i>Mexico</i>	October 9, 2018
40-count carton (bottle) - <i>Spain</i>	October 9, 2018
40-count immediate container (bottle)	October 9, 2018
50-count carton (bottle) - <i>Mexico</i>	October 9, 2018
50-count carton (bottle) - <i>Spain</i>	October 9, 2018
50-count immediate container (bottle)	October 9, 2018
65-count carton (bottle) - <i>Mexico</i>	October 9, 2018
65-count carton (bottle) - <i>Spain</i>	October 9, 2018
65-count immediate container (bottle)	October 9, 2018
70-count immediate container (bottle) - <i>Mexico</i>	October 9, 2018
70-count immediate container (bottle) - <i>Spain</i>	October 9, 2018
78-count "BONUS! 13 FREE TABLETS" carton (bottle) - <i>Mexico</i>	October 9, 2018
78-count "BONUS! 13 FREE TABLETS" carton (bottle) - <i>Spain</i>	October 9, 2018
78-count immediate container (bottle)	October 9, 2018
80-count dispenser (pouch) - <i>Mexico</i>	October 9, 2018
80-count dispenser (pouch) - <i>Spain</i>	October 9, 2018
90-count "VALUE SIZE 90 TABLETS" carton (bottle) - <i>Mexico</i>	October 9, 2018
90-count "VALUE SIZE 90 TABLETS" carton (bottle) - <i>Spain</i>	October 9, 2018
90-count immediate container (bottle)	October 9, 2018

140-count (2 x 70) Club backer card (bottle)	October 9, 2018
Consumer Information Leaflet (blister)	October 9, 2018
Consumer Information Leaflet (bottle)	October 9, 2018
ZANTAC 150 COOL MINT	
8-count carton – <i>Cool Mint</i> (blister) - <i>Mexico</i>	October 9, 2018
8-count immediate container (blister)	January 22, 2019
24-count carton – <i>Cool Mint</i> (blister) - <i>Mexico</i>	October 9, 2018
32-count “BONUS! 8 FREE TABLETS” carton - <i>Cool Mint</i> (blister) - <i>Mexico</i>	October 9, 2018
40-count carton – <i>Cool Mint</i> (bottle) - <i>Mexico</i>	October 9, 2018
40-count immediate container – <i>Cool Mint</i> (bottle)	October 9, 2018
50-count carton – <i>Cool Mint</i> (bottle) - <i>Mexico</i>	October 9, 2018
50-count immediate container – <i>Cool Mint</i> (bottle)	October 9, 2018
65-count carton – <i>Cool Mint</i> (bottle) - <i>Mexico</i>	October 9, 2018
65-count immediate container – <i>Cool Mint</i> (bottle)	October 9, 2018
78-count “BONUS! 13 FREE TABLETS” carton - <i>Cool Mint</i> (bottle) - <i>Mexico</i>	October 9, 2018
78-count immediate container – <i>Cool Mint</i> (bottle)	October 9, 2018
90-count “VALUE SIZE 90 TABLETS” carton – <i>Cool Mint</i> (bottle) - <i>Mexico</i>	October 9, 2018
90-count immediate container – <i>Cool Mint</i> (bottle)	October 9, 2018
Consumer Information Leaflet – <i>Cool Mint</i> (bottle)	October 9, 2018
Consumer Information Leaflet – <i>Cool Mint</i> (blister)	October 9, 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 21698/S-029.**” Approval of this submission by FDA is not required before the labeling is used.

It is recommended that the consumer information leaflet from both the *regular* and *Cool Mint* lines be consistent in format. We also remind you that the statement of identity will need to increase in size to approximately 25% of the proprietary name in the next supplement.

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 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 04:23:32 PM