NDA 020238/S-026

SUPPLEMENT APPROVAL

Medtech Products Inc.
Attention: Mary Beth Fritz
Senior Vice President, Quality and Regulatory Affairs
660 White Plains Road
Tarrytown, NY 10591

Dear Ms. Fritz:

Please refer to your supplemental new drug application (sNDA) dated and received on August 6, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tagamet HB 200 (cimetidine hydrochloride) tablets, 200 mg.

We acknowledge receipt of your amendment dated January 24, 2022, which constituted a complete response to our September 30, 2021, action letter.

This "Prior Approval" supplemental new drug application provides for an alternate formulation that involves the addition of two excipients (flavor and colorant) (b) (4) to create an "Icy Cool Mint Flavor" variant for Tagamet HB 200 (cimetidine hydrochloride) tablets.

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.

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 in the "Drug Facts" format (21 CFR 201.66), where applicable and must be identical to the following labeling submitted on March 14, 2022:

Submitted Labeling	Date Submitted
Tagamet HB 200 40-ct outer container (carton with 4x10-ct blisters)	March 14, 2022
Tagamet HB 200 10-ct immediate container (blister)	January 24, 2022

Tagamet HB 200 70-ct outer container (carton)	March 14, 2022
Tagamet HB 200 70-ct immediate container (bottle)	March 14, 2022

As currently presented in the proposed container label blister card, the format for the expiration date is defined as "MM/YYYY." However, the carton labeling contains a different expiration date format, "MM/YY." Therefore, for consistency and to reduce the risk for deteriorated drug medication errors, use the expiration date format "MM/YYYY" on all the container labels and carton labeling in the final labeling.

In addition, remove the text "New" flag following 6 months from the time of marketing.

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 020238/S-026**." 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*. 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).

[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

If you have any questions, call Cynthia Kim, PharmD, Regulatory Project Manager, at 301-796-0879.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- 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/

NUSHIN F TODD
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