NDA 20238/S-024

SUPPLEMENT APPROVAL

Medtech Products Inc.
Attention: Mary Beth Fritz
Senior Vice President, Quality and Regulatory Affairs
660 White Plains Road, Suite 250
Tarrytown, NY 10591

Dear Ms. Fritz:

Please refer to your supplemental new drug application (sNDA) dated and received October 25, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tagamet HB (cimetidine) tablet, 200 mg.

This supplemental application provides for labeling changes as requested in the FDA supplement request letter dated August 28, 2019. The FDA supplement request letter stated:

> "Tips for Managing Heartburn" is clinically important labeling information for the consumer. The inner surface of the outer carton is not an appropriate surface to bear clinically important labeling information because it could be easily missed by the consumer. Options to consider for the placement of "Tips for Managing Heartburn" are to place it on the outer carton panels or include "Tips for Managing Heartburn" in a consumer information leaflet.

In this submission, you have moved the statement "Tips for Managing Heartburn" to the outside of the carton.

Additionally, you removed all information from the inner label including efficacy charts and the drug interaction warning and table, and the warning now appears under "Ask a doctor or pharmacist..." as requested in the FDA supplement request letter dated June 29, 2018.

New Bonus count (36- and 40-ct) sizes have also been submitted.

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 be identical to the following:

Submitted Labeling	Date Submitted
6-count carton	January 15, 2020
30-count carton	January 15, 2020
36-count *Bonus* carton	January 15, 2020
40-count *Bonus* carton	January 15, 2020
50-count carton	January 15, 2020

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 20238/S-24**." 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.

[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

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We remind you that the addition of new promotional statements, including bonus count statements (e.g. “MORE FREE” and “Better Value”), requires prior approval from FDA.

If you have any questions, call Helen Lee, Regulatory Project Manager at 301-796-6848.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Acting Deputy Director, Office of Nonprescription Drugs
Acting Director, Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

KAREN M MAHONEY
04/13/2020 08:12:18 AM