



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20238/S-023

SUPPLEMENT APPROVAL

Medtech Products Inc.
Attention: Mary Beth Fritz
Sr. 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 9, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tagamet HB (cimetidine) tablet, 200 mg.

This “Prior Approval” supplemental new drug application provides for the following:

- Adds two new warnings “[bullet] kidney disease” and “[bullet] liver disease under the Warnings subheading “Ask a doctor before use if you have”.
- Replaces, adds, or deletes drug-drug interactions warnings under the Warnings subheading “Ask a doctor or pharmacist before use if you are taking”. Replaces the current list of interacting drugs with “[bullet] a prescription drug.” Adds the statement “Acid reducers may interact with certain prescription drugs.” Deletes the statement “If you are not sure you are taking one of these medicines, talk to your doctor or pharmacist.”
- Revises the labeling on the principal display panel.

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 (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	Submission Date
6-count carton (blister) with consumer information leaflet	October 9, 2018
30-count carton (blister) with consumer information leaflet	October 9, 2018
50-count carton (blister) with consumer information leaflet	October 9, 2018

The FPL 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 20238/S-023.**” 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 <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 Helen Lee, Regulatory Project Manager, at 301-796-6848.

Sincerely,

[See appended electronic signature page]

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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
03/26/2019 05:03:48 PM