NDA 020670/S-041

SUPPLEMENT APPROVAL

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

Dear Mary Beth Fritz:

Please refer to your supplemental new drug application (sNDA) dated and received June 16, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monistat 3 Combination Pack (miconazole nitrate) suppository and cream, 200 mg and 2%.

This "Prior Approval" supplemental new drug application provides for the addition of a new claim ("Suppositories contain just 2 ingredients") on the outer carton's principal display panel (PDP).

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 identical to the submitted labeling (carton container label submitted November 7, 2023), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. Include the immediate container label and consumer information leaflet as part of the FPL submission for this supplement, in order to maintain a record of the complete labeling.

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**

[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.

Labeling for approved NDA 020670/S-041." 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).

If you have any questions, contact Suzanne Strayhorn, MS, Senior Regulatory Project Manager, at suzanne.strayhorn@fda.hhs.gov or (240) 402-4247.

Sincerely,

{See appended electronic signature page}

Pamela Horn, MD
Director, Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

PAMELA J HORN
11/17/2023 09:22:08 AM