NDA 17450/S-075
NDA 20670/S-036
NDA 21261/S-025
NDA 21308/S-031

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 applications (sNDAs) dated and received March 26, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 17450/S-075	Monistat 7 (miconazole nitrate) cream, 2%
NDA 20670/S-036	Monistat 3 Combination Pack (miconazole nitrate) suppository and cream, 200 mg and 2%
NDA 21261/S-025	Monistat 3 Combination Pack (miconazole nitrate) cream, 4% and 2%
NDA 21308/S-031	Monistat 1 Combination Pack (miconazole nitrate) suppository and cream, 1,200 mg and 2%

These "Prior Approval" supplemental new drug applications provide for the following:

- Replacement of the approved 9-gram tube of external cream with a 15-gram tube (miconazole nitrate, 2% external cream), as an alternate configuration for a limited time
- Addition of "50% MORE EXTERNAL CREAM FREE*" and "*LIMITED TIME OFFER" to the top panel of the outer carton
- Addition of "Stop use and ask a doctor if symptoms last more than 7 days" to the immediate container label
- Addition of "[bullet] Keep this carton for future reference. It contains important information" to the outer carton.
- Revision to the declaration of net quantity statement referencing the 15-gram tube
- Deletion of "ORTHO" and revision to the tamper-evident feature statement [redacted] (b) (4) on the immediate container label

- Update of distributor information on the immediate container label

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 identical to the following:

1. Immediate container label (15-gram tube) submitted on July 6, 2020

NDA 17450/S-075:
2. Monistat® 7 (miconazole nitrate) cream, 2% (45-gram and 15-gram tubes + 7 disposable applicators) outer carton labeling submitted on July 6, 2020

NDA 20670/S-036:
3. Monistat® 3 Combination Pack (miconazole nitrate) vaginal inserts and cream, 200 mg and 2% outer carton labeling submitted on July 15, 2020
4. Monistat® 3 Combination Pack (miconazole nitrate) suppository and cream, 200 mg and 2% outer carton labeling submitted on July 6, 2020

NDA 21261/S-025:
5. Monistat® 3 Combination Pack (miconazole nitrate) cream, 4% and 2% outer carton labeling submitted on July 6, 2020

NDA 21308/S-031:
6. Monistat® 1 Combination Pack (miconazole nitrate) suppository and cream, 1200 mg and 2% outer carton labeling submitted on July 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 17450/S-075**," "**Final Printed Labeling for approved**

[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.

NDA 20670/S-036," "**Final Printed Labeling for approved NDA 21261/S-025**," and "**Final Printed Labeling for approved NDA 21308/S-031**." 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, call Anna Thai, Regulatory Project Manager, at 301-796-6533.

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

ENCLOSURES:

- Carton and Container Labeling

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

---

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
07/22/2020 01:00:56 PM