NDA 17450/S-073
NDA 20670/S-035
NDA 20827/S-031
NDA 21261/S-024
NDA 21308/S-030

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 8, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

- NDA 17450/S-073: Monistat 7 (miconazole nitrate) cream, 2%
- NDA 20670/S-035: Monistat 3 Combination Pack (miconazole nitrate) suppository and cream, 200 mg and 2%
- NDA 20827/S-031: Monistat 3 (miconazole nitrate) cream, 4%
- NDA 21261/S-024: Monistat 3 Combination Pack (miconazole nitrate) cream, 4% and 2%
- NDA 21308/S-030: 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:

- Revision to the statement of identity to include increased font size, boldface type, and consistent nomenclature
- Revision to the declaration of net quantity
- Repositioning of the tamper-evident feature statement to the top panel of the outer carton
- Multiple labeling deletions, revised layout changes, and updated distributor information
- Addition of the statement “MAXIMUM STRENGTH OVULE®” to the right side of the principal display panel and back panel of the outer carton (NDA 21308 only)

- Addition of “[bullet] if you do not get complete relief ask a doctor before using another product” to the “When using this product” subheading under the *Warnings* heading (NDA 21308 only)

In addition, NDA 017450/S-073 provides for the Monistat 7 (miconazole nitrate) cream, 2% (45g and 9g tubes + 7 disposable applicators) line extension.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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:

NDA 17450/S-073:

1. Monistat 7 (miconazole nitrate) cream, 2% (45g tube + 1 reusable applicator) outer carton labeling submitted on January 10, 2020
2. Monistat 7 (miconazole nitrate) cream, 2% (45g tube + 7 disposable applicators) outer carton labeling submitted on January 10, 2020
3. Monistat 7 (miconazole nitrate) cream, 2% (45g and 9g tubes + 7 disposable applicators) outer carton labeling submitted on December 9, 2019

NDA 20670/S-035:

4. Monistat 3 Combination Pack (miconazole nitrate) vaginal inserts and cream, 200 mg and 2% outer carton labeling submitted on January 10, 2020
5. Monistat 3 Combination Pack (miconazole nitrate) suppository and cream, 200 mg and 2% outer carton labeling submitted on December 9, 2019

NDA 20827/S-031:

6. Monistat 3 (miconazole nitrate) cream, 4% outer carton labeling submitted on December 9, 2019

NDA 21261/S-024:

7. Monistat 3 Combination Pack (miconazole nitrate) cream, 4% and 2% outer carton labeling submitted on December 9, 2019

NDA 21308/S-030:

8. Monistat 1 Combination Pack (miconazole nitrate) suppository and cream, 1,200 mg and 2% outer carton labeling submitted on December 9, 2019

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 the submissions "**Final Printed Labeling for approved NDA 17450/S-073**", "**Final Printed Labeling for approved NDA 20670/S-035**", "**Final Printed Labeling for approved NDA 20827/S-031**", "**Final Printed Labeling for approved NDA 21261/S-024**", and "**Final Printed Labeling for approved NDA 21308/S-030**." Approval of these submissions 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 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 Deputy Director, Division of Nonprescription Drugs II
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
01/28/2020 04:42:50 PM