NDA 020827 0 r

UPPLEMENT APPROVAL

Medtech P oducts Inc.
Attention: Ma y Beth F itz
. Vice P esident, Quality and Regulato y Affai s
660 White Plains Road
uite 250
Ta ytown, NY 10591

Dea Ms. F itz:

Please efe to you supplemental new d ug application (sNDA) dated and eceived May 21, 2021, and you amendments, submitted unde section 505(b) of the Fede al Food, D ug, and Cosmetic Act (FDCA) fo Monistat (miconazole nit ate) c eam, 4%.

This "P io App oval" supplemental new d ug application p ovides fo the fo lowing changes:

Replacement of the th ee disposable applicato s with a single eusable applicato r

Inc ease in length of the 25 g am tube

Revision of labeling to include cleaning inst uctions fo the eusable applicato

APPROVAL & LABELING

We have completed ou eview of this application, as amended. It is app oved, effective on the date of this le te , fo use as ecommended in the enclosed ag eed upon labeling.

LABELING

ubmit final p inted labeling (FPL), as soon as they a e available, but no mo e than 0 days afte they a e p inted. The FPL must be identical to the enclosed labeling, desc ibed in the table below and must be in the "D ug Facts" fo mat (21 CFR 201.66), whe e applicable. r

Submitted Labeling	Date Submitted
Outer carton label	August 20, 2021
Immediate container labels S	eptember 2, 2021
Consumer Information Leaflet	August 20, 2021

The F L 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 020827/S-033**." 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 (L) files (eLI T). At the time that you submit your final printed labeling (F L), the content of labeling (Drug Facts) should be submitted in L format as described at FDA.gov.[2] Information on submitting L files using eLI T 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 J G file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 14.80 and 14.81).

[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 Data tandards tructured roductLabeling default.htm

If you have any questions, call Anna Thai, Regulatory roject Manager, at s
01 796 65 . s

incerely,

{See appended electronic signature page}

Francis E. Becker, MD, FAC
Director, Division of Nonprescription Drugs II
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLO SURE( ):
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- Consumer Information Leaflet
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This is a r r s a i f a C l c r ic r c rd ha was sig d l c r ically. F ll wi g his ar ma if s a i s f a y a d all l c r ic sig a ur s f r his l c r ic r c rd.

/s/ C

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