NDA 020310/S-27

**SUPPLEMENT APPROVAL**

Kramer Laboratories, Inc.
Attention: Chinna Chinnakaruppan
Chief Operating Officer
440 US Highway 22 East
Suite 210
Bridgewater, NJ 08807

Dear Mr. Chinnakaruppan:

Please refer to your supplemental new drug application (sNDA) dated and received March 8, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nizoral A-D (ketoconazole) topical shampoo, 1%.

We acknowledge receipt of your amendment dated January 19, 2022, which constituted a complete response to our July 7, 2021, action letter.

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

- Change in manufacturing site,
- Change in drug substance source,
- Change in (b) (4) and
- Addition of two new packaging configurations (11 oz and 14 oz).

## 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 labeling listed in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

| Draft Submitted Labeling | Date submitted |
|---|---|
| 4 oz front immediate container label - (b) (4) | 1/19/22 |
| 4 oz back immediate container label - | 1/19/22 |
| 4 oz outer carton label - (b) (4) | 1/19/22 |
| 4 oz front immediate container label - (b) (4) | 1/19/22 |
| 4 oz back immediate container label - | 5/9/22 |
| 4 oz outer carton label - (b) (4) | 1/19/22 |
| 7 oz front immediate container label - (b) (4) | 1/19/22 |
| 7 oz back immediate container label - | 1/19/22 |
| 7 oz outer carton label - (b) (4) | 1/19/22 |
| 7 oz front immediate container label - (b) (4) | 1/19/22 |
| 7 oz back immediate container label - | 1/19/22 |
| 7 oz outer carton label - (b) (4) | 1/19/22 |
| 11 oz front immediate container label - (b) (4) | 1/19/22 |
| 11 oz back immediate container label - | 1/19/22 |
| 11 oz outer carton label - (b) (4) | 1/19/22 |
| 14 oz front immediate container label - (b) (4) | 1/19/22 |
| 14 oz back immediate container label - | 1/19/22 |
| 14 oz outer carton label - (b) (4) | 1/19/22 |

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 020310/S-027**." Approval of this submission by FDA is not required before the labeling is used.

[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.

## 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 CDR Trang Tran, PharmD, MBA, Senior Regulatory Health Project Manager, at (240) 402-7945.

Sincerely,

*{See appended electronic signature page}*

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription 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.**

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/s/

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