NDA 020310/S-024

SUPPLEMENT APPROVAL

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

Dear Mr. Chinnakaruppan:

Please refer to your supplemental new drug application (sNDA) dated and received December 4, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nizoral® (ketoconazole) shampoo, 1%.

This "Prior Approval" supplemental new drug application provides for revisions to the immediate container and carton labeling for the 125 mL and 200 mL products to align the labeling from this previously approved (b) (4) formulation (supplement 022 approved November 30, 2018) with the recently approved labels for the (b) (4) formulation (supplement 023 approved November 25, 2019).

APPROVAL & LABELING

We have completed our review of this application, as amended. Effective on the date of this letter, it is approved 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 following FPL must be identical to the Nizoral® AD (ketoconazole) shampoo, 1%, immediate container labels submitted on December 4, 2019 and outer container labels submitted on February 26, 2020 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- 125 mL outer container
- 125 mL immediate container (Front)
- 125 mL immediate container (Back)

- 200 mL outer container
- 200 mL immediate container (Front)
- 200 mL immediate container (Back)

We remind you to remove the "NEW LOOK" flag from the top of the principal display panel 6 months after marketing.

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-024**." 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 are 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, Regulatory Project Manager, at (240) 402-7945.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD
Acting Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

[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

ENCLOSURE(S):

- Immediate and Outer Container 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/

NUSHIN F TODD
04/20/2020 10:35:33 AM