NDA 020310/S-026

SUPPLEMENT APPROVAL

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

Dear Mr. Chinnakaruppan:

Please refer to your supplemental new drug application (sNDA) dated and received August 17, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nizoral Anti-Dandruff (ketoconazole) shampoo, 1%.

This "Prior Approval" supplemental new drug application provides for the changes in the proprietary name and statement of identity (SOI) to the immediate container and carton labeling for the 4 fl oz (125 mL) and 7 fl oz (200 mL) products:

- The revised proprietary name is Nizoral Anti-Dandruff.
- The revised SOI is Ketoconazole 1% Anti-Dandruff Shampoo.

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, which is listed in the table below:

Final Printed Labeling	Date submitted
4 fl oz front immediate container label	1/18/2021
4 fl oz back immediate container label	1/18/2021
4 fl oz outer carton label	1/18/2021
7 fl oz front immediate container label	1/18/2021
7 fl oz back immediate container label	1/18/2021
7 fl oz outer carton label	1/18/2021

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.[1] 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, PhD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[1] 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.

/s/

NUSHIN F TODD
02/02/2021 11:31:00 AM