

NDA 020310/S-023

## **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 May 28, 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 “(b) (4)” formulation.

### **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® (ketoconazole) shampoo, 1%, immediate container labeling submitted on November 21, 2019 and carton labeling submitted on November 25, 2019 and must be in the “Drug Facts” format (21 CFR 201.66), where applicable:

- 125 mL carton
- 125 mL immediate container (Front)
- 125 mL immediate container (Back)
- 200 mL carton
- 200 mL immediate container (Front)
- 200 mL immediate container (Back)

We remind you to remove the “NEW LOOK, SAME FORMULA” 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.*<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 020310/S-023.**” 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.<sup>2</sup> 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}*

Theresa Michele, MD  
Director  
Division of Nonprescription Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

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<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

ENCLOSURE(S):

- Carton and Container Labeling

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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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THERESA M MICHELE  
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