NDA 202736/S-006

SUPPLEMENT APPROVAL

Arbor Pharmaceuticals LLC
Attention: Justin Kilby
Senior Manager, Regulatory Affairs
6 Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Mr. Kilby:

Please refer to your supplemental new drug application (sNDA) dated and received December 27, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sklice® (ivermectin) lotion, 0.5%.

This Prior Approval supplemental new drug application provides for a complete switch of Sklice® (ivermectin) lotion, 0.5% from prescription to over-the-counter status.

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

Submitted Labeling	Date of Submission
Sklice® Outer Carton*	October 9, 2020
Sklice® Immediate Container (Front) – 4 oz Tube*	September 11, 2020
Sklice® Immediate Container (Back) – 4 oz Tube*	September 4, 2020
Sklice® Outer Carton**	October 9, 2020
Sklice® Immediate Container (Front) – 4 oz Tube**	September 11, 2020
Sklice® Immediate Container (Back) – 4 oz Tube**	September 4, 2020

Sklice® Consumer Information Leaflet	October 9, 2020

* Labeling states product is manufactured by DPT Laboratories, Ltd. (DPT)
** Labeling states product is manufactured by Jubilant HollisterStier (JHS)

We remind you to remove the "**New**" flag on your product labels six months after the product has been introduced to the marketplace to be consistent with the Division's current labeling practices for prescription to OTC switch products. 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 202736/S-006**." 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 (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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

[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

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}

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

Kendall A. Marcus, MD
Director
Division of Dermatology and Dental Products
Office of Immunology and Inflammation
Center for Drug Evaluation and Research

ENCLOSURES:

- Carton and Container Labeling
- Consumer Information Leaflet

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/

KENDALL A MARCUS
10/27/2020 11:42:00 AM

FRANCIS E BECKER
10/27/2020 11:47:28 AM