DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020666/S-011

SUPPLEMENT APPROVAL

Impax Laboratories, LLC
Attention: Marcy Macdonald
Vice President, Regulatory Affairs
31047 Genstar Road
Hayward, CA 94544

Dear Ms. Macdonald:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 2, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALBENZA (albendazole) Tablets, 200 mg.

This "Changes Being Effected" supplemental new drug application provides for correction to the National Drug Code (NDC) numbers in the prescribing information (PI) that was approved in S10 on 12/20/2017. The following changes are also proposed in PI and carton and container labels:

Package Insert:
- Changed the NDC number from 64896-671-49 to 64896-693-49 for bottles of 2
- Removed NDC number for bottles of 28
- Revised LA number from 1908-01 to 1908-02
- Changed the revision date from 12/2017 to 05/2018.

Container labels:
- Revised Barcode number from 6489667149 to 6489669349
- Revised NDC number from 64896-671-49 to 64896-693-49
- Converted to 16 mm x 46.04 mm unvarnished area
- Removed upper right corner box
- Moved barcode and UPC code to right side
- Revised vendor number from A116306 to AXXXXXX
- Revised Label size from 140 mm x 61 mm to 96.84 mm x 46.04 mm
- Revised LA number from 1909-01 to 1909-02
- Revised date from 06/2017 to 05/2018

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to carton and immediate container labels submitted on May 2, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020666/S-011.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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.

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 Chinedu Ebonine, Regulatory Business Process Manager, at (240) 402 - 3448.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Content of Labeling

David Lewis

Digitally signed by David Lewis
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