



NDA 050786/S-030

## SUPPLEMENT APPROVAL

Laboratoires Juvisse Pharmaceuticals  
c/o H2-Pharma LLC  
Attention: Brooke Cantey  
President  
611 Industrial Park Boulevard  
Montgomery, AL 36117

Dear Brooke Cantey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 30, 2025, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PYLERA (bismuth subcitrate potassium, metronidazole, tetracycline hydrochloride) (biskalcitrate potassium/metronidazole/te) capsule.

This “Changes Being Effected” supplemental new drug application provides for to add all approved Safety Labeling Changes (SLCs) into the labeling for the new site, (b) (4) and harmonizes the approved labeling text across approved drug product sites.

### **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.

### **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(I)(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 CONTAINER LABELS**

Submit final printed carton and container labels that are identical to enclosed carton and container labels, 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 050786/S-030.**” 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.

### **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, contact Markerra Lindon, Regulatory Business Process Manager, [Markerra.lindon@fda.hhs.gov](mailto:Markerra.lindon@fda.hhs.gov) or (240) 402 - 0716.

Sincerely,

*{See appended electronic signature page}*

For:

David Lewis, Ph.D.

Supervisor

Division of Product Quality Assessment XI

Office of Product Quality Assessment II

Office of Pharmaceutical Quality

Center for Drug Evaluation and Research

**Enclosure(s):**

Content of Labeling

**INSTRUCTIONS FOR ENCLOSURES:**

- **CONTENT OF LABELING (INCLUDING PATIENT LABELING (PPI), MEDGUIDE, & INSTRUCTIONS FOR USE, IF APPLICABLE) – REQUIRED TO BE ATTACHED**



Rishi  
Thakur

Digitally signed by Rishi Thakur

Date: 11/21/2025 03:03:25PM

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Comments: Signing as a proxy for Dr. David B. Lewis