



NDA 050813/S-008

## SUPPLEMENT APPROVAL

Pragma Pharmaceuticals, LLC  
Attention: John D'Angelo, MS, RPh  
Vice President, Regulatory Affairs  
134 Birch Hill Road  
Locust Valley, NY 11560

Dear Mr. D'Angelo:

Please refer to your supplemental new drug application (sNDA) dated May 3, 2019, received May 6, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MOXATAG (amoxicillin extended-release) Tablets, 775 mg.

This Prior Approval supplemental new drug application provides for revisions to the prescribing information to be in compliance with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR), as published in the Federal Register, December 4, 2014 (79 FR 233) and requested in the Agency letter of December 11, 2018. Additionally, this supplement provides for changes to the container label(s) to reflect new manufacturer and distribution information, including a new NDC number, manufacturer name, and logo.

### **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.

### **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 [FDA.gov](http://www.fda.gov).<sup>1</sup> 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.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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*.<sup>2</sup>

The SPL will be accessible from 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

### **CONTAINER LABELING**

We acknowledge your June 12, 2019, submission containing final printed container labeling.

### **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 Kristine Park, PhD, RAC, Regulatory Health Project Manager, at (301) 796-0471.

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infectives  
Office of Infectious Diseases  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

- Content of Labeling
  - Prescribing Information
- Container Labeling

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<sup>2</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>.

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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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DMITRI IARIKOV  
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