DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50813/S-003

SUPPLEMENT APPROVAL

Pragma Pharmaceuticals, LLC
Attention: John D'Angelo, M.S., R.Ph.
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 June 2, 2015, received June 3, 2015, 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 application provide for revisions to the subsection **12.4, Microbiology.**

APPROVAL & LABELING

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and the minor editorial revisions listed below and included in the enclosed labeling:

- Addition of reference 2 to the last sentence in the text under the heading **Quality Control**
- Deletion of the sentence under the heading **Quality Control:**
  ~~For the disk diffusion technique, the criteria in Table 2 should be achieved.~~
- Addition of the heading "**Antimicrobial Activity**" before the list of organisms
- Replacement of the word "MOXATAG" with the word "Amoxicillin" in the following sentence: "MOXATAG has been shown to be active in vitro against isolates of the microorganism *S. pyogenes* and in clinical infections as described in the INDICATIONS AND USAGE section."

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 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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes 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).

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
06/09/2015