



NDA 205931/S-005  
NDA 208253/S-003

## SUPPLEMENT APPROVAL

Almirall, LLC  
Attention: Jane Yi, PhD  
Associate Director, Regulatory Affairs  
707 Eagleview Blvd, Suite 200  
Exton, PA 19241

Dear Dr. Yi:

Please refer to your supplemental new drug applications (sNDAs) dated January 27, 2020, received January 27, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ACTICLATE (doxycycline hyclate) tablets 75mg and 150mg, and ACTICLATE CAP (doxycycline hyclate) capsules 75 mg.

These sNDAs submitted as “Changes Being Effected” supplements provide added pediatric data to **SECTION 12 CLINICAL PHARMACOLOGY, subsection 12.3 Pharmacokinetics**. The sNDAs were submitted per the Agency’s supplement request dated December 27, 2019, requiring the Applicant under Section 409I of the Public Service Act, also known as the Best Pharmaceutical for Children Act, to update the label with pediatric information.

### **APPROVAL & LABELING**

We have completed our review of these applications. They are 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.<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. If the content of labeling in SPL format initially submitted with these CBE-0 labeling supplements is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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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 these sNDA, 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 these supplemental applications, 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).

## **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 Jacquelyn Rosenberger, PharmD, RAC, Regulatory Project Manager, at (301) 796-9179.

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

### ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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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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