



NDA 205931/S-004
NDA 208253/S-002

SUPPLEMENT APPROVAL

Almirall, LLC
Attention: Wendy Jones
Head of Regulatory Affairs
707 Eagleview Boulevard, Suite 200
Exton, PA 19341

Dear Ms. Jones:

Please refer to your supplemental new drug applications (sNDAs) dated June 28, 2019, received June 28, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 205931/S-004 ACTICLATE (doxycycline hyclate) Tablets, 75 mg and
150 mg
NDA 208253/S-002 ACTICLATE CAP (doxycycline hyclate) Capsules,
75 mg

These Prior Approval supplemental new drug applications have been submitted in response to the Pregnancy and Lactation Rule (PLLR) published in the Federal Register in December 2014, "Content and Format of Labeling Rule for Human Prescription Drug and Biological Products: Requirements for Pregnancy and Lactation Labeling," 79 FR 233, December 4, 2014, and 21 CFR 201.56 (a and d) and 201.57 (c) (9) (I, ii, and iii) updating Section 8 USE IN SPECIFIC POPULATIONS, specifically sub-sections 8.1 Pregnancy, 8.2 Lactation, and 8.3 Females and Males of Reproductive Potential of the Prescribing information (PI). Minor editorial revisions were also made throughout the PI.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions reflected in the enclosed 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.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Instructions for Use), 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.

¹ <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*.²

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).

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

² 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>.

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.

/s/

DMITRI IARIKOV
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