



NDA 209816/S-009  
NDA 209817/S-008

## SUPPLEMENT APPROVAL

Paratek Pharmaceuticals, Inc.  
Attention: Kristen Manion  
Head, Regulatory Affairs and Quality  
1000 First Avenue, Suite 200  
King of Prussia, PA 19406

Dear Ms. Manion:

Please refer to your supplemental new drug applications (sNDAs) dated April 28, 2020, received April 28, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

**NDA NUMBER:** 209816  
**SUPPLEMENT NUMBER:** S-009  
**PRODUCT NAME:** NUZYRA (omadacycline) Tablets, 150 mg

**NDA NUMBER:** 209817  
**SUPPLEMENT NUMBER:** S-008  
**PRODUCT NAME:** NUZYRA (omadacycline) For Injection, 100 mg

These supplemental applications have been submitted in response to the Agency supplemental request letter dated March 30, 2020, requesting an update to the **WARNINGS AND PRECAUTIONS** section (5), ***Clostridioides difficile*-Associated Diarrhea** subsection (5.5) and the **Microbiology** subsection (12.4) of the Prescribing Information (PI).

### **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

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

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 *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 NDAs, 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, contact Deepak Aggarwal, Regulatory Project Manager, at 301-796-0746.

Sincerely,

*{See appended electronic signature page}*

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

### ENCLOSURE(S):

- 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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