NDA 209816/S-008
NDA 209817/S-007

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 (sNDA) 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:	008
PRODUCT NAME:	NUZYRA (omadacycline) Tablets, 150 mg

NDA NUMBER:	209817
SUPPLEMENT NUMBER:	007
PRODUCT NAME:	NUZYRA (omadacycline) For Injection, 100 mg

These "Changes Being Effected" supplemental new drug applications provide for an update to Section **(11) DESCRIPTION** 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.[1] 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

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

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 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

[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
09/02/2020 10:12:40 AM
Deepak, thank you. Dmitri