NDA 209816
NDA 209817

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Paratek Pharmaceuticals, Inc.
Attention: Stephen Viccica, MS
Executive Director and Head, Regulatory Affairs
1000 First Avenue, Suite 200
King of Prussia, PA 19406

Dear Stephen Viccica:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for the following drugs, which were approved on October 2, 2018.

NDA 209816 Nuzyra (omadacycline) tablet
NDA 209817 Nuzyra (omadacycline) injection

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for these applications because you have not yet submitted your pediatric assessment for:

PMR 3487-1 which was deferred until February 28, 2025.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

While you are required to respond to this Non-Compliance letter as instructed above, you are not required to submit another deferral extension request, as we have received your April 7, 2025, deferral extension request, and it is currently under review.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, contact Eva Zuffova, Regulatory Project Manager, at 301-796-0697 or email eva.zuffova@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

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/

PETER W KIM
05/06/2025 03:06:32 PM