NDA 209816/S-012, 209817/S-011

SUPPLEMENT APPROVAL

Paratek Pharmaceuticals Inc
Attention: Kristin Manion
1000 First Avenue
Suite 200
King of Prussia, PA 19406

Dear Ms. Manion:

Please refer to your supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 209816/S-012	NUZYRA (omadacycline) Tablets, 150 mg	July 27, 2020	July 27, 2020
NDA 209817/S-011	NUZYRA (omadacycline) For Injection, 100 mg	July 27, 2020	July 27, 2020

These Prior Approval supplemental new drug applications provide for addition of a new carton/container packaging presentation for a 6-count Professional Sample for NUZYRA tablets.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA**

209816/S-012." Approval of this submission by FDA is not required before the labeling is used.

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 Chinedu Ebonine, Regulatory Business Process Manager, at (240) 402 - 3448.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Branch Chief, B2
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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