NDA 209816/S-011
NDA 209817/S-010

SUPPLEMENT APPROVALS

Paretek 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 and received July 27, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NUZYRA (omadacycline) tablets, 150 mg (NDA 209816) and NUZYRA (omadacycline) for injection, 100 mg (NDA 209817).

These Prior Approval supplemental new drug applications provide for revisions to the prescribing information (PI), **DOSAGE and ADMINISTRATION (2)** section, **Dosage in Adults with Community-Acquired Bacterial Pneumonia (CABP) (2.2)** subsection, and **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection, to add information on an oral loading and maintenance dose.

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.

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.

[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 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

These supplemental new drug applications provide for a new dosing regimen for adult patients with CABP and are therefore subject to PREA requirements. We remind you that there are postmarketing requirements listed in the October 02, 2018, approval letter that are still open. The deferred pediatric postmarketing CABP study (3487-3) listed in the October 02, 2018, approval letter will address dosing in pediatric patients with CABP.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[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.

If you have any questions, call Carmen DeBellas, Chief Regulatory Project Manager, at 301-796-1203.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

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/

SUMATHI NAMBIAR
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