Dear Mr. Brenner:

Please refer to your supplemental new drug applications (sNDAs) dated December 20, 2018, received December 20, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 209816/S-004 NUZYRA (omadacycline) Tablets
NDA 209817/S-003 NUZYRA (omadacycline) Injection

These supplemental applications provide for changes to the section 14 CLINICAL STUDIES in subsections 14.1 Community-Acquired Bacterial Pneumonia and 14.2 Acute Bacterial Skin and Skin Structure Infections.

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, 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.\textsuperscript{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 this NDA, 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 this supplemental application, 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).

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.\textsuperscript{3} Information and Instructions for completing the form can be found at FDA.gov.\textsuperscript{4} For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see FDA.gov.\textsuperscript{5}

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

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

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\textsuperscript{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.

\textsuperscript{3} [http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf)

\textsuperscript{4} [http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf)

\textsuperscript{5} [http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm)

U.S. Food and Drug Administration  
Silver Spring, MD 20993  
[www.fda.gov](http://www.fda.gov)
ENCLOSURE(S):
  • Content of Labeling
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
06/13/2019 10:25:05 AM