NDA 209776/S-004

SUPPLEMENT APPROVAL

Rempex Pharmaceuticals Inc., a wholly owned subsidiary of Melinta Therapeutics, LLC
Attention: Zhi Chen
Director, CMC Regulatory Affairs
300 Tri-State International, Suite 272
Lincolnshire, IL 60069

Dear Zhi Chen:

Please refer to your supplemental new drug application (sNDA) dated and received September 1, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vabomere (meropenem-vaborbactam) powder for injection, 1g/1g per vial.

This Prior Approval sNDA provides for:

- Revisions to the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, **TABLE OF CONTENTS**, and **FULL PRESCRIBING INFORMATION**. Specifically,
    - Under the **HIGHLIGHTS OF PRESCRIBING INFORMATION**, the **DRUG INTERACTIONS** section was inserted to add clinically significant drug interaction information with hormonal contraceptives.
    - Under the **TABLE OF CONTENTS,** Section **7 DRUG INTERACTIONS** was revised to add subsections **7.3 Potential for Vabomere to Affect Other Drugs**, **7.4 Hormonal Contraceptives**, and Section 8, **USE IN SPECIFIC POPULATIONS** was revised to add subsection **8.3 Females and Males of Reproductive Potential**.
    - Under the **FULL PRESCRIBING INFORMATION,** the following revisions were made:
        - Under Section **7 DRUG INTERACTIONS**, subsections **7.3 Potential for Vabomere to Affect Other Drugs** and **7.4 Hormonal Contraceptives** were added with new drug interaction related information.
        - Under Section **8 USE IN SPECIFIC POPULATIONS**, subsection **8.3 Females and Males of Childbearing Potential** was added withimportant information regarding interactions with hormonal contraceptives.
        - Under Section **12 CLINICAL PHARMACOLOGY**, subsection **12.3**

Pharmacokinetics, the "Drug Interaction Studies" section was revised with new drug interaction related information.

- Under Section **17 PATIENT COUNSELING INFORMATION,** important information regarding interactions with hormonal contraceptives was added.

- Minor editorial revisions were made throughout the prescribing information (PI).

APPROVAL & LABELING

We have completed our review of this application, as amended. It is 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.

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 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).

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

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, please contact Jennifer Grant, MSHS, Regulatory Project Manager, at jennifer.grant@fda.hhs.gov or (301) 796-0480.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- 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/

DMITRI IARIKOV
09/21/2023 10:14:29 AM