NDA 209776

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Rempex Pharmaceuticals, Inc.
A wholly owned subsidiary of Melinta Therapeutics, Inc.
Attention: Starr Shangle, Senior Director Regulatory Affairs
300 Tri-State International, Suite 272
Lincolnshire, IL 60069

Dear Starr Shangle:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Vabomere, Powder for Injection, 1 gram/vial, which was approved on August 29, 2017.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR 3248-1, which was deferred until March 31, 2020. Furthermore, you did not submit a deferral extension request at least 90 days prior to this date [505B(a)(4)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or 21 U.S.C. 355c(a)(4)(B)(ii)]. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the 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.

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, call Christopher L. Smith, PharmD, MPH, Regulatory Project Manager at (301) 796-4851.

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

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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