NDA 211672
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NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Hong Kong King-Friend Industrial Company Limited
c/o Meitheal Pharmaceuticals, Inc.
Attention: Roopang Shah
US Agent for Hong Kong King-Friend Industrial Company Limited
8700 W Bryn Mawr Ave, Suite 600S
Chicago, IL 60631

Dear Roopang Shah:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for the following drugs, which were approved on August 19, 2019:

NDA 211672 Xenleta (lefamulin) tablets
NDA 211673 Xenleta (lefamulin) injection

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for these applications because you have not yet submitted your pediatric assessment for:

PMR 3672-8, which was deferred until December 31, 2024.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (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. We note that you requested a deferral extension on November 26, 2024; however, we have determined that your request did not qualify for an extension.

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 NDAs with a cross-reference letter to the investigational new drug applications (INDs) to which your protocol has been submitted.

If you have any questions, call Deborah Kim, PharmD, RAC, Senior Regulatory Project Manager, at (301) 796-9053 or email Deborah.Wang@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Office of New Drugs
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/

PETER W KIM
01/10/2025 03:58:25 PM