NDA 210910

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Cosmo Technologies, Ltd.
c/o Conventus BioMedical Solutions, Inc.
Attention: Steven A. Kradjian, RAC
President, Principal Consultant
9920 Pacific Heights Boulevard, Suite #150
San Diego, CA 92121

Dear Steven A. Kradjian:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Aemcolo (rifamycin) delayed release tablets, which was approved on November 16, 2018.

The Agency has determined that you have failed to meet the postmarketing requirements (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for the following PMRs:

PMR 3505-1, which was deferred until December 31, 2025.
PMR 3505-2, which was deferred until December 31, 2025.

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.

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, contact Kristin Singh, Regulatory Project Manager, at 240-402-6432 or kristin.singh@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
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