

**RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED**

April 15, 2024

Rigoberto Roca, M.D.
Director
Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP)
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RE: Response to PREA Non-Compliance Letter
Deferral Extension Request for PMR 4228-2
NDA 215457 Serial #0083
Cross-Reference IND 112292 Serial #0078
Naloxone Hydrochloride Injection auto-injector**

Attn: Namrata Thakkar, PharmD, BCPS, Regulatory Project Manager

Dear Dr. Roca:

On April 9, 2024, kaleo, Inc. received an [FDA letter](#), dated April 3, 2024, notifying kaleo, Inc. of non-compliance with the Pediatric Research Equity Act (PREA) regarding Post-Marketing Requirement (PMR) 4228-2. This submission includes kaleo, Inc.'s formal written response to the non-compliance letter and a deferral extension request for the nonclinical juvenile animal toxicity studies required for PMR 4228-2. The extension request is provided in [Section 1.9.2](#) and includes the reasons for the delayed pediatric assessments and the dates by which kaleo, Inc. expects to submit the assessments.

This submission meets the 45-calendar day timeline defined in Section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act.

Thank you in advance for your time and efforts in the review of these materials. Should you have any questions or require additional information, please do not hesitate to contact me at (804) 256-7812.

With sincere regards,



DN: cn=Breanne N. Gjurich, Ph.D., RAC, o=Sr.
Manager, Regulatory Affairs, ou=kaleo, Inc.,
email=breanne.gjurich@kaleo.com, c=US
Date: 2024.04.11 12:50:56 -04'00'

Breanne Gjurich, Ph.D., RAC
Senior Manager, Regulatory Affairs at kaleo, Inc.

Electronic Submission Specifications

This submission is compliant with FDA's Guidelines for Industry and current eCTD specifications.

All files were checked and verified to be free of viruses prior to transmission through the electronic submission gateway.

Anti-Virus Program	Microsoft Defender Antivirus
Program Version	4.18.24030.9
Virus Definition Date	04/15/2024
Submission Size	Approx. 5.19 MB