EXELA PHARMA SCIENCES
P.O. Box 818
1245 Blowing Rock Blvd
Lenoir, NC 28645

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

October 21, 2025

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

RE: AKOVAZ – Ephedrine Sulfate Injection, USP, 25 mg/5mL (5 mg/mL)
NDA 208289, Sequence 0096
Response to PREA Noncompliance Letter
Deferral Extension Request

Dear Dr. Roca,

Reference is made to Exela Pharma Sciences, LLC ("Exela") NDA 208289 for AKOVAZ® (ephedrine sulfate injection, USP) approved on April 29, 2016. It should be noted that the ownership of AKOVAZ® was transferred from Avadel Legacy Pharmaceuticals (Avadel) to Exela on June 30, 2020. The current submission is in response to the Communication received by mail on October 16, 2025 from Aliza Thompson, MD, MS, Director, Division of Cardiology and Nephrology, Center for Drug Evaluation and Research.

Exela apologizes for the oversight in not requesting a deferral extension by September 30, 2025. Exela submitted a pediatric study protocol on September 30, 2021 in Sequence 0014 to the IND 116266 and received approval from the Agency on September 8, 2022. Exela has chosen (b) (4), a CRO located in (b) (4) to perform the study as indicated in the annual report (Seq 0019, IND 116266, submitted on August 25, 2025).

Exela, 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)], hereby acknowledges the PREA Noncompliance Letter received on October 16, 2025 and requests a deferral extension. Proposed timelines for submission of the pediatric assessment are as follows:

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Study Completion: 12/2027
Final Report Submission: 12/2028

In accordance with 21 C.F.R § 314.96(d), we certify that the proposed changes described in this amendment are not any of the following:

(i) (b) (4)
(ii)
(iii
(iv

The submission has been formatted in accordance with the ICH Common Technical Document and FDA's guidance on electronic submissions. Exela certifies that this submission is virus free as tested by CrowdStrike Windows Sensor Version 7.21.19205.0. We trust you will find the information in this application satisfactory for your review and approval. If there are any questions concerning this application, please do not hesitate to contact me.

Sincerely,

Taylor Edwards Digitally signed by Taylor Edwards
Date: 2025.10.21 15:00:47 -04'00'

Mrs. Taylor Edwards
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