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

RESPONSE TO PREA NON-COMPLIANCE LETTER
DEFERRAL EXTENSION REQUESTED

July 30, 2021

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, (b) (4)
NDA 208289, Sequence 0080
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 through email on June 17, 2021 from Kimberly Compton, RPh, RAC, Senior Regulatory Project Manager, Anesthesiology, Addiction, and Pain Medicine Group, Division of Regulatory Operations for Neuroscience, Center for Drug Evaluation and Research.

Exela apologizes for the oversight in not requesting a deferral extension by May 31, 2021. Exela acquired the ownership of NDA 208289 from Avadel Legacy Pharmaceuticals, LLC ("Avadel") on July 08, 2020. Based on documents transferred from Avadel, Exela understood that the clinical study proposed in the agreed upon iPSP (Seq 0019, submitted on April 05, 2016) was pending (b) (4) This was the reason for Exela not submitting the clinical study as per the timelines proposed in the agreed upon iPSP.

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 June 17, 2021 and requests a deferral extension. Exela has taken the initial steps to begin the development of a

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pediatric study protocol. Exela is in contact with multiple CROs and plans to submit a protocol, based on the agreed upon iPSP (Seq 0019, submitted on April 05, 2016), to IND (b) (4), by September 2021.

Proposed timelines for submission of the pediatric assessment are as follows:

Submission of Final Protocol: 09/2021
Study Completion: 09/2024
Final Report Submission: 09/2025

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) To add a new indication or other condition of use;
(ii) To add a new strength;
(iii) To make other than minor changes in product formulation; or
(iv) To change the physical form or crystalline structure of the active ingredient.

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 Carbon Black Cloud Version 3.5.0.1523. 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,

Aruna Koganti
Digitally signed by Aruna Koganti
Date: 2021.07.30 12:58:18 -04'00'

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