



November 3, 2021

**DEFERRAL EXTENSION  
REQUESTED**

Rigoberto A. Roca, MD  
Acting Division Director  
Division of Anesthesiology, Analgesia and Pain Medicine  
Center for Drug Evaluation and Research  
Food and Drug Administration  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

**Re: NDA 022382; Sequence 0144  
SPRIX® (ketorolac tromethamine) Nasal Spray  
Response to PREA Non-Compliance Letter  
PREA Deferral Extension Request**

Dear Dr. Roca,

Reference is made to the Notification of Non-Compliance with PREA letter dated September 8, 2021.

We wish to inform the Agency that Assertio Therapeutics, Inc. (Assertio) recently assumed the responsibility to address this pediatric assessment as a result of a merger with Zyla Life Sciences as of May 2020. The merged company went through a subsequent change in the executive leadership team and a substantive downsizing and loss of staff. (b) (4)

Assertio is currently working on (b) (4) to fulfill the Post Marketing Requirement PMR 1551-3.

**NDA #022382**

**Sprix® (ketorolac tromethamine) Nasal Spray 15.75 mg**

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Assertio takes this pediatric PMR for Sprix under NDA 022382 very seriously. We would like to formally request a deferral extension to August 31, 2022 for this PMR to allow Assertio sufficient time to address the issues raised [REDACTED] <sup>(b) (4)</sup>  
[REDACTED]

Again, Assertio is committed to working with the Agency towards the timely completion of the assigned PMR under NDA 022382. We appreciate the Agency's consideration of this request for deferral extension based upon the described circumstances.

Please do not hesitate to contact me at 224-441-6390 or via email at [RA@assertiotx.com](mailto:RA@assertiotx.com) should you have any questions or if you require additional information.

Sincerely,



Vasilios Iskos,  
Senior Vice President, Operations

## Electronic Submission Specifications

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The technical point of contact for this submission is:

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