January 30, 2026

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Office of Neuroscience, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

NDA #:	**212994**
Submission:	**RESPONSE TO PREA NON-COMPLIANCE LETTER**
eCTD Sequence:	**0086**
Reference:	**Azstarys (Serdexmethylphenidate & Dexmethylphenidate) Capsules**

Dear Dr. Farchione:

Reference is made to new drug application (NDA) 212994 for Azstarys (serdexmethylphenidate chloride and dexmethylphenidate hydrochloride) 26.1 mg/5.2 mg, 39.2 mg/7.8 mg, and 52.3 mg/10.4 mg capsules, approved on March 2, 2021. Azstarys is a central nervous system (CNS) stimulant prescription medicine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in people 6 years of age and older.

Reference is also made to Investigational New Drug (IND) Application 130463 and PMR 3980-3.

Further reference is made to FDA's 01DEC2025 Notification of Non-Compliance with PREA.

This submission is composed of the cover letter, FDA Form 356h, and 1.4.4 References.

As requested, this response is being submitted to NDA 212994 with a cross-reference to the IND.

Commave and Corium verify that none of the proposed changes in this amendment are of the type described in 21 CFR 314.60(f)(1) requiring patent certification or recertification.

The purpose of this submission is to provide a response to the 01DEC2025 Notification of Non-Compliance with PREA.

After submitting the Clinical Study Report (CSR) to fulfill PMR 3980-3, [redacted (b) (4)]. The same was also communicated to the FDA Project Manager via email correspondence in Dec 2024. However, since this correspondence, as FDA is aware, a class-wide safety label update was issued in June 2025 for all extended-release amphetamine and methylphenidate stimulants, indicating that they are not recommended for use in patients younger than 6 years of age due to a higher incidence of adverse events. Based on this update, it was Corium's understanding that submissions [redacted (b) (4)] would no longer be appropriate or actionable, as the anticipated [redacted (b) (4)] outcomes were no longer aligned with current safety recommendations.

Upon receiving the Non-Compliance Notification letter dated 01DEC2025, we have made multiple attempts via email to the FDA Project Manager to obtain clarification prior to the 45-day response deadline regarding why the letter was issued and whether an efficacy or labeling supplement is still required despite recent safety-related updates, however, we have not received substantive

feedback or confirmation from the FDA. We apologize for not responding to the non-compliance letter within 45 calendar days as we were awaiting clarification in response to a prior email.

Of note, the CSR to fulfill PMR 3980-3 was submitted on 27Nov2024 (SN0068), and more recently, the CSR to fulfill PMR 3980-4 was submitted on 22JAN2026 (SN0085)

Considering the above, we respectfully request that FDA reconsider the issuance of the PREA noncompliance letter. We further request confirmation of FDA's current expectations regarding any remaining PREA obligations for Azstarys considering the class-wide safety updates.

Please contact me by phone at 617-752-1941, or by email at Manisha.amin@corium.com with any questions. We welcome the opportunity to discuss this matter further.

Sincerely,

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Antivirus Statement

Number and Type of Electronic Media	Electronic transmission via ESG
Size of Submission	Approximately 4 MB
Virus Protection Statement	This submission is virus free.
Software Information	SentinelOne Agent

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