

June 28, 2024

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Director, Division of Psychiatry  
Office of Neuroscience, Center for Drug Evaluation and Research  
U.S. Food and Drug Administration  
5901-B Ammendale Road  
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**NDA #:** 212994  
**Submission:** RESPONSE TO PREA NON-COMPLIANCE LETTER  
**Submission:** DEFERRAL EXTENSION REQUESTED  
**eCTD Sequence:** 0066  
**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 17MAY2024 Notification of Non-Compliance with PREA.

The purpose of this submission is to provide a response to the 17MAY2024 Notification of Non-Compliance with PREA and to request a deferral for PMR 3980-3 until Nov 29, 2024.

This submission is composed of the cover letter, [FDA Form 356h, 1.17.2](#) (Response to PREA Letter), [1.9.2](#) (Deferral Extension Request) and [1.4.4 References](#).

As requested, this response is being submitted to NDA 212994 with a cross-reference to IND 130463, to which the protocol for PMR 398-3 has been submitted.

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.

Please contact me by phone at 617-752-1941, or by email at [Blythe.Buchanan@corium.com](mailto:Blythe.Buchanan@corium.com) with any questions.

Sincerely,

**Blythe Buchanan**

Digitally signed by Blythe  
Buchanan  
Date: 2024.06.28 09:57:09 -04'00'

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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

### **Technical Point of Contact**

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