NDA 209963

Noden Pharma Designated Activity Company
c/o APCER Life Sciences, Inc.
111 Town Square Place, Suite 860
Jersey City, NJ 07310

Thursday, 19 April 2024

NDA #: **209963**
Sequence: **0121**
Product: **GOPRELTO (Cocaine Hydrochloride) Nasal Solution 160 mg/4 mL**

Subject: RESPONSE TO PREA NONCOMPLIANCE LETTER.

Dear Sir or Madam,

We would like to reply to your letter dated from 30-March-2024 concerning the failed postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for our GOPRELTO application (NDA #209963 and IND #118527), because we have not yet submitted our pediatric assessment for PMR 3241-10, which was deferred until July 31, 2023.

- 3241-10 Conduct a multicenter trial to evaluate the pharmacokinetic and safety profiles of a single topical administration of GOPRELTO for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the nasal cavities in pediatric subjects 12 years of age to less than 17 years of age.

Please note that GOPRELTO changed Marketing Authorization Holder from Genus Lifesciences, Inc. to Noden Pharma Designated Activity Company as of the date, January 12, 2024 – Sequence 0118.

As previous Marketing Authorization Holder, Genus Lifesciences, Inc. did some research to find a CRO and start the pediatric study, however none of the CRO contacted gave a positive answer and they decided to decline this study.

You can find a summary of the different CRO's contacted by Genus Lifesciences, Inc. and the details of why this study was not completed by the CRO, see **Appendix 1 – CRO Vendor Summary – Cocaine Pediatric Study Genus Lifesciences**.

On September 19, 2023 Bill Reightler from Genus Lifesciences, Inc. provided you with an update as to the status of the pediatric study, see **Appendix 2 – Email – Update of the Pediatric Study Genus Lifesciences**.
From this email, it could be deducted that the initial agreed timelines would not be completed.

Indeed, the timelines were as follow:

Draft Protocol Submission: 09/2019
Final Protocol Submission: 06/2020
Study Completion: 06/2022 – 01/2023 (extension)
Final Report Submission: 12/2022 – 07/2023 (extension)

(b) (4)

As Noden Pharma DAC just became the Marketing Authorization Holder, we became aware of the failed postmarketing requirement of the Pediatric study only recently, we saw that the timelines were expired:

- Study Completion: 01/2023,
- Final Report Submission: 07/2023.

(b) (4)

Thus, we would like to ask the FDA if it would be possible to ask for a deferral extension. As Noden Pharma DAC still needs to find a CRO and it is written in the approved protocol (RA-VP-000-357) that the pediatric study would last approximatively two years, we would like to ask for a deferral extension until:

- Study Completion: 06/2026,
- Final Report Submission: 12/2026.

Please contact Claire Reymann at +33649219169 or via email at clairereymann@laboratoirexo.fr and Sayeed Syed at +1 609-721-8479 or via email at USAgent@apcerls.com if you have any questions or require additional information.

Sincerely,

Claire Reymann
Regulatory Affairs and Pharmacovigilance Director

4 Pages have been Withheld in Full as b4 (CCI/tS) immediately following this page