Lannett Company, Inc.
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August 4, 2021

Office of New Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Immediate Office – Mail Stop 6311
10903 New Hampshire Avenue
Silver Spring, MD 20993

NDA #: **209575**
Sequence #: **0071**
Product: **Numbrino™ (cocaine hydrochloride) Nasal Solution, 4%**
Subject: **RESPONSE TO PREA NON-COMPLIANCE LETTER**
DEFERRAL EXTENSION REQUESTED
Pediatric Assessment for Juvenile Animal Study (3768-1)

Dear Sir or Madam:

Lannett Company, Inc. (Lannett) submits this correspondence for Numbrino™ (cocaine hydrochloride) Nasal Solution, 4%, in response to the Notification of Non-Compliance with PREA Letter dated 07/09/2021.

Lannett requests a deferral extension in regards to submission of the pediatric assessment for FDA Study No.: 3768-1, a juvenile animal study to characterize the impact of cocaine on brain development and male reproductive tissue and development to support pediatric dosing in children 12 years of age to less than 17 years of age. As noted in the Postmarketing Study Commitments Annual Status Report submitted on 03/03/2021 (sn0066, Module 1.13.12), this study is delayed. The associated draft study protocol (COCA4-NC-2001) was submitted to IND 106499 on 3/30/2020. Agency comments on the draft protocol were provided on 11/03/2020 and Lannett submitted the final protocol to IND 106499 on 01/26/2021 (sn0051). As noted in the final protocol, prior to the initiation of this study, a dose range finding study in juvenile rats is needed to determine the final dose levels. The results of the dose range finding study are expected by August 2021. Initiation of the animal study is targeted to begin in March 2022 based on the first available slot at the CRO. The final study report will be submitted to the FDA by March 2023. Please note, this is a change from what was previously communicated. The additional postponement is due to the delay in the dose range finding study and longer than expected timelines provided by the clinical site as a result of the current COVID-19 pandemic situation.

A cross-reference letter will be submitted to IND 106499 where the PMR 3768-1 protocol has been submitted.

This submission is virus free and has been scanned using Symantec Endpoint Protection (virus definition updated daily).

Please direct all questions or comments regarding the application to my attention via phone at 215-333-9000 ext. 2102 or email at regaffairs@lannett.com.

Sincerely,
KS/amw

Kristie Stephens

Digitally signed by Kristie Stephens
DN: c=US, st=PA, l=Philadelphia, o=Lannett Company Inc, cn=Kristie Stephens, email=kstephens@lannett.com
Date: 2021.08.04 10:36:40 -04'00'

Kristie Stephens
Vice President of Regulatory and Government Affairs