Genus Lifesciences Inc.
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August 9, 2024

Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville, MD 20855

RESPONSE TO PREA NON-COMPLIANCE LETTER

Reference: **NDA 200535**
Oxycodone Hydrochloride Oral Solution, 100 mg/5 mL (20 mg/mL) and 5 mg/5 mL, CII
Response to PREA Non-Compliance Letter
Sequence 0164

Dear Madam/Sir:

Reference is made to NDA 200535, Oxycodone Hydrochloride Oral Solution, 100 mg/5 mL (20 mg/mL) and 5 mg/5 mL, held by Genus Lifesciences Inc. (Genus), approved on October 10, 2010 and the associated Postmarketing Requirement (PMR) under the Pediatric Research Equity Act (PREA) 1695-1.

As previously agreed with the Division, additional cross-reference is made to Genus' collaborative partner [redacted] (b) (4) for Oxycodone Hydrochloride Oral Solution, 5 mg/5 mL.

Genus submitted a supplemental New Drug Application (sNDA) to the aforementioned NDA on January 17, 2020 to satisfy the full requirement for the PMR 1695-2. Genus also received Fulfillment of Post Marketing Requirement from FDA dated July 21, 2021 indicating that the requirements for PMR 1695-2 were fulfilled.

As committed within the PMRs, PMR 1695-2 must be completed and the final CSR submitted prior to initiating PMR 1695-1 to allow for the pharmacokinetic and safety data from this study, to dictate the proposed dosing for PMR 1695-1. Furthermore, during the teleconference with FDA held on May 23, 2019, the Agency discussed concerns with the proposed protocol for PMR 1695-1, submitted on August 17, 2017. As such, the updated Efficacy Study Protocol for PREA PMR 1695-1 was submitted on October 14, 2019.

Genus is completing the required PMR 1695-1 in collaboration with [redacted] (b) (4)

On December 6, 2023, Genus received guidance from Jaimin Patel, PharmD, Senior Regulatory Project Manager to submit a deferral extension request as the Agency has not yet made a determination regarding this study. Therefore, Genus submitted a deferral extension request on February 5, 2024 with a final report completion date of (b) (4) and this request is currently under review.

The deferral request of (b) (4) for study report completion is based on the anticipated time period necessary to reach an agreement with the Agency on the study protocol PREA PMR 1695-1 submitted October 14, 2019, the challenges associated with enrolling patients in the age group of 0 to < 2 years into an efficacy study with a pharmacokinetic component requiring multiple, sequential blood draws and the time required to prepare and finalize the study report including data compilation and analysis for submission of the sNDA.

Please do not hesitate to contact me by telephone at (610) 782-9780 ext. *210 or by email at breightler@genuslifesciences.com or Sherry Schultz at (610) 841-2540 or by email at sschultz@genuslifesciences.com with any questions or comments.

Sincerely,

William Reightler

William Reightler
Vice President of Regulatory Affairs
Genus Lifesciences Inc.

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This submission is compliant with FDA's Guidelines for Industry and current eCTD specifications.

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The IT point of contact for this submission is:

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