August 22, 2019

Office of Generic Drugs (HFD 600)
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
&
DEFERRAL EXTENSION REQUESTED

Reference: NDA 201194, Oxycodone Hydrochloride Oral Solution, USP 5 mg/5 mL, CII
eCTD 0064 – Response to PREA Non-Compliance Letter and Deferral Extension Request for PREA PMR 1863-1
Electronic Submission Size: 1 MB (Approx.)

Dear Madam/Sir:

Reference is made to NDA 201194, Oxycodone Hydrochloride Oral Solution, 5 mg/5 mL CII, held by VistaPharm, Inc. (VistaPharm), approved on January 12, 2012 and the associated Postmarketing Requirements (PMRs) under Pediatric Research Equity Act (PREA) 1863-1 and 1863-2. A cross-reference is made to IND 105754, Oxycodone Hydrochloride Oral Solution, 5 mg/5 mL.

Reference is made to the May 17, 2016 (Reference ID: 3932359), July 31, 2017 (Reference ID: 4132455) and February 22, 2019 (Reference ID: 4394649) FDA notifications with Deferral Request Granted for extension of final report submission dates for PREA PMRs, 1863-2 until June 2020 and 1863-1 until June 2019. Reference is also made to the FDA Non-Compliance letter dated July 9, 2019 received on July 16, 2019 due to failure to submit pediatric assessment final report for PMR 1863-1.

Further reference is made to the PREA Study Deferral Request submitted on March 15, 2019 (eCTD 0057), Teleconference with FDA held on April 1, 2019, and the General Correspondence filed on April 5, 2019 (eCTD 0059) to withdraw the PREA Study Deferral Request as agreed in the teleconference with FDA.

During the teleconference with FDA held on April 1, 2019 it was agreed that VistaPharm will close out the enrollment and will move as quickly as possible to accomplish the reporting by June 30, 2019; however, if the June 30, 2019 was not attainable, VistaPharm may request an extension at least 45 days before the final report submission due date (June 30, 2019).

It was VistaPharm's understanding from the Teleconference that since the final study report for 13 years to 17 years age group had already been submitted to the IND 105754 on July 27, 2018 (eCTD 0007), only the final study report for the age group >2 to <13 years submission was required. However, as per the Teleconference clarification email from Shelly Kapoor dated May 10, 2019, it was later on discovered by VistaPharm that in addition to the study data for age group >2 to <13 years, tables comparing the safety findings of the >2 to <13 years age group with the

>13 to 17 years age group needs to be included in the final study report. As such, VistaPharm needed more time to integrate the data. Hence, VistaPharm submitted another PREA Study Deferral Request for PMR-1 on May 15, 2019 (eCTD 0061) which is 45 days before the final report submission due date in accordance with the Agency's advice during April 1, 2019 teleconference.

In the teleconference with the Agency on June 20, 2019, VistaPharm was informed that the deferral request dated May 15, 2019 has not been granted and that we will receive a non-compliance letter for the PMR-1 commitment. Subsequently, VistaPharm received the Deferral Extension Denied letter from FDA dated June 28, 2019 on July 1, 2019 and the FDA Non-Compliance letter dated July 9, 2019 on July 16, 2019 due to failure to submit pediatric assessment final report for PMR 1863-1, which was deferred until June 30, 2019.

As agreed upon in the Teleconference with FDA held on June 20, 2019 and as per the Non-Compliance letter dated July 9, 2019, we are requesting the Agency to grant this deferral request for PMR 1863-1. VistaPharm's formal deferral request is provided in Section 1.9.2 Request for Deferral of Pediatric Studies.

Please be advised that VistaPharm has concluded the study and the final report is being compiled and is actively working to comply with the commitment of submitting the final reports for PMR 1863-1 at the earliest.

This submission has been created in eCTD format and its being submitted via Electronic Submission Gateway. An antivirus scan was conducted using Webroot Secured*Anywhere* Endpoint Protection version 9.0.26.61 and the submission is virus-free.

Should you have any questions, or require additional information related to this request, please contact me, at the information provided below.

Sincerely,

Deepa V. Adiga
Digitally signed by Deepa V. Adiga
Date: 2019.08.22 13:12:00 -04'00'

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