NOSTRUM LABORATORIES, INC.

1800 N Topping Ave, Kansas City, MO 64120. Tel: 816 308 4636 Fax: 816 308 4975

September 19, 2023

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Resources
5630 Fisher Lane, Room 1061
Rockville, MD 20852

REQUEST TO WITHDRAW SUITABILITY PETITION/Docket No. FDA-2022-P-0966

Re: Oxycodone Hydrochloride and Acetaminophen Oral Solution

Dear Sir or Madam,

Reference is made to the Suitability Petition docket number FDA-2022-P-0966 filed by Nostrum Laboratories, Inc. (NLI) on June 1, 2023.

As per the Agency email communication dated August 18, 2023, NLI is requesting the withdrawal of the Suitability Petition, Docket No. FDA-2022-P-0966.
We are planning to resubmit our suitability petition after October 1, 2023, to receive a goal date.

Any further communication regarding this correspondence should be directed to the attention of the undersigned at 732-993-6210 and/or via facsimile at 816-308-4975.

Sincerely,

Zoia Ploscaru
Digitally signed by Zoia Ploscaru
Date: 2023.09.19 14:19:29 -04'00'

Zoia Ploscaru,
Vice President, Regulatory Affairs
Nostrum Laboratories, Inc.
1800 N Topping Ave
Kansas City, MO 64120
Tel: 732-993-6210
Fax: 816-308-4975
Email: zploscaru@nostrumlabs.com

Zoia Ploscaru

From: ANDAFiling <ANDAFiling@fda.hhs.gov> on behalf of ANDAFiling
Sent: Friday, August 18, 2023 12:03 PM
To: zploscaru@nostrumlabs.com
Cc: ANDAFiling
Subject: Suitability Petition FDA-2022-P-0966 General Correspondence
Signed By: ANDAFiling@fda.hhs.gov

Dear Petitioner:

This email is regarding your suitability petition received on June 1, 2022, requesting that FDA determine and declare that the drug product, Oxycodone Hydrochloride and Acetaminophen Oral Solution, 2.5 mg/325 mg per 5 mL, 7.5 mg/325 mg per 5 mL, and 10 mg/325 mg per 5 mL, are suitable for submission in an Abbreviated New Drug Application ("ANDA"). (Docket No. FDA-2022-P-0966).

The Agency and industry agreed to certain commitments related to Suitability Petitions as part of the reauthorization of the Generic Drug User Fee Amendments and as described in "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023- 2027" (GDUFA III commitment letter)[1]. We note that, in accordance with the GDUFA III commitment letter FDA agreed to certain goals and procedures for the review of suitability petitions. FDA agreed to take appropriate action prior to FY 2024 to determine if petitioners who submitted suitability petitions prior to FY 2023 remain interested in a response. FDA also agreed that any suitability petition submitted in FY 2024-2027 will receive a goal date. More details about these goal dates are included in the GDUFA III commitment letter. Any suitability petitions submitted to FDA prior to FY 2024 will not receive a goal date. If a petitioner wants to receive a goal date on a suitability petition submitted prior to FY 2024, the petitioner may withdraw and submit a new suitability petition in FY 2024-2027.

In light of this commitment, you may want to consider withdrawing and resubmitting your suitability petition. In order to receive a goal date for a resubmitted petition, you must not resubmit before October 1, 2023; however, you do not need to wait until October 1, 2023 to withdraw your petition. In addition, if you no longer require an answer, you may also withdraw your petition. Instructions for how to withdraw and resubmit your petition are below.

To withdraw your petition, please submit a letter stating that you are withdrawing your petition. You should submit the letter electronically to the petition docket at www.regulations.gov (search for your petition docket number to find your petition. Then select Comment Now to upload your letter).

Suitability petitions are a type of Citizen Petition and are submitted through the Division of Dockets Management.

MAPP 5240.5 Rev. 2 entitled ANDA Suitability Petitions is publicly available. It provides additional information about the suitability petition process.

For questions regarding submitting a suitability petition, contact the FDA Office of Generic Drugs: GenericDrugs@fda.hhs.gov

Best Regards,

Division of Filing Review

Center of Drug Evaluation and Research
Office of Generic Drugs
U.S. Food and Drug Administration

ANDAFiling@fda.hhs.gov

[1] The GDUFA III Commitment Letter is available at: https://www.fda.gov/media/153631/download