June 1, 2022

Zoia Ploscaru
Nostrum Laboratories, Inc.
1800 N Topping Avenue
Kansas City, MO 64120

Sent via email to: zploscaru@nostrumlabs.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug declare that Oxycodone Hydrochloride and Acetaminophen Oral Solution, in strengths of 2.5 mg/325 mg per 5 mL, 7.5 mg/325 mg per 5 mL and 10 mg/325 mg per 5 mL strengths, are suitable for review under an Abbreviated New Drug Application (ANDA) supplement (PAS), pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act, as amended was received and processed under CFR 10.30 & 10.35 by this office on 06/01/2022.

It was assigned docket number FDA-2022-P-0966. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.06.01 17:02:04 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)