April 13, 2022

Scott Talbot
Odin Pharmaceuticals, LLC
300 Franklin Square Drive
Somerset, NJ 08873

Sent via email to: regulatory@odinpharm.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to determine whether the Reference Listed Drug, NORFLEX (Orphenadrine Citrate) Injection, 30 mg/mL, approved under New Drug Application 013055, held by PAI HOLDINGS LLC DBA PHARMACEUTICAL ASSOCIATES INC, has been voluntarily withdrawn for reasons of safety or effectiveness was received and processed under CFR 10.30 by this office on 04/12/2022.

It was assigned docket number FDA-2022-P-0585. Please refer to this docket number in future correspondence on this subject with the Agency.

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

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2022.04.13 11:01:00 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)