U.S. FOOD & DRUG ADMINISTRATION

Scott Talbot
Vice President, Quality and Regulatory Affairs
Odin Pharmaceuticals, LLC
300 Franklin Square Drive
Somerset, NJ 08873

October 7, 2022

Re: Docket No. FDA-2022-P-0585

Dear Mr. Talbot:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 12, 2022. Your petition requests that the Agency determine whether the reference listed drug, Norflex (orphenadrine citrate) Injection, 30 mg/mL, approved under New Drug Application 013055, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

David Joy -S
Digitally signed by David Joy -S
Date: 2022.10.07 09:21:35 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov