



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

December 8, 2022

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

Dear Mr. Talbot:

This letter responds to your citizen petition received on April 12, 2022, requesting that the Food and Drug Administration (FDA) determine whether the reference listed drug Norflex (orphenadrine citrate) Injection, 30 milligrams (mg)/milliliter (mL), approved under new drug application 013055, has been voluntarily withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Norflex (orphenadrine citrate) Injection, 30 mg/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Norflex (orphenadrine citrate) Injection, 30 mg/mL, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-2246.

Sincerely,

Anuj A. Shah -S

Digitally signed by Anuj A. Shah -
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Date: 2022.12.08 09:38:19 -05'00'

Anuj Shah, Senior Regulatory Counsel
Office of Regulatory Policy, DRP IV
Center for Drug Evaluation and Research

Enclosure