April 11, 2022

VIA ELECTRONIC SUBMISSION

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

CITIZEN PETITION

Dear Sir or Madam:

Odin Pharmaceuticals LLC submits this Petition in accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.

I. Action Requested

Petitioner requests that FDA determine whether the Reference Listed Drug ("RLD"), NORFLEX (Orphenadrine Citrate) Injection, 30 mg/mL, approved under New Drug Application (NDA) 013055, held by PAI HOLDINGS LLC DBA PHARMACEUTICAL ASSOCIATES INC, has been voluntarily withdrawn for reasons of safety or effectiveness.

II. Statement of Grounds

Under the FDC Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for an RLD. *See* FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. *See* 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). *See id.* § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book currently identifies NORFLEX (Orphenadrine Citrate) Injection, 30 mg/mL, approved on October 2, 1960 under NDA 013055, in the "Discontinued Drug Product List" section of the Orange Book. FDA appears to have moved NDA 013055 to the "Discontinued Drug Product List" in the March 2015 Cumulative Supplement to the Orange Book.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of NORFLEX (Orphenadrine Citrate) Injection, 30 mg/mL, under NDA 013055 was due only to commercial considerations.

Petitioner requests that FDA determine that NORFLEX (Orphenadrine Citrate) Injection, 30 mg/mL, approved under NDA 013055, was not withdrawn for reasons of safety or effectiveness.

III. Environmental Impact

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

IV. Economic Impact

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

V. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned. This petition includes all the information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Sincerely,

Scott Talbot Digitally signed by Scott Talbot
Date: 2022.04.12 08:52:53
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