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May 21, 2024

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20552

CITIZEN PETITION

Dear Sir/Madam:

Innogenix 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§§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.

A. Action Requested

Petitioner requests that FDA determine whether the Reference Listed Drug (RLD), **Flagyl®** (metronidazole) Tablets 250 mg and 500 mg; approved under New Drug Application **(NDA) N012623,** held by Pfizer Inc., has been voluntarily withdrawn for reasons of safety or effectiveness.

B. 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a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.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 If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing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. lf FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.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 **Flagyl®** (metronidazole) Tablets 250 mg and 500 mg, approved Prior to Jan 1, 1982 under **N012623**, in the " Discontinued Drug Product List" section of

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the Orange Book. FDA appears to have moved **N012623** to the "Discontinued Drug Product List" in October 2023 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 **Flagyl®** (metronidazole) Tablets 250 mg and 500 mg, under **N012623** was due only to commercial considerations.

Petitioner requests that FDA determine that **Flagyl®** (metronidazole) Tablets 250 mg and 500 mg, under **N012623**, was not withdrawn for reasons of safety or effectiveness.

C. Environmental Impact:

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

D. Economic Impact:

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

E. Certification:

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

Sincerely,
For Innogenix, LLC.

Sita Ramam Nuti

Digitally signed by Sita Ramam Nuti
Date: 2024.05.21 11:08:38 -04'00'

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