Aug 22, 2022

VIA ELECTRONIC SUBMISSION

Division of Dockets Management

Food and Drug Administration

Department of Health and Human Services

5630 Fishers Lane, Room 1061

Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam,

The undersigned submits this petition on behalf of a client, pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 C.F.R. § 10.25(a), § 10.30(b), and § 314.161, requesting the Commissioner of Food and Drug Administration ("FDA") to provide a determination on whether a listed drug was voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration to determine whether the Reference Listed Drug (RLD) OFIRMEV® (ACETAMINOPHEN) Injection, solution 1000 mg/100 mL (10 mg/mL) strength under New Drug Application ("NDA") 022450 held by Mallinckrodt Hosp Products IP Ltd., has been withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

Under the FD&C Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). See FD&C 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for the drug product, must petition FDA for a determination of whether the drug product was withdrawn for safety or effectiveness reasons. See 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug product was withdrawn from sale for safety or effectiveness reasons (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See id. § 314.162. If FDA determines that the listed drug was not withdrawn from sale for safety or effectiveness reasons, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book lists the OFIRMEV® (ACETAMINOPHEN) Injection, solution 1000 mg/100 mL 1000 mg/100 mL (10 mg/mL) strength, approved on Nov 02, 2010 under NDA 022450, in the "Discontinued Drug Product List" section of the Orange Book[1]. FDA appears to have moved 1000 mg/100 mL (10 mg/mL) strength of NDA 022450 to the "Discontinued Drug Product List" in the February 2022 Cumulative Supplement 02 to the 42nd Edition of 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 OFIRMEV® (ACETAMINOPHEN) Injection, solution, 1000 mg/100 mL (10 mg/mL) strength under NDA 022450 was due only to commercial considerations.

Petitioner requests that FDA determine that OFIRMEV® (ACETAMINOPHEN) Injection, solution, 1000 mg/100 mL (10mg/mL) strength under NDA 022450, were not withdrawn for reasons of safety or effectiveness reasons.

C. Environmental Impact

The petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31(a).

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 Petitioner that are unfavorable to the Petition.

[1] accessed on August 22, 2022

Please direct any questions or comments regarding this submission to the attention of Nehru Gaddipati, CEO, Phone: 646-476-1515, Email: Nehru.gaddipati@ninespharma.com.

Sincerely,

Nehru Gaddipati

Digitally signed by Nehru Gaddipati
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