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November 11, 2022

Division of Dockets Management

Department of Health and Human Services

Food and Drug Administration

5630 Fishers Lane, Room 1061, HFA-305

Rockville, MD 20852

CITIZEN PETITION

Dear Sir/Madam,

The undersigned, Baxter Healthcare Corporation (Baxter) 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§ 314.122 and § 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for reasons of safety or effectiveness.

A. Action Requested

Petitioner requests that FDA to determine whether D.H.E 45® (dihydroergotamine mesylate) injection, USP 1 mg/mL, approved under New Drug Application ("NDA") 005929, held by BAUSH HEALTH US LLC, has been voluntarily withdrawn for reasons of safety or effectiveness.

B. Statement of Grounds

Under the FDC Act, an ANDA must rely on FDA's approval findings for a Reference Listed Drug ("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to submit an Abbreviated NDA ("ANDA") for the drug must petition FDA for a determination of whether the drug was withdrawn for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 If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing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 the 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 If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies D.H.E 45® (dihydroergotamine mesylate) injection, USP 1 mg/mL, approved prior to January 1, 1982 under NDA 005929, in the "Discontinued Drug Product List" section (Attachment 1) 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 D.H.E 45® (dihydroergotamine mesylate) injection, USP 1 mg/mL under NDA 005929 was due to only commercial considerations. Hence, we are requesting that FDA formally determine that D.H.E 45® (dihydroergotamine mesylate) injection, USP 1 mg/mL, NDA No. 005929, was not withdrawn for 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 CFR § 25.31.

D. Economic Impact

Petitioner will, upon request by the Commissioner, submit an economic impact information, in accordance with 21 CFR § 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.

Baxter

Rajesh Gurjar

Digitally signed by: Rajesh Gurjar
DN: CN = Rajesh Gurjar
Date: 2022.11.11 17:21:41 +05'30'

Rajesh Gurjar
Senior Manager, Regulatory Affairs
Baxter Healthcare Corporation
Phone: (224) 285-9653
Fax: (224) 270-4119
E-mail: rajesh_gurjar@baxter.com