齐鲁制药(海南)有限公司
QILU PHARMACEUTICAL (HAINAN) CO., LTD.

July 24 2024

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, Qilu Pharmaceutical (Hainan) Co., Ltd. submits this Citizen Petition in accordance with 21 C.F.R. 10.25 (a) 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C.F.R. 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.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 JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg 6 mg, and 8 mg, approved under New Drug Application ("NDA") number 216951, held by GLAXOSMITHKLINE INTELLECTUAL PROPERTY NO 2 LTD ENGLAND, has been voluntarily withdrawn for reasons of safety or effectiveness.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an Abbreviated New Drug Application ("ANDA") for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.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 If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing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 If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.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 JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg 6 mg, and 8 mg, approved on Feb. 1, 2023 under NDA 216951, in the "Discontinued Drug Product List" section 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 JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg 6 mg, and 8 mg under NDA 216951 was due only to commercial considerations.

Petitioner requests that FDA determine that JESDUVROQ (daprodustat) tablets, 1 mg, 2 mg, 4 mg 6 mg, and 8 mg under NDA 216951, were not withdrawn for reasons of safety or effectiveness.

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.

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.

Sincerely,

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