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July 9, 2020

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

Citizen Petition

Dear Sir/Madam,

The undersigned submits this petition in accordance with 21 CFR parts 10.25, 10.30 and pursuant to Sections 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 CFR parts 314.122 and 314.161 requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether DOBUTREX (Dobutamine hydrochloride), EQ 12.5 MG BASE/ML, held by ELI LILLY AND CO. has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). The list, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book", lists all FDA approved drug products. DOBUTREX (Dobutamine hydrochloride), EQ 12.5 MG BASE/ML, was approved by the FDA prior to January 1, 1982, and the product was then considered to be a reference listed drug (RLD) in the Orange Book. (see attachment A)

In a Federal Register Notice, dated May 23, 2006, the FDA stated that the holder of DOBUTREX, NDA 017820, informed the Agency that the drug product was no longer marketed and requested that the approval of the application be withdrawn. Accordingly, the FDA withdrew approval of the application, effective June16, 2006 (see attachment B). The electronic Orange Book, accessed on June 22, 2020, identifies DOBUTREX (Dobutamine hydrochloride), EQ 12.5 MG BASE/ML, (N017820) as a discontinued drug product without any determination as to whether a listed drug is withdrawn from sale for safety and/or effectiveness reasons (see attachment A).

Under current FDA regulations, drugs are removed from the Orange Book list if the Agency withdraws or suspends approval of the drug product's applications for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

It is requested that the FDA determine whether the NDA holder for DOBUTREX (Dobutamine hydrochloride), EQ 12.5 MG BASE/ML, (N017820) has withdrawn the product for reasons of safety or effectiveness.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, Petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact

Pursuant to 21 CFR 10.30(b) an economic impact analysis will be provided upon request.

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 includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

Lund, Boyd M

Digitally signed by Lund, Boyd M
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Enclosures