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VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this Citizen Petition under the provisions of Section 505(j) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 10.25(a), 10.30, 314.122 and 314.161, requesting that the Commissioner of Food and Drugs determine that the reference listed drug ("RLD"), Merck's Decadron-LA, Dexamethasone Acetate Injection 8 mg/mL, NDA No. 16-675, was not withdrawn for reasons related to safety or effectiveness.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs make a determination that the RLD, Merck's Decadron-LA, Dexamethasone Acetate Injection 8 mg/mL, NDA No. 16-675, was not withdrawn from sale for reasons related to safety or effectiveness.

B. Statement of Grounds

The U.S. Food and Drug Administration ("FDA") maintains a list of drug products that are eligible for submission as abbreviated new drug applications ("ANDAs") (hereinafter "the List"). The *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book, contains all FDA-approved drug products. The RLD, Decadron-LA, Dexamethasone Acetate Injection 8 mg/mL, NDA No. 16-675, was approved by FDA, but is currently listed in the discontinued section of the Orange Book.

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Under FDA regulations, drugs are withdrawn from the List if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn, discontinued from marketing or withheld from sale for reasons of safety or effectiveness. 21 C.F.R. § 314.162. The regulations also provide that the agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. 21 C.F.R. § 314.161(a)(1).

The undersigned has no information or evidence concerning the reason that Merck discontinued selling Decadron-LA, Dexamethasone Acetate Injection 8 mg/mL, NDA No. 16-675. Nonetheless, the undersigned asserts that the discontinuation of the marketing of the product may well have been strictly an economic/strategic decision by Merck and is, therefore, totally unrelated to safety or efficacy.

C. Environmental Impact

A claim for categorical exclusion of the requirement of an environmental assessment is made pursuant to 21 C.F.R. §25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

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, which are unfavorable to the petition.

Sincerely yours,

David L. Rosen, R.Ph., J.D.