FOLEY
FOLEY & LARDNER LLP

ATTORNEYS AT LAW
WASHINGTON HARBOUR
3000 K STREET, N.W.
6TH FLOOR
WASHINGTON, D.C. 20007-5109
202.672.5300 TEL
202.672.5399 FAX
foley.com

WRITER'S DIRECT LINE
202.672.5430
drosen@foley.com EMAIL

February 26, 2013

VIA FEDERAL EXPRESS

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Foley & Lardner LLP (the "Petitioner") submits this Petition under the provisions of section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §§ 10.30, 314.93 and 314.161 requesting that the Commissioner of Food and Drugs issue a determination that Cytoxan® for Injection, originally approved by FDA as a lyophilized powder under NDA 12-142 was not withdrawn for reasons related to safety or effectiveness.

A. Action Requested

This petition requests FDA to determine whether Cytoxan for Injection, originally approved by FDA as a lyophilized powder under NDA 12-142 has been voluntarily withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

I. The above-referenced drug product, Cytoxan (cyclophosphamide) for Injection NDA # 12-142, was originally approved on November 16, 1959. The product was approved as a dry powder form which included sodium chloride.

II. On January 4, 1984, Bristol obtained approval for a new formulation, cyclophosphamide lyophilized (which included mannitol in the formulation), under NDA 12-142 (supplement number 058). Bristol discontinued marketing of the Cytoxan sodium chloride powder product in 1997.

III. On November 7, 2003, Bristol obtained approval for the current dry powder formulation (cyclophosphamide alone) and discontinued sale of the lyophilized product. The Petitioner knows of no information or documentation that establishes that the lyophilized formulation was with voluntarily withdrawn from sale for reasons of safety or efficacy. This product is now currently marketed by Baxter Healthcare.

IV. On March 1, 2004, FDA determined that the Cytoxan sodium chloride powder product was not withdrawn from sale reasons of safety or efficacy (see FDA Docket No. 01P-0333). Generic ready to use solution and lyophilized cyclophosphamide products were approved and subsequently discontinued from the market.

V. Under FDA regulations, an abbreviated new drug application ("ANDA") seeking approval of a generic product referencing a discontinued product must be accompanied by a Citizen Petition for FDA's determination that the discontinued reference listed drug was not voluntarily withdrawn for safety or efficacy reasons.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR § 25.31.

D. Economic Impact

By allowing the submission and filing of an ANDA for a Cyclophosphamide for Injection lyophilized formulation, the public will be afforded access to a, high quality, lower cost, therapeutically equivalent version of the reference listed drug. Having another formulation, i.e., a lyophilized form will also help ensure that there are alternative products available in the event that there is a drug shortage associated with the dry powder formulations.

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.

David L. Rosen, B.S. Pharm., J.D.
Foley & Lardner LLP
3000 K Street, NW, 6th Floor
Washington, DC 20007-5143
(202) 672-5430
(202) 672-5399 (fax)

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