Gordon Johnston Regulatory Consultants, LLC

December 13, 2013

2013 DEC 17 P 12:14

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

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate, pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161 on behalf of an interested party 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.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 Leucovorin Calcium Injection-Preservative Free, 10 mg/1mL, 10 mL total fill volume (ANDA 40147) held by Hospira has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.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 which 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. Leucovorin Calcium Injection-Preservative Free, 10 mg/mL, 10 mL total fill volume (001) was approved by the FDA on June 25, 1997. The product was then considered to be a "listed drug product" in the Orange Book. ANDA 40147 now appears in the "Discontinued Section" of the Orange Book (see attachment A).

The FDA has approved multiple applications for Leucovorin Calcium Injection-Preservative Free with different strengths (total fill volumes) that are currently marketed. See attachment B.

Gordon Johnston Regulatory Consultants, LLC

3631 Martins Dairy Circle Olney, MD 20832 ♦ Phone 240-401-7616
Fax 301.570.7075 ♦ email: johnstongj@aol.com

2013-10313

FDA-2013-P-1654

CP

Under 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drug product's applications for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). Applicants may also voluntarily withdraw safe and effective drug products from sale for business or other reasons. The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).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 ANDA holder has discontinued its Leucovorin Calcium Injection-Preservative Free, 10 mg/mL, 10 mL total fill volume product for reasons of safety or effectiveness.

C. Environmental Impact

In accordance with the requirements set forth in 21 CFR 25.31, Gordon Johnston Regulatory Consultants, LLC 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

Gordon Johnston Regulatory Consultants, LLC 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.

Respectfully Submitted,

Gordon Johnston

Attachments: A. Product Listing from the Discontinued Section of Orange Book
B. Product Listing from the Active Section of the Orange Book

cc: Iain Margand (Office of Generic Drugs)

Gordon Johnston Regulatory Consultants, LLC

3631 Martins Dairy Circle Olney,MD 20832 ♦ Phone 240-401-7616
Fax 301.570.7075 ♦ email: johnstongj@aol.com

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