



Fresenius Kabi USA, LLC

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04 October 2020

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

**CITIZEN PETITION**

Dear Sir/Madam:

Fresenius Kabi USA, LLC (FK USA) submits this petition pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 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the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug product has been withdrawn for reasons of safety or efficacy.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**

FK USA requests that the Commissioner of the Food and Drug Administration determine whether the NDA holder (Abraxis Pharmaceutical Products) for Manganese Sulfate, Eq 0.1mg manganese/mL, (NDA 019228) has withdrawn the product for reasons of safety or efficacy.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. Manganese Sulfate Eq 0.1mg manganese/mL, (NDA 019228) held by Abraxis Pharmaceutical Products was approved on May 5, 1987. Manganese Sulfate Eq 0.1mg manganese/mL, (NDA 019228) now appears in the "Discontinued Section" of the Orange Book (see attachment A).

Under FDA regulations, drugs are removed from the Orange Book list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the Agency determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162).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 The regulations provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161 (a)(1)).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requested that the FDA determine whether the NDA holder for Manganese Sulfate Eq 0.1mg manganese/mL, (NDA 019228) has withdrawn the products for reason of safety of effectiveness.

### **C. Environmental Impact**

In Accordance with the requirements set forth in 21 CFR 25.31, the 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**

FK USA 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 is unfavorable to the petition.

Sincerely,

**Aparna  
Dagar**

Digitally signed by Aparna Dagar  
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**Attachment A:** Product listing from the current (04 October 2020) Orange Book listing