VIA ELECTRONIC SUBMISSION

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January 30, 2019

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

CITIZEN PETITION

The undersigned submits this petition on behalf of a client pursuant to the Federal Food, Drug and Cosmetic Act ("FD&C Act") and in accordance with regulations at 21 C.F.R. §§ 10.25(a), 10.30(b), and 314.161, requesting the Commissioner of Food and Drugs to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. ACTION REQUESTED

The Petitioner requests that the Commissioner of the Food and Drug Administration determine whether the Reference Listed Drug (RLD) Tham Solution (Tromethamine Injection), New Drug Application (NDA) No. N013025 ("Tromethamine"), held by Hospira Inc. ("Hospira"), has been voluntarily withdrawn from the commercial market or withdrawn from sale for safety or efficacy reasons.

B. STATEMENT OF GROUNDS

The Food and Drug Administration maintains a list of drug products in the Orange Book. These drug products are eligible for submission under Section 505(j) of the FD&C Act as ANDAs. Tham Solution was approved prior to January 1, 1982.

If an RLD appears in the Discontinued Section of the Orange Book and the FDA has not determined whether the drug was withdrawn from sale for reasons of safety or effectiveness, the applicant must submit a citizen petition under 21 C.F.R. §§ 10.25(a) and 10.30 before or at the same time as the ANDA submission, seeking a determination on whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. Such a petition must contain all evidence available to the petitioner concerning the reason that the drug product was withdrawn from sale under 21 C.F.R. § 314.122(a). If the FDA determines that the listed drug was

withdrawn from sale for reasons of safety or effectiveness, then the drug listing is removed from the Orange Book. *See* 21 C.F.R. §§ 314.122, 314.161, and 314.162.

Petitioner is unaware of any reason why Tham Solution may have been removed from sale.

C. ENVIRONMENTAL IMPACT

The actions requested in this petition are subject to a categorical exclusion under 21 C.F.R. § 25.31 or an environmental assessment under 21 C.F.R. § 25.40.

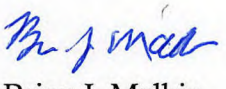
D. ECONOMIC IMPACT

According to 21 C.F.R. § 10.30(b), the petitioner will, upon request by the Commissioner, submit economic impact information.

E. CERTIFICATION

The undersigned certifies 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 is unfavorable to the petition.

Sincerely,



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