



Brian J. Malkin  
Arent Fox LLP  
1717 K Street, NW  
Washington, DC 20006

Re: Docket No. FDA-2019-P-0692

JUL 03 2019

Dear Mr. Malkin:

This letter responds to your citizen petition received on January 30, 2019 (Petition), requesting that the Food and Drug Administration (FDA) determine whether Tham Solution (tromethamine) injectable, 3.6 grams (g)/100 milliliters (mL), was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Tham Solution (tromethamine) injectable, 3.6 g/100 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Tham Solution (tromethamine) injectable, 3.6 g/100 mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-1054.

Sincerely,

Katelyn Mineo  
Office of Regulatory Policy  
Center for Drug Evaluation and Research

Enclosure