U.S. FOOD & DRUG ADMINISTRATION

Boyd Lund
Cardinal Health Regulatory Sciences
7400 W 11th Street
Overland Park, KS 66210

Re: Docket No. FDA-2019-P-1366

JUL 0 3 2019

Dear Mr. Lund:

This letter responds to your citizen petition received on March 21, 2019 (Petition). In your Petition you request that the Food and Drug Administration (FDA) determine whether CLAFORAN (Cefotaxime Sodium for Injection, 500 milligrams (mg), 1 gram (g), 2 g, and 10 g/vial) held by US Pharmaceutical Holdings II LLC was voluntarily withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Claforan (Cefotaxime Sodium for Injection, 500 mg, 1 g, 2 g, and 10 g/vial), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Claforan (Cefotaxime Sodium for Injection, 500 mg, 1 g, 2 g, and 10 g/vial, 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 (240) 402-7133

Sincerely,

Beth Holck

Beth Holck
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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Silver Spring, MD 20993
www.fda.gov