Boyd Lund
Director, Chemistry, Manufacturing, and Controls
Cardinal Health Regulatory Sciences
7400 W 110th Street
Overland Park, KS 66210

December 21, 2020

Re: Docket No. FDA-2020-P-1650

Dear Mr. Lund:

This letter responds to your citizen petition received on July 9, 2020, requesting that the Food and Drug Administration (FDA) determine whether DOBUTREX (dobutamine hydrochloride), equivalent 12.5 milligram base/milliliter, held by Eli Lilly and Co., was voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.

FDA has reviewed its records and determined that Dobutrex (dobutamine hydrochloride), equivalent 12.5 milligram base/milliliter, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Dobutrex (dobutamine hydrochloride), equivalent 12.5 milligram base/milliliter, 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) 796-9120.

Sincerely,

Jessica G. Tierney -S

Digitally signed by Jessica G. Tierney -S
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Jessica Tierney
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure