DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

July 10, 2020

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

Sent via email to: boyd.lund@cardinalhealth.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to determine whether DOBUTREX (Dobutamine hydrochloride), EQ 12.5 MG BASE/ML, held by ELI LILLY AND CO. has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy was received by this office on 07/09/2020.

It was assigned docket number FDA-2020-P-1650. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.10 12:42:59 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)