DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

July 20, 2020

Boyd Lund, Director, CMC
Cardinal Health Regulatory Sciences
7400 West 110th St., Ste. 300
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 to determine whether Nipride RTU (sodium nitroprusside), 10 MG/50 ML (0.2 MG/ML), (NDA 209387) held by EXELA PHARMA SCS LLC has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy was received by this office on 07/16/2020.

It was assigned docket number FDA-2020-P-1678. 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: 2020.07.20 09:40:54 -04'00'

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