U.S. FOOD & DRUG ADMINISTRATION

Boyd Lund
Director, CMC
Cardinal Health Regulatory Sciences
7400 West 110th St., Ste. 300
Overland Park, KS 66210

January 15, 2021

Re: Docket No. FDA-2020-P-1678

Dear Mr. Lund:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on July 16, 2020. Your petition requests that the Food and Drug Administration (FDA) determine whether Nipride RTU (sodium nitroprusside), 10 milligrams (mg)/50 milliliters (mL) (0.2 mg/mL) (NDA 209387), held by Exela Pharma Sciences, LLC, has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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Carol J. Bennett
Deputy Director
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