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

March 16, 2021

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

Dear Mr. Lund:

This letter responds to your citizen petition received on July 15, 2020, requesting that the Food and Drug Administration (FDA) determine whether Nipride RTU (sodium nitroprusside), 10 milligrams (mg)/50 milliliters (mL) (0.2 mg/mL) (new drug application 209387), held by Exela Pharma Sciences, LLC, has been voluntarily withdrawn or withheld from sale for reasons of safety or efficacy.

FDA has reviewed its records and determined that Nipride RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Nipride RTU (sodium nitroprusside), 10 mg/50 mL (0.2 mg/mL), 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) 796-3478.

Sincerely,

Michael D. Bernstein -S

Digitally signed by Michael D. Bernstein -S
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Date: 2021.03.16 10:32:34 -04'00'

Michael Bernstein
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure