Madhusudan Rao
Chief Operating Officer
BE Pharmaceuticals AG
3 Bundesstrasse, Zug
Canton of Zug, Switzerland - 6302

May 25, 2023

Re: Docket No. FDA-2022-P-2952

Dear Mr. Rao:

This letter responds to your citizen petition received on November 18, 2022 (Petition). In the Petition you request that the Food and Drug Administration (FDA) determine whether HEPARIN SODIUM Injection 5000 USP Units (IU)/Milliliters (mL), has been withdrawn from sale for safety or efficacy reasons.

FDA has reviewed its records and determined that HEPARIN SODIUM Injection 5000 USP IU/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain HEPARIN SODIUM Injection 5000 USP IU/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) 796-3601.

Sincerely,

nicole mueller
Digitally signed by nicole mueller
Date: 2023.05.25 07:10:46 -04'00'

Nikki Mueller
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

bcc:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
w ww.fda.gov