November 18, 2022

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

Sent via email to: Madhu.B@biologicale.com

Dear Petitioner:

Your submission requesting that the Commissioner determine whether Heparin sodium injection, 5000 USP Units/mL of Fresenius Kabi USA LLC approved by FDA under NDA 017029 has been voluntarily withdrawn from sale for safety or effectiveness reasons was received and processed under CFR 10.30 by this office on 11/18/2022.

It was assigned docket number FDA-2022-P-2952. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S
Digitally signed by Karen P. Malvin -S
Date: 2022.11.18 16:11:46 -05'00'

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)