



BE Pharmaceuticals AG

CHE – 163.345.959

October 18, 2022

VIA ELECTRONIC SUBMISSION

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

BE Pharmaceuticals AG (the “Petitioner”) submits this Petition under the provisions of section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act and 21 CFR §§ 10.30, 314.93, 314.122 and 314.161 requesting that the Commissioner of Food and Drugs issue a determination that Heparin sodium injection, 5000 USP Units/mL of Fresenius Kabi USA LLC approved by FDA under NDA 017029 was not withdrawn for reasons related to safety or effectiveness.

A. Action Requested

This petition requests FDA to 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sodium injection, 5000 USP Units/mL of Fresenius Kabi USA LLC approved by FDA under NDA 017029 has been voluntarily withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

- I. The above-referenced drug product, Heparin sodium injection, 5000 USP Units/mL of Fresenius Kabi USA LLC approved by FDA under NDA 017029 was originally approved prior to January 01, 1982
- II. The product is currently listed in the FDA’s Orange Book as Discontinued.
- III. BE Pharmaceuticals AG is not aware of any documentation establishing that the product Heparin sodium injection, 5000 USP Units/mL of Fresenius Kabi USA LLC approved by FDA under NDA 017029 was discontinued for reasons related to safety or effectiveness.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 CFR § 25.31.



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D. Economic Impact

Pursuant to 21 CFR § 10.30(b), economic impact information is submitted only upon the Commissioner's request.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.

Sincerely,

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