B. Braun Medical Inc.
Regulatory Affairs
901 Marcon Blvd.
Allentown, PA 18109

January 10, 2022

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

RE: NDA 019802, Heparin Sodium in Sodium Chloride Injection in Plastic Container
Citizen Petition - Not Withdrawn for Safety or Effectiveness Reasons

Dear Sir/Madam:

The following citizen petition is being submitted by B. Braun Medical Inc.

Citizen Petition

The undersigned submits this petition under the authority of 21 CFR §§ 10.25(a) and 10.30 and in accordance with 21 CFR 314.161(b) to request that the Commissioner of Food and Drugs make a determination that specific listed drug products have not been withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The Petitioner (B. Braun Medical Inc.) requests that the Commissioner of the Food and Drug Administration determine that Heparin Sodium in Sodium Chloride Injection in Plastic Container products listed below, approved under NDA 019802, held by B. Braun Medical Inc., were not withdrawn from marketing for safety or effectiveness reasons.

- Heparin Sodium 12,500 Units (5,000 Units/100 mL) in 0.45% Sodium Chloride Injection
- Heparin Sodium 25,000 Units (5,000 Units/100 mL) in 0.45% Sodium Chloride Injection
- Heparin Sodium 25,000 Units (10,000 Units/100 mL) in 0.45% Sodium Chloride Injection
- Heparin Sodium 25,000 Units (5,000 Units/100 mL) in 0.9% Sodium Chloride Injection

B. Statement of Grounds

The Food and Drug Administration maintains a list of all FDA approved drug products. This "List" is referred to as the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"). The "Orange Book" contains products for which the FDA has made a determination that they were not withdrawn for safety or effectiveness reasons, along with products for which FDA has not yet made such a determination.

B. Braun Medical withdrew NDA 019802 in 2016. The withdrawal notification was posted in the Federal Register on June 21, 2017 (Ref: FR FDA-2017-N-3203-0001). The above referenced Heparin Sodium in Sodium Chloride Injection in Plastic Container products, approved under NDA 019802,

appear on the Discontinued Drug Products List, but there is no notation on the List as to whether they were withdrawn for safety or effectiveness reasons. To the best knowledge and belief of the Petitioner, no safety or effectiveness issues have arisen with respect to NDA 019802 or with any of the Heparin Sodium in Sodium Chloride drug in Plastic Container products approved under this application. Accordingly, the Petitioner respectfully requests that the Commissioner of Food and Drugs determine that the above referenced Heparin Sodium in Sodium Chloride Injection in Plastic Container products, approved under NDA 019802, were **not** withdrawn for safety or effectiveness reasons.

The appropriate page from the electronic edition of the Orange Book is enclosed for your reference.

C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. The Petitioner hereby commits to promptly provide this information, if so requested.

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 is unfavorable to the petition.

Yours truly,

Cindy Katsempris

Electronically signed by: Cindy Katsempris Reason: For the reason(s) specified in the document. Date: Jan 10, 2022 11:03 EST

Cindy Katsempris
Director, Regulatory Affairs
B. Braun Medical Inc.