



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

March 10, 2020

Cindy Katsempris
Director, Regulatory Affairs
B. Braun Medical Inc.
901 Marcon Boulevard
Allentown, PA 18109

Sent via email to: cindy.katsempris@bbraunusa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to add therapeutic equivalence ratings for various B. Braun drug products in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) was received by this office on 03/09/2020.

It was assigned docket number FDA-2020-P-1065. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)