



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

September 2, 2020

Re: Docket No. FDA-2020-P-1065

Dear Ms. Katsempiris:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 9, 2020. Your petition requests that the Agency add a therapeutic equivalence rating of “AP” for various B. Braun drug products in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research