DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 2, 2020

Sheila Denton
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Boehringer Ingelheim USA Corporation
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Ridgefield, CT 06877

Sent via email to: sheila.denton@boehringer-ingelheim.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA the Commissioner to take the following actions with respect to parenteral solutions regulated as biological products under section 351 of the PHS Act (42 U.S.C. § 262):

1. Interpret the term "strength" as used in section 351(k) of the PHS Act (42 U.S.C. § 262(k)) to mean the "total drug content" in the relevant container (*e.g.*, singledose vial, prefilled syringe) without regard to concentration or total volume;

2. Revise applicable Agency guidance documents, including FDA's *Draft Guidance for Industry: New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2)* (Dec. 2018), *Guidance for Industry: Questions and Answers on Biosimilar Development and the BPCI Act (Revision 1)* (Dec. 2018), and *Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act* (Nov. 2020), to be consistent with this interpretation; and

3. Apply this interpretation to pending and approved 351(k) applications, amendments, and supplements, including in advice provided during Biosimilar Biological Product Development ("BPD") meetings and in review correspondence (*e.g.*, Complete Response Letters).

Your submission was received by this office on 12/02/2020 and assigned docket number FDA-2020-P-2247. 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,

Dynna Gorham-Bigby
Digitally signed by Dynna Gorham-Bigby
Date: 2021.02.26 11:11:44 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)