June 16, 2022

Sheila Denton, Esq.
Senior Vice President and General Counsel
Boehringer Ingelheim USA Corporation
900 Ridgebury Road
Ridgefield, CT 06877

Re: Docket No. FDA-2020-P-2247

Dear Ms. Denton:

Your letter to Commissioner Califf dated May 19, 2022, was forwarded to the Office of Regulatory Policy in the Food and Drug Administration's (FDA or the Agency) Center for Drug Evaluation and Research for response.

In your letter, you refer to the citizen petition received by FDA on December 2, 2020, that you submitted on behalf of Boehringer Ingelheim Pharmaceuticals, Inc. Your petition requests that the Agency interpret the term "strength" in section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) with respect to parenteral solutions to mean the "total drug content" in the relevant container without regard to concentration or total volume. Your petition also requests that FDA revise applicable Agency guidance documents to be consistent with this interpretation and apply this interpretation to pending and approved 351(k) applications, amendments, and supplements, including in advice provided during Biosimilar Biological Product Development meetings and in review correspondence.

Your recent letter requests that Commissioner Califf "instruct responsible FDA officials to rule on the Citizen Petition immediately."

Thank you for your continued interest in your citizen petition. As noted in the interim response that we provided to you in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)), FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. We will respond to your petition as soon as we have reached a decision on your request. The Agency does not otherwise comment on the status of pending citizen petitions.

Sincerely,

Elizabeth R. Jungman -S

Digitally signed by Elizabeth R. Jungman -S
Date: 2022.06.16 11:25:51 -04'00'

Elizabeth Jungman
Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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