U.S. FOOD & DRUG ADMINISTRATION

May 28, 2021

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

Sent via e-mail to sheila.denton@boehringer-ingelheim.com

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

Dear Ms. Denton:

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 December 2, 2020, and 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.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2021.05.27 15:51:57 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov