



Kiran Krishnan, PhD  
Senior Vice President, Global Regulatory Affairs  
Apotex Inc.  
150 Signet Drive  
Toronto, ON M9L 1T9

June 8, 2023

Re: Docket No. FDA-2022-P-3206

Dear Kiran Krishnan:

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 14, 2022. Your petition requests that the Agency assign a Therapeutic Equivalence Code of “AP” to Apotex’s Bendamustine Hydrochloride Injection, 100 milligrams (mg)/4 milliliter (mL) (25 mg/mL), New Drug Application number 215033.

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  
Date: 2023.06.08 10:12:48  
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Carol J. Bennett  
Deputy Director  
Office of Regulatory Policy  
Center for Drug Evaluation and Research