



December 14, 2022

Kiran Krishnan, PhD
Apotex Inc.
150 Signet Drive
Toronto, ON M9L 1T9

Sent via email to: asteinbl@apotexcorp.com

Dear Petitioner:

Your submission requesting that the Commissioner to assign a Therapeutic Equivalence Evaluation Code to Apotex's Bendamustine Hydrochloride Injection, 100 mg/4 mL (25 mg/mL), NDA No. 215033 was received and processed under CFR 10.30 by this office on 12/13/2022.

It was assigned docket number FDA-2022-P-3206. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)