Kurt R. Karst
Hyman, Phelps, & McNamara, PC.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

December 11, 2020

Re: Docket No. FDA-2020-P-1626

Dear Mr. Karst:

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 July 1, 2020. Your petition requests that the Agency designate Vancocin (vancomycin hydrochloride) oral solution, 250 milligrams (mg) / 5 milliliters (mL) and 500 mg/6 mL, approved under abbreviated new drug application (ANDA) 061667 as reference listed drugs (RLDs), and amend the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) to reflect these products' RLD status.

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
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Date: 2020.12.11 10:11:47 -05'00'

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