



April 6, 2022

Maria Hinklin, Associate Director
Hospira Inc., a Pfizer Company
275 North Field Drive
Lake Forest, IL 60045

Sent via email to: maria.hinklin@pfizer.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine that Vancomycin Hydrochloride for Injection, USP, ADD-Vantage® Vial, 1.25 grams (base)/vial is suitable for ANDA submission as an additional strength was received and processed under CFR 10.30 by this office on 04/05/2022.

It was assigned docket number FDA-2022-P-0535. Please refer to this docket number in future correspondence on this subject with the Agency.

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

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)