**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 18, 2019

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

*Sent via email to: kkarst@hpm.com*

Dear Petitioners:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA determine that Cefazolin for Injection USP, 3 g vial-administered via intramuscular injection, intravenous direct (bolus) injection, and intravenous infusion-is suitable for submission as an ANDA was received by this office on 09/17/2019.

It was assigned docket number FDA-2019-P-4362. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.09.18 16:22:50 -04'00'

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