DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

October 1, 2020

Philip J Almeter
Kentucky Drug Quality Study
800 Rose Streer, Room H110
Lexington, KY 40536

Sent via email to: philip.almeter@uky.edu

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting:

1) A recall on identified lots of Acetazolamide for injection on the basis that, due to under-potency and excessive impurities in some vials, these drugs are adulterated under Section 501 of the FDCA (21 U.S.C. § 351) and misbranded under Section 502 of the FDCA (21 U.S.C. § 352)

2) Conduct examinations and investigation under Section 702(a) of the FDCA (21 U.S.C. § 372(a)) regarding these products, their manufacturing processes, and the manufacturer submissions made for FDA approval under 704(a) of the FDCA (21 U.S.C. § 374(a)) and effect labeling revisions as needed

3) Provide information to the public regarding this product under Section 705(b) of the FDCA (21 U.S.C. § 375(b))

4) Promulgate regulations requiring robust independent chemical batch-level testing and verification of the chemical content of batches of pharmaceuticals of drugs and, while these regulations are pending, issue guidance requesting such testing and verification

was received by this office on 09/30/2020.

It was assigned docket number FDA-2020-P-2033. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.10.01 14:27:07 -04'00'

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