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Re: Docket No. FDA-2020-P-2033

March 29, 2021

Dear Petitioners:

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 September 30, 2020, and submitted on behalf of the University of Kentucky Drug Quality Study team. Your petition requests that the Agency take the following actions:

1. request 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)); and
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.

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 requests.

Sincerely,

David Joy -S

Digitally signed by David Joy -S
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
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