Guvam Pharma LLC
33 South Wood Avenue, Suite 600
Iselin, NJ 08830
Attention: Mahender Korapati

Docket No. FDA-2019-P-5791

Dear Mahender Korapati:

This is in response to your petition received on December 8, 2019, by the U.S. Food and Drug Administration (FDA), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug products: Phenazopyridine Hydrochloride Tablets 50 mg, 100 mg, and 200 mg. The listed drug products to which you refer in your petition are Azo Gantanol (phenazopyridine hydrochloride and sulfamethoxazole) tablets, 100 mg; 500 mg, and Azo Gantrisin (phenazopyridine hydrochloride and sulfisoxazole) tablets, 50 mg; 500 mg, approved under New Drug Applications (NDAs) 013294 and 019358, respectively, held by Hoffman La Roche Inc, and sulfamethoxazole and trimethoprim tablets, 800 mg; 160 mg, and phenazopyridine hydrochloride tablets, 200 mg, approved under NDA 021105, held by Able Laboratories, Inc.

Your request involves a change in the active ingredients from that of the listed drug products (i.e., from phenazopyridine hydrochloride and sulfamethoxazole to phenazopyridine hydrochloride; from phenazopyridine hydrochloride and sulfisoxazole to phenazopyridine hydrochloride; and from sulfamethoxazole, trimethoprim, and phenazopyridine hydrochloride to phenazopyridine hydrochloride). The change that you request is not a type of change for which the Agency will accept a petition under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act) and the implementing regulations at 21 CFR 314.93, which only allow for differences in route of administration, dosage form, or strength from that of a listed drug, or for one active ingredient to be substituted for one of the active ingredients in a listed combination drug. Because the change that you request is not one of the aforementioned changes described in section 505(j)(2)(C) of the Act and 21 CFR 314.93, the Agency does not approve your petition.

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the decision not to approve your petition following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

William H. Chong -S

Digitally signed by William H. Chong -S
Date: 2023.12.01 14:38:35 -05'00'

William Chong
Director, Office of Safety and Clinical Evaluation
for Ilun Murphy
Director
Office of Generic Drugs
Center for Drug Evaluation and Research