U.S. FOOD & DRUG ADMINISTRATION

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

March 6, 2023

Re: Docket No. FDA-2022-P-2229

Dear Mr. Karst:

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 13, 2022. Your petition requests that the Agency determine whether Hydrochlorothiazide Oral Solution, 50 mg/mL, Abbreviated New Drug Application (ANDA) 088587, was withdrawn for reasons of safety or effectiveness.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S
Digitally signed by Carol Bennett -S
Date: 2023.03.06 11:42:41 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

U.S. Food & Drug Administration
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