U.S. FOOD & DRUG ADMINISTRATION

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

May 11, 2023

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

Dear Mr. Karst:

This letter responds to your citizen petition received September 13, 2022, requesting that the Food and Drug Administration (FDA) determine whether hydrochlorothiazide oral solution, 50 milligrams (mg)/5 milliliters (mL), approved under abbreviated new drug application 088587, held by Roxane Laboratories, Inc., has been withdrawn for reasons of safety or effectiveness.

FDA has reviewed its records and determined that hydrochlorothiazide oral solution, 50 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain hydrochlorothiazide oral solution, 50 mg/5 mL, in the "Discontinued Drug Product List" section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 796-2395.

Sincerely,

Alaina M. Kupperman -S

Digitally signed by Alaina M. Kupperman -S
Date: 2023.05.11 13:57:23 -04'00'

Alaina Kupperman
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

U.S. Food & Drug Administration
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