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

November 19, 2024

Re: Docket Nos. FDA-2020-P-1991 and FDA-2021-P-0940

Dear Mr. Karst:

This letter responds to your citizen petitions received on September 21, 2020, and August 25, 2021, requesting that the Food and Drug Administration (FDA) determine whether Hydrocortone (hydrocortisone sodium phosphate) injection, Equivalent to (EQ) 50 milligrams (mg) base/milliliter (mL), was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and determined that Hydrocortone (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Hydrocortone (hydrocortisone sodium phosphate) injection, EQ 50 mg base/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 (240)-402-7133.

Sincerely,

Beth R. Holck -S

Digitally signed by Beth R. Holck -S
Date: 2024.11.19 10:10:21 -05'00'

Beth Holck
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure