Kurt R. Karst
Hyman, Phelps & McNamara, P.C.
700 13th Street, N.W., Suite 1200
Washington, D.C. 20005-5929

March, 18, 2021

Re: Docket No. FDA-2020-P-1991

Dear Mr. Karst:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on September 21, 2020. Your petition requests that the Agency determine whether Hydrocortone (hydrocortisone sodium phosphate) injection, 50 mg base/mL approved under NDA 012052 was voluntarily withdrawn for reasons of safety or efficacy.

FDA has been unable to reach a decision on your petition due to 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 we have reached a decision on your request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2021.03.18 12:26:05 -04'00'

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

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