DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 21, 2020

Kurst Karst
Law Office Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W., Suite 1200
Washington, DC 20005

Sent via email to: kkarst@hpm.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to determine whether HYDROCORTONE (hydrocortisone sodium phosphate) Injection, 50 mg base/mL, approved under New Drug Application ("NDA") number 012052, held by Merck and Co. Inc., has been voluntarily withdrawn for reasons of safety or effectiveness was received by this office on 09/21/2020.

It was assigned docket number FDA-2020-P-1991. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.09.21 14:50:34 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)