LAW OFFICES
HYMAN, PHELPS & MCNAMARA, P.C.
700 THIRTEENTH STREET, N.W.
SUITE 1200
KURT R. KARST WASHINGTON, D.C. 20005-5929 Direct Dial (202) 737-7544
(202) 737-5600 Kkarst@hpm.com
FACSIMILE
(202) 737-9329
www.hpm.com

September 21, 2020

**VIA ELECTRONIC SUBMISSION**

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

# CITIZEN PETITION

Hyman, Phelps & McNamara, P.C. submits this Petition in accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.

## A. ACTIONS REQUESTED

Petitioner requests that FDA 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mg base/mL, approved under New Drug Application ("NDA") number 012052, held by Merck and Co. Inc., has been voluntarily withdrawn for reasons of safety or effectiveness.

## B. STATEMENT OF GROUNDS

Under the FDC Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). *See* FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. *See* 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. *See id.* § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies HYDROCORTONE, approved on June 8, 1960 under NDA 012052, in the "Discontinued Drug Product List" section of the Orange Book. FDA appears to have moved NDA 012052 to the "Discontinued Drug Product List" in the April 2003 Cumulative Supplement to the Orange Book. In May 2004, FDA published a notice in the *Federal Register* that approval of NDA 012052 for HYDROCORTONE was being withdrawn pursuant to the applicant's request. *See* FDA, Notice, Schering Corp. et al.; Withdrawal of Approval of 92 New Drug Applications and 49 Abbreviated New Drug Applications, 69 Fed. Reg. 25,124, 25,125 (May 5, 2004), *available at* https://www.govinfo.gov/content/pkg/FR-2004-05-05/pdf/04-10194.pdf.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of HYDROCORTONE under NDA 012052 was due only to commercial considerations.

Petitioner requests that FDA determine that HYDROCORTONE, approved under NDA 012052, was not withdrawn for reasons of safety or effectiveness.

## C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.31.

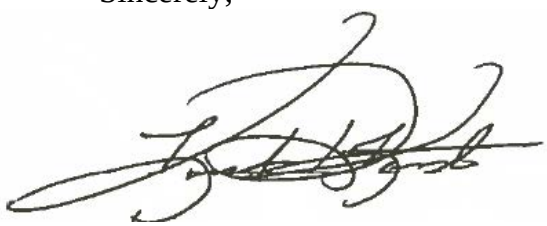
## D. ECONOMIC IMPACT STATEMENT

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

## E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Sincerely,



Kurt R. Karst