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March 30, 2022

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

RE: FDA-2020-P-1991: HYDROCORTONE (hydrocortisone sodium phosphate) Injection, 50 mg base/mL (NDA 012052) Relisting Petition

Hyman, Phelps & McNamara, P.C., on behalf of a client, submitted the above-referenced Citizen Petition to the Food and Drug Administration ("FDA") on September 21, 2020, 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, requesting that the Agency determine whether HYDROCORTONE (hydrocortisone sodium phosphate) Injection, 50 mg base/mL, approved under New Drug Application ("NDA") 012052 has been voluntarily withdrawn for reasons of safety or effectiveness. FDA acknowledged the petition as received as of September 21, 2020, and issued an "interim response" on March 18, 2021, within the regulatory 180-day deadline for such a non-substantive response, stating that the Agency "has been unable to reach a decision on your petition due to other Agency priorities." Since then, FDA has failed to provide any final determination in the matter, despite a (now-past) statutory deadline to do so. Prompt action on the petition is needed and required by law.

The statute, at FDC Act § 505(w), could not be any clearer as to the requirement for FDA to promptly act on a so-called "relisting petition":

> (w) DEADLINE FOR DETERMINATION ON CERTAIN PETITIONS.—The Secretary ***shall issue a final, substantive determination on a petition*** submitted pursuant to subsection (b) of section 314.161 of title 21, Code of Federal Regulations (or any successor regulations), ***no later than 270 days after the date the petition is submitted***.

Petitioner submitted its petition to FDA on September 21, 2020. 270 days after that date was ***June 19, 2021***. But June 19, 2021 came and went without any FDA determination, or even any update from FDA on the status of the Agency's response timeframe. As of today, it has been ***more than 550 days*** since FDA received the petition.

In the meantime, FDA has adhered to the 270-day deadline at FDC Act § 505(w) in responding to several other relisting petitions submitted before and well after the relisting petition submitted here, including:

- Docket No. FDA-2021-P-0885 concerning NDA 019462 for PEPCID (famotidine) Tablets. The petition was submitted to FDA on August 3, 2021, and the Agency issued a determination ***169 days*** later, on January 18, 2022.

- Docket No. FDA-2021-P-0959 concerning NDA N017944 for MPI DMSA KIDNEY REAGENT (Technetium Tc-99m Succimer Kit) Injectable. The petition was submitted to FDA on August 27, 2021, and the Agency issued a determination ***200 days*** later, on March 14, 2022.

- Docket No. FDA-2021-P-0306 concerning NDA 018613 for OVIDE (malathion) Lotion. The petition was submitted to FDA on March 19, 2021, and the Agency issued a determination ***57 days*** later, on May 14, 2021.

- Docket No. FDA-2020-P-1511 and Docket No. FDA-2020-P-1549 concerning NDA 203340 for NYMALIZE (nimodipine) Oral Solution. The petitions were submitted to FDA on June 6, 2020 and June 10, 2020, respectively, and the Agency issued a determination ***257 days and 253 days*** later, on February 17, 2021.

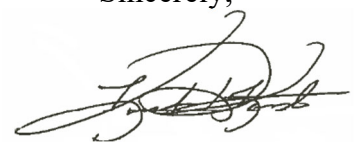
- Docket No. FDA-2021-P-0923 concerning NDA 020696 for ANTIZOL (fomepizole) Injection. The petition was submitted to FDA on August 19, 2021, and the Agency issued a determination ***126 days*** later, on December 22, 2021.

- Docket No. FDA-2021-P-0162 concerning NDA 018686 for NORMODYNE (labetalol hydrochloride) Injection. The petition was submitted to FDA on February 4, 2021, and the Agency issued a determination ***106 days*** later, on May 20, 2021.

FDA's failure to meet the 270-day statutory deadline in this case concerning HYDROCORTONE (hydrocortisone sodium phosphate) Injection, approved under NDA 012052, is inexplicable and inexcusable, particularly considering the above instances in which FDA handily met the statutory deadline.

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

Sincerely,



Kurt R. Karst

KRK/eam