Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Frequently asked Questions—Developing Potential Cellular and Gene Therapy Products.'' The draft guidance document provides industry with answers to FAQs and commonly faced issues that arise during the development of CGT products. The FAQs represent common questions directed to the Agency and span multiple disciplines, including regulatory review; CMC; pharmacology/toxicology; clinical; and clinical pharmacology.

The guidance was created as part of FDA's response to the PDUFA VII commitment to increase efficiency and to support development of CGT products by providing a repository of common questions posed to the Office of Therapeutic Products by sponsors and other key stakeholders. The Agency compiled FAQs received from a variety of sources, including FDA interactions with sponsors in development programs.

The guidance covers relevant, current, and timely topics related to the development of CGT products, which may be updated to include additional FAQs as appropriate. Sponsors are encouraged to visit the Cellular and Gene Therapy Guidances web page on the FDA website for a full list of finalized as well as draft guidances relevant to the development of CGT products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Frequently asked Questions—Developing Potential Cellular and Gene Therapy Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Action of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to investigational new drug applications, clinical trials and clinical trial design, meetings with FDA, and Form FDA 1571, have been approved under OMB control number 0910–0014. The collections of information in section 402(j)(5)(B) of the Public Health Service Act (42 U.S.C. 282(j)(5)(B)), which requires certification that all applicable requirements of section 402(j) have been met on Form FDA 3674, and the collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications and Form FDA 356h have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26918 Filed 11–18–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–P–1991 and FDA–2021–P–0940]

Determination That HYDROCORTONE (Hydrocortisone Sodium Phosphate) Injection, Equivalent to 50 Milligrams Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that HYDROCORTONE (hydrocortisone sodium phosphate) injection, equivalent to (EQ) 50 milligrams (mg) base/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Beth Holck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 240–402–7133, *Beth.Holck@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or

suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is the subject of NDA 012052, held by Merck & Co., Inc., and initially approved on June 8, 1960. HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is synthetic glucocorticoid for use as an anti-inflammatory or immunosuppressant agent.

The indications for glucocorticoid drugs, including HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL (Merck Sharpe & Dohme (now Merck & Co., Inc.); NDA 012052) were reviewed for efficacy under the Drug Efficacy Study Implementation program. Under this program, which was implemented in response to the 1962 amendments to the FD&C Act requiring demonstration of effectiveness (Kefauver-Harris Amendments of 1962 (Pub. L. 87–781)), the National Academy of Sciences-National Research Council (NAS–NRC) studied about 4,000 drug formulations to assess the efficacy of the drug products. Upon consideration of the findings and recommendations of the NAS–NRC, FDA set forth in the **Federal Register** its conclusions and assessment of whether and under what circumstances the reviewed drug products are considered ''effective'' for use as required by the FD&C Act. In the **Federal Register** of February 19, 1972 (37 FR 3775), FDA announced that preparations containing hydrocortisone sodium phosphate are effective or probably effective for parenteral use by the appropriate route of administration.

FDA published a subsequent notice in the **Federal Register** of March 1, 1977 (42 FR 11893), in which the Agency set forth the indications that it found to be effective for certain drug products, including for HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL (NDA 012052). The March 1, 1977, notice announced FDA was prepared to approve NDAs and supplements to previously approved NDAs under the conditions described in the notice, including the condition that the revised labeling include only the indications for which the drug was classified as effective set forth in that notice (42 FR 11893 at 11894–5).

HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated April 4, 2003, Merck & Co., Inc., notified FDA that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was discontinued effective September 20, 2002. In the same letter, Merck & Co., Inc., also requested withdrawal of NDA 012052 for HYDROCORTONE (hydrocortisone sodium phosphate), and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In the **Federal Register** of May 5, 2004 (69 FR 25124), FDA announced that it was withdrawing approval of NDA 012052, effective June 4, 2004.

Hyman, Phelps & McNamara, P.C., submitted an initial citizen petition dated September 21, 2020 (Docket No. FDA–2020–P–1991) as well as a second citizen petition dated August 25, 2021 (Docket No. FDA–2021–P–0940), under 21 CFR 10.30, requesting that the Agency determine whether HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to HYDROCORTONE (hydrocortisone sodium phosphate) injection, EQ 50 mg base/mL, may be approved by the Agency if they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–26916 Filed 11–18–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3111]

Ivette Maria Portela Martinez: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Ivette Maria Portela Martinez from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Portela Martinez was convicted of two felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Ms. Portela Martinez was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of September 14, 2024 (30 days after receipt of the notice), Ms. Portela Martinez has not responded. Ms. Portela Martinez's failure to respond and request a hearing constitutes a waiver of Ms. Portela Martinez's right to a hearing concerning this matter.