

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 803 days of patent term extension.

### III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 7, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–14916 Filed 7–12–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2022–P–0115]

#### **Determination That REGLAN Injection (Metoclopramide Injection, USP), Equivalent to 5 Milligrams Base/Milliliter and Equivalent to 10 Milligrams Base/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**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 REGLAN Injection (metoclopramide injection, USP), equivalent to (EQ) 5 milligrams (mg) base/milliliter (mL) and EQ 10 mg base/mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

#### **FOR FURTHER INFORMATION CONTACT:**

Daniel Gottlieb, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6210, Silver Spring, MD 20993–0002, 301–796–6650, [daniel.gottlieb@fda.hhs.gov](mailto:daniel.gottlieb@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 FDA’s approval of 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.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is the subject of NDA 017862, held by Hikma Pharmaceuticals USA Inc., and initially approved on February 7, 1979 (EQ 5 mg base/mL) and May 28, 1987 (EQ 10 mg base/mL). REGLAN is indicated for the relief of symptoms associated with acute and recurrent diabetic gastric stasis, prophylaxis of vomiting associated with emetogenic cancer therapy, and prophylaxis of postoperative nausea and vomiting in those circumstances where nasogastric suction is undesirable. REGLAN may also be used to facilitate small bowel intubation in adults and pediatric patients in whom the tube does not pass the pylorus with conventional maneuvers or to stimulate gastric emptying and intestinal transit of barium in cases where delayed emptying interferes with radiological examination of the stomach and/or small intestine.

REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Baxter Healthcare Corp. submitted a citizen petition dated February 1, 2022 (Docket No. FDA–2022–P–0115), under 21 CFR 10.30, requesting that the Agency determine whether REGLAN Injection (metoclopramide injection, USP), 5 mg base/mL, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the EQ 10 mg base/mL strength, that strength has also been discontinued. On our own initiative, we have also determined whether that strength was withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 mg base/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 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 REGLAN Injection (metoclopramide injection, USP), EQ 5 mg base/mL and EQ 10 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as 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: July 7, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-14929 Filed 7-12-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-0049]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by August 12, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to [https://](https://www.reginfo.gov/public/do/PRAMain)

[www.reginfo.gov/public/do/PRAMain](https://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0732. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St. North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

*OMB Control Number 0910-0732—Extension*

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))).

In accordance with that authority, on May 10, 2016, FDA issued a final rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA’s tobacco product authority (final deeming rule) (81 FR 28974).

Chapter IX of the FD&C Act now applies to newly regulated products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as

a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand. We note that for cigarettes, smokeless tobacco, cigarette filler, and RYO tobacco products, this initial reporting was completed in 2012.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) of the FD&C Act at least 90 days prior to introducing the product into interstate commerce.

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA’s current thinking on the meaning of the term “harmful and potentially harmful constituent” in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/harmful-and-potentially-harmful-constituents-tobacco-products-used-section-904e-federal-food-drug>. The current established list of HPHCs also is available on the internet at <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list> (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in certain tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a-j, for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.*, Forms FDA 3787a-j). A proposed information collection for deemed products will be published in a separate **Federal Register** notice, and we will solicit comments on that collection at that time.

Manufacturers or importers, or their agents, may submit HPHC information either electronically or in paper format. The FDA eSubmitter tool, available at <https://www.fda.gov/industry/fda->