

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN—CENTER FOR DRUG EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 3926.	752	1.3484	1,014	0.75 (45 minutes)	761
§§ 312.310(b) and 312.305(b); submissions related to expanded access and treatment of an individual patient: Form FDA 1571.	10	10.8	108	3	324
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 3926.	394	1.1371	448	0.75 (45 minutes)	336
§ 312.310(d); submissions related to expanded access and treatment of an individual patient for emergency use: Form FDA 1571.	7	3.2857	23	3	69
§§ 312.315(c) and 312.305(b); submissions related to expanded access and treatment of an intermediate-size patient population (Form FDA 1571).	37	1.0541	39	120	4,680
§ 312.320(b) and 312.305(b); submissions related to a treatment IND or treatment protocol (Form FDA 1571).	18	1.0555	19	300	5,700
Total			1,651		11,870

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Numbers may be rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—CENTER FOR BIOLOGICS EVALUATION AND RESEARCH^{1 2 3}

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§§ 312.310(b) and 312.305(b); number of submissions related to expanded access and treatment of an individual patient: Form FDA 3926	256	1.4804	379	8	3,032
§ 312.310(d); number of submissions related to emergency use of an investigational new drug: Form FDA 3926	80	1.2	96	16	1,536
§§ 312.315(c) and 312.305(b); number of submissions related to expanded access and treatment of an intermediate-size patient population: Form FDA 1571	14	1	14	120	1,680
§ 312.320(b) and 312.305(b); number of submissions related to a treatment IND or treatment protocol: Form FDA 1571	3	1	3	300	900
Total			492		7,148

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

³ Numbers may be rounded.

Burden estimates we attribute to the recordkeeping requirements established by the applicable regulations have been updated to include the reporting of data elements using Form FDA 1571. We have characterized the collection activity as recordkeeping, consistent with 5 CFR 1320.3(m) which defines a recordkeeping requirement to include the task of reporting the records to the Federal government. Upon our most recent review, the information collections reflect a cumulative decrease of 11,767 responses and 236,308 burden hours annually.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20765 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1882 and FDA–2020–E–1892]

Determination of Regulatory Review Period for Purposes of Patent Extension; MONOFERRIC

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for MONOFERRIC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are

incorrect may submit either electronic or written comments and ask for a redetermination by December 8, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 7, 2027. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 8, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.

Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket Nos. FDA-2020-E-1882 and FDA-2020-E-1892 for "Determination of Regulatory Review Period for Purposes of Patent Extension; MONOFERRIC." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in

its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

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.

FOR FURTHER INFORMATION CONTACT: Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 240-402-5276.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an

application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, MONOFERRIC (ferric derisomaltose). MONOFERRIC is an iron replacement product indicated for the treatment of iron deficiency anemia in adult patients:

- who have intolerance to oral iron or have had unsatisfactory response to oral iron.
- who have non-hemodialysis dependent chronic kidney disease.

Subsequent to this approval, the USPTO received a patent term restoration application for MONOFERRIC (U.S. Patent Nos. 8,815,301 and 10,414,831) from Pharmacosmos Holding A/S. USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 7, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of MONOFERRIC represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for MONOFERRIC is 3,292 days. Of this time, 2,990 days occurred during the testing phase of the regulatory review period, while 302 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* 1/13/2011. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on 1/13/2011.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* 3/21/2019. FDA has verified the applicant's claim that the

new drug application (NDA) for MONOFERRIC (NDA 208171) was initially submitted on 3/21/2019.

3. *The date the application was approved:* 1/16/2020. FDA has verified the applicant's claim that NDA 208171 was approved on 1/16/2020.

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 1,136 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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20766 Filed 10–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–4567]

Determination That LASIX (Furosemide) Oral Solution, 10 Milligrams/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, Agency, or we) has determined that LASIX (furosemide) oral solution, 10 milligrams (mg)/milliliter (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: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, Awo.Archampong-Gray@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.

LASIX (furosemide) oral solution, 10 mg/mL, is the subject of NDA 017688, held by Sanofi-Aventis U.S. LLC., and initially approved on March 8, 1977. LASIX is indicated in adults, infants, and children for the treatment of edema associated with congestive heart failure, cirrhosis of the liver, and renal disease, including the nephrotic syndrome. Oral LASIX may be used in adults for the treatment of hypertension alone or in combination with other antihypertensive agents.

LASIX (furosemide) oral solution, 10 mg/mL, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated April 23, 2026 (Docket No. FDA–2026–P–4567), under 21 CFR 10.30, requesting that the Agency determine whether LASIX (furosemide) oral solution, 10 mg/mL, has been voluntarily withdrawn for reasons of safety or effectiveness.

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 LASIX (furosemide) oral solution, 10 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that LASIX (furosemide) oral solution, 10 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of LASIX (furosemide) oral solution, 10 mg/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 LASIX (furosemide) oral solution, 10 mg/mL, in the “Discontinued Drug Product List”