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: Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

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, GRAFAPEX (treosulfan), indicated in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML). Subsequent to this approval, the USPTO received a patent term restoration application for GRAFAPEX (U.S. Patent No. 7,199,162) from Medac Gesellschaft fur Klinische Spezialpraparate mbH and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 27, 2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of GRAFAPEX 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 GRAFAPEX is 9,906 days. Of this time, 8,281 days occurred during the testing phase of the regulatory review period, while 1,625 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:* December 10, 1997. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 10, 1997.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* August 11, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for GRAFAPEX (NDA 214759) was initially submitted on August 11, 2020.

3. *The date the application was approved:* January 21, 2025. FDA has verified the applicant's claim that NDA 214759 was approved on January 21, 2025.

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(s) for patent extension, this applicant seeks 5 years 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.

Lowell M. Zeta,

Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22382 Filed 12–9–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5473]

Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled

''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' The guidance addresses questions that manufacturers, packers, distributors, and their representatives (firms) may have when developing FDA-regulated promotional labeling and advertisements (promotional communications) for prescription reference products, biosimilar products, and interchangeable biosimilar products licensed under the Public Health Service Act (PHS Act). This guidance finalizes the revised draft guidance of the same title issued on April 25, 2024.

DATES: The announcement of the guidance is published in the **Federal Register** on December 10, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

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 No. FDA–2019–D–5473 for ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' Received comments 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 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.

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

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Twyla Mosey, Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993–0002, 301–796–1200, *CDER-OPDP-RPM@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' This guidance addresses questions firms may have when developing FDA-regulated promotional communications for prescription reference products licensed under section 351(a) of the PHS Act (42 U.S.C. 262(a)) and prescription biosimilar products, including interchangeable biosimilar products, licensed under section 351(k) of the PHS Act.

Section 351(k) of the PHS Act provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product. Section 351(i) of the PHS Act defines *biosimilarity* to mean ''that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components'' and that ''there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.'' To meet the standard for *interchangeability,* an applicant must provide sufficient information to demonstrate biosimilarity and also to demonstrate that the biological product can be

expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (section 351(k)(4) of the PHS Act). Interchangeable biosimilar products may be substituted for the reference product without the intervention of the prescribing healthcare provider (section 351(i)(3) of the PHS Act). Decisions regarding pharmacy-level substitution are subject to State pharmacy law.

The guidance discusses considerations for presenting data and information about reference products or biosimilar products, including interchangeable biosimilar products, in promotional communications to help ensure that they are accurate, truthful, and non-misleading. The guidance includes information about general requirements for the content of FDA-regulated promotional communications that apply to reference products and biosimilar products and includes more specific considerations for developing these promotional communications for reference products and biosimilar products, such as:

- Identifying reference products and biosimilar products
- Presenting information from the studies conducted to support licensure of the reference product when the information is included in the FDA-approved labeling of both the reference product and the biosimilar product
- Presenting data or information for a biosimilar product related to the safety or effectiveness of the biosimilar product that is not included in the FDA-approved labeling but is consistent with the FDA-approved labeling for that product
- Comparing a biosimilar product and its reference product
- Submitting promotional communications to FDA

The guidance also provides examples to illustrate some of the considerations outlined in the guidance.

This guidance finalizes the revised draft guidance of the same title issued on April 25, 2024 (89 FR 31757) (2024 draft guidance). FDA considered comments received on the 2024 draft guidance as the guidance was finalized.

Changes from the 2024 draft guidance to the final guidance include:

- Clarification that the recommendations in the guidance apply regardless of the medium of communication (*e.g.,* paper, digital)
- Further discussion related to the considerations that firms should take into account when comparing biosimilar products and reference products
- Editorial changes for consistency, readability, and clarity

In conjunction with the enactment of the Biosimilar User Fee Amendments of 2022 (BsUFA III), FDA agreed to work toward publishing a final guidance on promotional labeling and advertising considerations for interchangeable biosimilar products within 18 months after the close of the public comment period on the draft guidance, as described in the document titled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

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 Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314, Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use), and the guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format: Promotional Labeling and Advertising Materials for Human Prescription Drugs'' have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 202.1 and in the guidance for industry entitled ''Medical Product Communications That Are Consistent With the Food and Drug Administration Required Labeling: Questions and Answers'' have been approved under OMB control number 0910–0686. The collections of information in 21 CFR part 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information relating to the submission of biosimilar and interchangeable product applications under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, 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*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22427 Filed 12–9–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Health Resources and Services Administration Uniform Data System

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate below, or any other aspect of the ICR.