

eRulemaking Docket ID Number: CMS-2024-0250.
Docket Web Address: <https://www.regulations.gov/docket/CMS-2024-0250>.

For Policy Related Questions Contact: Ali Fokar at 410-786-0020.

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-15185 Filed 7-10-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Intergovernmental Reference Guide (IRG) (Office of Management and Budget No.: 0970-0209)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Child Support Services (OCSS), is requesting the Office of Management and Budget (OMB) to approve the Intergovernmental Reference Guide

(IRG), for an additional three years. The IRG contains State and Tribal child support information that helps child support agencies (CSAs) administer their respective programs. Minor updates are proposed, as described below. The current OMB approval (OMB #: 0970-0209) expires on February 28, 2025.

DATES: *Comments due* September 9, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, the ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The IRG is a centralized and automated repository of State and Tribal profiles that contains high-level descriptions of each CSA program. These profiles provide State, Tribal, and foreign country CSAs with an effective and efficient method for updating and accessing information needed to process intergovernmental child support cases.

Revisions are proposed as a result of feedback from respondents suggesting changes, recommendations from the program team, or from the program team workgroup of interested partners. The

workgroup is engaged to evaluate the efficacy of the instruments. Specifically, the following changes are proposed:

- Minor edits to change Office of Child Support Enforcement (OCSE) to Office of Child Support Services (OCSS).
 - Edits to the State profile based on recommendations that were received but not implemented in 2022 when the current version of the profile went through the OMB approval process. OCSS has an overview of those recommendations and OCSS responses available upon request.
 - Edits to clarify the State profile questions to make it easier for respondents to understand and complete them. Some of these edits were based on the comments referenced in the prior bullet and others based on other feedback from program staff and workgroup members.
 - Addition of questions in the State profile instrument that are designed to help States establish health care coverage and manage the financial aspects of child support services. The new questions pertain to policies and procedures associated with new hire reporting, income withholdings, lump sum payments, medical support, and State electronic funds transfers. The addition of these questions slightly increased the estimated time per response from .3 hours to .5 hours.
- Respondents:* State and Tribal CSAs.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total number of annual respondents	Number of annual responses per respondent	Average annual burden hour per response	Annual burden hours
IRG: State Profile Guide (states and territories)	54	18	0.5	486
IRG: Tribal Profile Guide	62	18	0.3	335

Estimated Total Annual Burden Hours: 821.

Comments: The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given

to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652(a)(7); 42 U.S.C. 666(f); 45 CFR 301.1; 45 CFR 303.7, and 45 CFR 309.120.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024-15277 Filed 7-10-24; 8:45 am]

BILLING CODE 4184-41-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-E-3084]

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

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 SPEVIGO 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by September 9, 2024. 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 January 7, 2025. 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 September 9, 2024. 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 No. FDA-2023-E-3084 for “Determination of Regulatory Review Period for Purposes of Patent Extension; SPEVIGO.” 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product SPEVIGO (spesolimab-sbzo). SPEVIGO is indicated for the treatment of generalized pustular psoriasis flares in adults. Subsequent to this approval, the USPTO received a patent term

restoration application for SPEVIGO (U.S. Patent No. 9,023,995) from Boehringer Ingelheim International GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 18, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of SPEVIGO 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 SPEVIGO is 1,729 days. Of this time, 1,393 days occurred during the testing phase of the regulatory review period, while 336 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 (21 U.S.C. 355(i)) became effective:* December 9, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 9, 2017.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 1, 2021. FDA has verified the applicant's claim that the biologics license application (BLA) for SPEVIGO (BLA 761244) was initially submitted on October 1, 2021.

3. *The date the application was approved:* September 1, 2022. FDA has verified the applicant's claim that BLA 761244 was approved on September 1, 2022.

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 1,033 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 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-15239 Filed 7-10-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-4853]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar or Interchangeable Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a biologics license application (BLA) for a biosimilar or interchangeable biosimilar product submitted under the Public Health Service Act (PHS Act) (a "subsection (k) applicant") notified FDA that an action for patent infringement was filed in connection with the applicant's BLA. Under the PHS Act, within 30 days after the subsection (k) applicant is served with a complaint in an action for patent infringement described under the PHS Act, the subsection (k) applicant shall provide the Secretary of Health and Human Services (HHS) with notice and copy of such complaint. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mustafa Ünlü, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1139, Silver Spring, MD 20993, 301-796-3396, Mustafa.Unlu@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)) sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product.

Section 351(l) of the PHS Act describes certain procedures for exchanging patent information and resolving patent disputes between a subsection (k) applicant and the holder of the BLA reference product. If a subsection (k) applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the subsection (k) applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act: *Regeneron Pharmaceuticals, Inc. v. Amgen Inc.*, 2:24-CV-00264 (C.D. Cal., filed January 10, 2024).

FDA has only a ministerial role that is limited to publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act and does not perform a substantive review of the complaint.

Dated: July 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-15237 Filed 7-10-24; 8:45 am]

BILLING CODE 4164-01-P