

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10494 Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel—CAC; *Use:* Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to

this authority, regulations establishing the certified application counselor program have been finalized at 45 CFR 155.225. In accordance with 155.225(d)(1) and (7), certified application counselors in all Exchanges are required to be initially certified and recertified on at least an annual basis and successfully complete Exchange-required training. *Form Number:* CMS-10494 (OMB control number: 0938-1205); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); individuals or households; *Number of Respondents:* 30,000; *Total Annual Responses:* 30,000; *Total Annual Hours:* 7,500. For policy questions regarding this collection contact Deborah Bryant at 301-492-5213.

Dated: January 10, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-00632 Filed 1-16-18; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-E-1235]

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

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 AVYCAZ 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 (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. 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

July 16, 2018. 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. Electronic comments must be submitted on or before March 19, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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-2016-E-1235 for "Determination of

Regulatory Review Period for Purposes of Patent Extension; AVYCAZ.” 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.

- **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.gpo.gov/fdsys/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.

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 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 AVYCAZ (ceftazidime pentahydrate and avibactam sodium). AVYCAZ is indicated for treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:

- Complicated intra-abdominal infections used in combination with metronidazole and
- Complicated urinary tract infections, including pyelonephritis.

Subsequent to this approval, the USPTO received a patent term restoration application for AVYCAZ (U.S. Patent No. 7,112,592) from Forest Laboratories Holdings Ltd., and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AVYCAZ 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 AVYCAZ is 2,579 days. Of this time, 2,333 days occurred during the testing phase of the regulatory review period, while 246 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 5, 2008. FDA has verified the applicant’s claim that February 5, 2008, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* June 25, 2014. FDA has verified the applicant’s claim that the new drug application (NDA) for AVYCAZ (NDA 206494) was initially submitted on June 25, 2014.

3. *The date the application was approved:* February 25, 2015. FDA has verified the applicant’s claim that NDA 206494 was approved on February 25, 2015.

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 1,411 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: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-00678 Filed 1-16-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-7012]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by February 16, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics.” 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, PRASStaff@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.

Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics—OMB Control Number 0910-NEW

This information collection supports the above captioned Agency guidance document. In the **Federal Register** of July 8, 2016 (81 FR 44611), FDA announced the availability of a draft guidance for industry entitled “Use of Public Human Genetic Variant Databases To Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics,” and

included an analysis of the associated information collection.

The draft guidance described FDA’s considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. This draft guidance further outlines the process by which administrators¹ of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would review such applications and periodically reevaluate recognized databases. The draft guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database’s website.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

FDA received 36 comments on the draft guidance, none of which pertained to the information collection burden estimate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Application for recognition of genetic database	5	1	5	80	400

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity	Number of recordkeepers	Number of records per record-keeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of recognition activities	5	1	5	20	100

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

¹ FDA acknowledges that many databases may not use the term “administrator” or may have a

committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a

genetic variant database administrator is the entity or entities that oversee database operations.