

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](mailto: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](mailto: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 administrators<sup>1</sup> 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 BURDEN<sup>1</sup>**

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

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

**TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of recognition activities .....	5	1	5	20	100

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

<sup>1</sup> 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.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Public disclosure of policies, procedures, and conflicts of interest .....	5	1	5	1	5

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

The draft guidance also refers to previously approved collections of information. These collections of information are subject to review by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the guidance document “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff” have been approved under OMB control number 0910–0756. The collections of information regarding premarket submissions have been approved as follows: The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231.

Dated: January 11, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–00685 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–2016–E–2227]

**Determination of Regulatory Review Period for Purposes of Patent Extension; SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM**

**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 SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM 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 medical device.

**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–2227 for “Determination of Regulatory Review Period for Purposes of Patent Extension; SYNERGY EVEROLIMUS–ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM.” 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