TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Description and 21 CFR section | FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|---|
| Registrations or Updates, § 118.11 ... | Form FDA 3733 [2] | 300 | 1 | 300 | 2.3 | 690 |
| Cancellations, § 118.11 ..... | Form FDA 3733 ... | 30 | 1 | 30 | 1 | 30 |
| Total ..... | ..... | ..... | ..... | ..... | ..... | 720 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *http://www.access.fda.gov* per § 118.11(b)(1).

This estimate is based on the average number of new shell egg producer registrations and cancellations received in the past 3 years under § 118.11. We estimate that we will receive an average of 300 registrations or updates per year over the next 3 years. Based on the number of cancellations previously received, we estimate that we will receive approximately 30 cancellations per year over the next 3 years.

We estimate that it takes the average farm 2.3 hours to register, taking into account that some respondents completing the registration may not have readily available Internet access. Thus, the total annual burden for new shell egg producer registrations or updates is calculated to be 690 hours ($300 \times 2.3$ hours).

We estimate cancelling a registration, on average, requires a burden of approximately 1 hour, taking into account that some respondents may not have readily available Internet access. Thus, the total annual burden for cancelling shell egg producer registrations is calculated to be 30 hours (30 cancellations $\times$ 1 hour).

Dated: June 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–14584 Filed 6–20–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–1593]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Accessories

**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 (the PRA).

**DATES:** Fax written comments on the collection of information by July 21, 2016.

**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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Medical Device Accessories.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

### Medical Device Accessories—OMB Control Number 0910–NEW

The draft guidance encourages manufacturers and other parties to utilize the process defined in section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to request risk- and regulatory control-based classifications of new types of accessories. This process provides a pathway to class I or class II classification for accessory devices for which general controls, or general and special controls, provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

In accordance with section 513(f)(2) of the FD&C Act, manufacturers and other parties may submit a de novo requesting FDA to make a classification determination for the accessory device according to the criteria in section 513(a)(1) of the FD&C Act. The de novo must include a description of the device and detailed information and reasons for any recommended classification (see section 513(f)(2)(A)(v) of the FD&C Act).

In the **Federal Register** of January 20, 2015 (80 FR 2710), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received a total of 12 comments on the guidance. Of these the following were related to the information collection:

Two comments raised concerns regarding the possible difficulties for manufacturers to submit a de novo for new accessories and for risk- and regulatory control-based classification of accessories that were approved under the premarket approval application (PMA) for the parent medical devices. One comment questioned whether FDA considered the possible ''practical and economic impact'' of the proposed definition of ''accessories'' that may result in manufacturers being obligated to list some components as accessories for FDA's registration and listing process. The second comment anticipates that ''few companies are likely to pursue this route given the associated costs and minimal advantage in time to market.'' Neither comment specifically discusses the potential PRA burden hours of voluntarily submitting a de novo application; however, it may be inferred that this could impact their resources under the PRA for submitting a de novo.

Also, FDA is not proposing to limit or remove any mechanism that currently exists for manufacturers to obtain marketing authorization for accessories. De novos are typically less burdensome than PMAs for the purpose of classifying a new accessory. Furthermore, if a manufacturer wishes for an accessory to remain in the same regulatory class as the parent device, that manufacturer may continue to submit the accessory for clearance or

approval under the submission type applicable to the parent device.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Accessory classification de novo request | 8 | 1 | 8 | 180 | 1,440 |

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

Respondents are medical device manufacturers seeking to market device accessories. Of the approximately 41 de novo applications received per year, only 2 have been associated with accessories. With heightened awareness of the availability of the de novo pathway for accessories, we expect to receive four to six additional accessories applications per year. Therefore, we estimate that we will receive approximately eight accessory classification de novo requests per year. Based on estimates by FDA administrative and technical staff who are familiar with the proposed submission process for accessory classification requests and on our burden estimate for a similar information collection request (see ''De Novo Classification Process Evaluation of Automatic Class III Designation; Draft Guidance for Industry and Food and Drug Administration Staff; Availability,'' 79 FR 47651 at 47653, August 14, 2014), we estimate that the submission process for each accessory classification request will take approximately 180 hours.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR part 860, subpart C, have been approved under OMB control number 0910–0138.

Dated: June 15, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–14562 Filed 6–20–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–E–2335]**

### Determination of Regulatory Review Period for Purposes of Patent Extension; XOFIGO

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for XOFIGO 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 August 22, 2016. 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 December 19, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

*Submit electronic comments in the following way:*

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2014–E–2335 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; XOFIGO.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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