approval under the submission type applicable to the parent device.

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessory classification de novo request</td>
<td>8</td>
<td>1</td>
<td>8</td>
<td>180</td>
<td>1,440</td>
</tr>
</tbody>
</table>

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information collection request (see “De Novo Classification Process Evaluation of Automatic Class III Designation; Draft Guidance for Industry and Food and Drug Administration Staff: Availability.” 79 FR 47651 at 47653, August 14, 2014), we estimate that the submission process for each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The draft guidance also refers to previously approved collections of information found in FDA regulations.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]
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 http://www.regulations.gov. Submit both copies to the Division of Dockets Management. 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: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://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 Division of Dockets Management, 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.

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 XOFIGO (radium 223 dichloride). XOFIGO is indicated for treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease. Subsequent to this approval, the USPTO received a patent term restoration application for XOFIGO (U.S. Patent No. 6,635,234) from Algeta ASA, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of XOFIGO 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 XOFIGO is 1,945 days. Of this time, 1,792 days occurred during the testing phase of the regulatory review period, while 153 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: January 19, 2008. Algeta ASA claims that February 21, 2008, is the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 19, 2008, which was 30 days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act: December 14, 2012. FDA has verified the applicant’s claim that the new drug application (NDA) for XOFIGO (NDA 203971) was initially submitted on December 14, 2012.

3. The date the application was approved: May 15, 2013. FDA has verified the applicant’s claim that NDA 203971 was approved on May 15, 2013. 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 1,032 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 ask for a redetermination (see DATES). 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. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (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 http://www.regulations.gov at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2015–D–1376]
Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices; Guidance for Industry and Food and Drug Administration Staff; 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 the final guidance entitled “Leveraging Existing