TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

<table>
<thead>
<tr>
<th>21 CFR section, activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>558.6(b)(3)–(5) and (b)(7)–(9); required disclosures when a veterinarian issues a VFD.</td>
<td>3,050</td>
<td>246</td>
<td>750,000</td>
<td>.125 (7 minutes)</td>
<td>93,750</td>
</tr>
<tr>
<td>558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another.</td>
<td>1,000</td>
<td>5</td>
<td>5,000</td>
<td>.125 (7 minutes)</td>
<td>625</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
</tr>
</tbody>
</table>

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

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and therefore do not constitute a “collection of information” under the PRA (44 U.S.C. 3501, et seq.). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: “Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian” (§ 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (§ 558.6(b)(3)(xii)): “Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.”

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (§ 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. “This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs” (§ 558.6(b)(6)(i)).
2. “This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs” (§ 558.6(b)(6)(ii)).
3. “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.” (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement. § 558.6(b)(6)(ii).
4. “This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component” (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)) and therefore do not constitute a “collection of information” under the PRA (44 U.S.C. 3501, et seq.). Our estimate of the annual burden for this information collection has not changed since the last OMB approval, which was associated with the June 3, 2015, final rule. However, the one-time burdens that we included in our analysis of the June 3, 2015, final rule (80 FR 31708 at 31729 to 31732) are not included in our current estimate.

Dated: January 11, 2018.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. FDA–2016–E–3619]

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

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 AXUMIN 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 redetermination 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://
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. 100–203) 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 approved for marketing the human drug product had undergone a testing phase of the regulatory review period, and that the approval of AXUMIN 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 AXUMIN is 4,006 days. Of this time, 3,763 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

2. The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act: September 28, 2015.
3. The date the application was approved: May 27, 2016.

FDA has verified the applicant’s claim that the new drug application (NDA) for AXUMIN (NDA 208054) was initially submitted on September 28, 2015.

FDA has determined that the new drug application (NDA) for AXUMIN (NDA 208054) was initially submitted on September 28, 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 5 years 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 comments by mail, fax, or in person to the Dockets Management Staff (HFA–305), c/o Resources Management Division (HFA–3), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Petitions should be in the format specified in 21 CFR 10.30.

Dated: January 11, 2018.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
[FWS–R1–ES–2017–N135; FF01EWF000–FXES111601M000]

Marine Mammal Protection Act; Stock Assessment Report for the Northern Sea Otter in Washington

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended, and its implementing regulations, we, the U.S. Fish and Wildlife Service, have developed a draft revised marine mammal stock assessment report for the northern sea otter stock in the State of Washington. We now make the draft stock assessment report available for public review and comment.

DATES: We will consider comments that are received or postmarked on or before April 17, 2018.

ADDRESSES: If you wish to review the draft revised stock assessment report for the northern sea otter stock in Washington, you may obtain a copy from our website at http://www.fws.gov/wafwo. Alternatively, you may contact the Washington Fish and Wildlife Office, 510 Desmond Dr., Suite 102, Lacey, WA 98503 (telephone: 360–753–9440). If you wish to comment on the stock assessment report, you may submit your comments in writing by any one of the following methods:

• U.S. mail: State Supervisor, at the above address;

• Hand delivery: Washington Fish and Wildlife Office at the above address;

• Fax: 360–753–9565; or

• Email: fw1_waseauotters@fws.gov.

FOR FURTHER INFORMATION CONTACT: Deanna Lynch, at the above street address, by telephone (360–753–9545), or by email (deanna.lynch@fws.gov). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: We announce the availability for review and comment of a draft revised marine mammal stock assessment report (SAR) for the northern sea otter (Enhydra lutris kenyoni) stock in the State of Washington.

Background

Under the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 et seq.), and its implementing regulations in the Code of Federal Regulations (CFR) at 50 CFR part 18, the U.S. Fish and Wildlife Service (Service) regulates the taking; import; and, under certain conditions, possession; transportation; purchasing; selling; and offering for sale, purchase, or export, of marine mammals. One of the goals of the MMPA is to ensure that stocks of marine mammals occurring in waters under U.S. jurisdiction do not experience a level of human-caused mortality and serious injury that is likely to cause the stock to be reduced below its optimum sustainable population (OSP) level. OSP is defined under the MMPA as “the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element” (16 U.S.C. 1362(9)).

To help accomplish the goal of maintaining marine mammal stocks at their OSPs, section 117 of the MMPA requires the Service and the National Marine Fisheries Service (NMFS) to prepare a SAR for each marine mammal stock that occurs in waters under U.S. jurisdiction. A SAR must be based on the best scientific information available; therefore, we prepare it in consultation with established regional scientific review groups established under 117(d) of the MMPA. Each SAR must include:

1. A description of the stock and its geographic range;
2. A minimum population estimate, current and maximum net productivity rate, and current population trend;
3. An estimate of the annual human-caused mortality and serious injury by source and, for a strategic stock, other factors that may be causing a decline or impeding recovery of the stock;
4. A description of commercial fishery interactions;
5. A categorization of the status of the stock; and
6. An estimate of the potential biological removal (PBR) level.

The MMPA defines the PBR as “the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its [OSP]” (16 U.S.C. 1362(20)). The PBR is the product of the minimum population estimate of the stock (Nmin), one-half the maximum theoretical or estimated net productivity rate of the stock at a small population size (Rmax); and a recovery factor (F) of between 0.1 and 1.0, which is intended to compensate for uncertainty and unknown estimation errors. This can be written as:

\[ PBR = \frac{N_{min}}{2} \times (F \times R_{max}) \]

Section 117 of the MMPA also requires the Service and NMFS to review the SARs (a) at least annually for stocks that are specified as strategic stocks, (b) at least annually for stocks for which significant new information is available, and (c) at least once every 3 years for all other stocks. If our review of the status of a stock indicates that it has changed or may be more accurately determined, then the SAR must be revised accordingly.

A strategic stock is defined in the MMPA as a marine mammal stock “(A) for which the level of direct human-caused mortality exceeds the [PBR] level; (B) which, based on the best available scientific information, is