TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section, activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)–(5) and (b)(7)-(9); required disclosures when a veterinarian issues a VFD.	3,050	246	750,000	.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another.	1,000	5	5,000	.125 (7 minutes)	625
Total					94,375

[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)(xiii)): ''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 authorizes the use of the VFD drug(s) cited in this order in the following 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).)

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'' (§ 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.

[FR Doc. 2018–00676 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–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 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–3619 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; AXUMIN.'' 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 AXUMIN (fluciclovine F-18). AXUMIN is indicated for positron emission tomography imaging in men with suspected prostate cancer recurrence based on elevated blood prostate specific antigen levels following prior treatment. Subsequent to this approval, the USPTO received a patent term restoration application for AXUMIN (U.S. Patent No. 5,808,146) from Emory University, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 1, 2016, FDA advised the USPTO that this human drug product had undergone a 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:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* June 10, 2005. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 10, 2005

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

3. *The date the application was approved:* May 27, 2016. FDA has verified the applicant's claim that NDA 208054 was approved on May 27, 2016.

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 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. 2018–00684 Filed 1–16–18; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2017–N135; FF01EWFW00–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_waseaottersar@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 (N_{min}); one-half the maximum theoretical or estimated net productivity rate of the stock at a small population size (R_{max}); and a recovery factor (F_r) of between 0.1 and 1.0, which is intended to compensate for uncertainty and unknown estimation errors. This can be written as:

$$PBR = (N_{min})(\tfrac{1}{2} \text{ of the } R_{max})(F_r)$$

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