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 TECFIDERA (dimethyl fumarate). TECFIDERA is indicated for treatment of patients with relapsing forms of multiple sclerosis. Subsequent to this approval, the USPTO received patent term restoration applications for TECFIDERA (U.S. Patent Nos. 6,509,376; 7,320,999; 7,619,001; and 7,803,840) from Biogen Idec International GmbH, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 4, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of TECFIDERA 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 TECFIDERA is 2,480 days. Of this time, 2,085 days occurred during the testing phase and 395 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:* June 14, 2006. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on June 14, 2006.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* February 27, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for TECFIDERA (NDA 204063) was initially submitted on February 27, 2012.

3. *The date the application was approved:* March 27, 2013. FDA has verified the applicant's claims that NDA 204063 was approved on March 27, 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 applications for patent extension, this applicant seeks 1,438 days, 1,144 days, 811 days, or 654 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, 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: *September 29, 2017.*

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21435 Filed 10–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0656]

Animal Drug User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a forthcoming public meeting entitled ''Animal Drug User Fee Act.'' The topic to be discussed is proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA IV). The meeting will be open to the public.

DATES: The public meeting will be held on November 2, 2017, from 9 a.m. to 12 noon. Submit either electronic or written comments on this public meeting to the docket by November 17, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at 7500 Standish Pl., Room N149 (first floor), Rockville, MD 20855. Free parking is available onsite. Attendees must provide a valid government issued photo ID (driver's license, identification card, or passport) to enter the facility. Entrance for the public meeting participants (non-FDA employees) is through the front of the building where routine security check procedures will be performed.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted on or before November 17, 2017.[1] The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 17, 2017. 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

[1] This date corrects the comment closing date of December 1, 2017, stated in the **Federal Register** notice announcing the initial ADUFA reauthorization public meeting held on May 16, 2016 (81 FR 23313, April 20, 2016).

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–2011–N–0656 for ''Animal Drug User Fee Act; Public Meeting; Request for Comments.'' 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 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.

In addition to being publicly viewable at *https://www.regulations.gov,* comments will also be published on *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm*.

FOR FURTHER INFORMATION CONTACT: Cassie Ravo, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6866, *cassie.ravo@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public meeting to discuss proposed recommendations for the reauthorization of ADUFA, which authorizes FDA to collect user fees and use them for the process of reviewing new animal drug applications and associated submissions. The authority for ADUFA expires September 30, 2018. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal drug review process for future fiscal years. Section 740A(d)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–13(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholder, and before transmitting the Agency's final recommendation to Congress for the reauthorized program (ADUFA IV), we do the following: (1) Present the recommendation to the relevant Congressional committees, (2) publish such recommendations in the **Federal Register**, (3) provide for a period of 30 days for the public to provide written comments on such recommendations, (4) hold a meeting at which the public may present its views on such recommendations, and (5) consider such public views and comments and revise such recommendations as necessary. This notice, the 30-day comment period, and the public meeting will satisfy certain of these requirements. After the public meeting, we will revise the draft recommendations as necessary. In addition, the Agency will present the draft recommendations to the Congressional committees.

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADAs) to be central to the Agency's mission to protect and promote human and animal health. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. The Animal Drug User Fee Act enacted in 2003 (Pub. L. 108–130; hereinafter referred to as ''ADUFA I'') authorized FDA to collect user fees dedicated to the timely review of new animal drug applications in accordance with certain performance goals and to expand and modernize the new animal drug review program. The Agency agreed, under ADUFA I, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process by 30 percent in ADUFA I.

In 2008, before ADUFA I expired, Congress passed the Animal Drug User Fee Amendments of 2008 (Pub. L. 110–316; hereinafter referred to as ''ADUFA II'') which included an extension of ADUFA for an additional 5 years (fiscal year (FY) 2009 through FY 2013). ADUFA II performance goals were established based on ADUFA I FY 2008 review time frames. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews. The ADUFA programs have enabled FDA to meet performance timeframes for application review for new animal drugs without compromising the quality of the Agency's review.

In 2013, Congress passed the Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013, reauthorizing ADUFA (Pub. L. 113–14; hereinafter referred to as ''ADUFA III''). ADUFA II was set to expire September 30, 2013, and the new reauthorization extends ADUFA until 2018.

ADUFA III reauthorization maintained the FY 2013 review timeframes for key submissions in addition to enhancements to the program. Enhancements included: Replacing the End Review Amendment with a short, second-round review; reducing time for microbial food safety hazard characterization submissions to

100 days; and adding a variable inflation adjuster to account for changes in the Center for Veterinary Medicine's costs using the Consumer Price Index as a guide. Also, the proportion of revenue collected from fees was redistributed as follows: Application fees from 25 percent to 20 percent; product fees from 25 percent to 27 percent; establishment fees from 25 percent to 26 percent; and sponsor fees from 25 percent to 27 percent.

Additionally, there were chemistry, manufacturing, and controls (CMC) enhancements, including: Permitting the manufacturing supplements to be resubmitted as ''Supplement-Changes Being Effected in 30 Days'' if deficiencies are not substantial for manufacturing supplements requiring prior approval according to 21 CFR 514.8(b); permitting comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as protocols without substantial data in an investigational new animal drug (INAD) file; and developing guidance for a two-phased CMC technical section submission and review process under the INAD file. The Agency agreed to explore the feasibility of pursuing expanded conditional approvals and of modifying the current requirement that the use of multiple new animal drugs in the same medicated feed (combination medicated feed) be subject to an approved application. The reauthorization of ADUFA is targeted to generate $114,000,000 in user fees over 5 years (FY 2014 through FY 2018).

FDA has published a number of reports that provide useful background on ADUFA I, II, and III. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm*.

II. Topics for Discussion at the Public Meeting

In preparing the proposed recommendations to Congress for ADUFA reauthorization (ADUFA IV), we have conducted discussions with the regulated industry, and we have consulted with stakeholders as required by the law. We began the ADUFA reauthorization process with a public meeting held on May 16, 2016 (81 FR 23313, April 20, 2016). Following the May 2016 public meeting, FDA conducted negotiations with regulated industry and continued regular consultations with public stakeholders from October 2016 through April 2017. As directed by Congress, FDA posted minutes of these discussions on its Web site at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm*.

The proposed enhancements from ADUFA IV address many of the top priorities identified by public stakeholders, the top concerns identified by regulated industry, and the most important challenges identified within FDA. The full descriptions of these proposed recommendations can be found in the proposed ADUFA IV Performance Goals and Procedures Letter. FDA intends to publish in the **Federal Register** the full text of the proposed ADUFA IV Performance Goals and Procedures Letter and a summary of proposed statutory changes, as well as post them at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm* before the public meeting and will provide for a period of 30 days for the public to provide written comments.

FDA will post the agenda approximately 5 days before the meeting at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm*.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please contact Cassie Ravo (see **FOR FURTHER INFORMATION CONTACT**). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patients and consumer advocacy groups; or the regulated industry, and whether you are requesting a scheduled presentation.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by October 26, 2017, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8:30 a.m. We will let registrants know if registration closes before the day of the public meeting. If you need special accommodations due to a disability, please contact Cassie Ravo (see **FOR FURTHER INFORMATION CONTACT**) no later than October 26, 2017.

Requests for Oral Presentations: When registering, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 27, 2017. All requests to make oral presentations must be received by the close of registration on October 26, 2017. If selected for presentation, any presentation materials must be emailed to the Cassie Ravo (see **FOR FURTHER INFORMATION CONTACT**) no later than October 31, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the public meeting: This public meeting will also be webcast.

Event: ADUFA IV Public Meeting. Event address for attendees: *https://fda.webex.com/fda/onstage/g.php?MTID=e9adcd215b7dba5d99361b002663e51fe*. Date and time: Thursday, November 2, 2017, 9 a.m. Eastern Daylight Time (New York, GMT–4). Duration: 3 hours. Event number: 812 395 634. Event password: 110217. Teleconference: Provide your number when you join the event to receive a call back. (1) Call one of the following numbers: Local: 1–301–796–7777; toll free: 1–855–828–1770. (2) Follow the instructions that you hear on the phone. Cisco Unified MeetingPlace meeting ID: 812 395 634.

FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at: *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm*.

Dated: September 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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