DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0655]

Animal Generic 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 the forthcoming public meeting entitled ''Animal Generic Drug User Fee Act.'' The topic to be discussed is proposed recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA III). The meeting will be open to the public.

DATES: The public meeting will be held on November 2, 2017, from 1 p.m. to 4 p.m. Submit either electronic or written comments on this public meeting 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., Rm. 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 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–0655 for ''Animal Generic 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/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.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 AGDUFA, which authorizes FDA to collect user fees and use them for the process of reviewing new animal generic drug applications and associated submissions. The authority for AGDUFA expires September 30, 2018. Without new legislation, FDA will no longer have the authority to collect user fees to fund the new animal generic drug review process for future fiscal years. Section 742(d)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j–22(d)(4)) requires that, after holding negotiations with regulated industry and periodic consultations with stakeholders, and before transmitting the Agency's final

[1] This date corrects the comment closing date of December 1, 2017, stated in the **Federal Register** notice announcing the initial AGDUFA reauthorization public meeting held on May 16, 2016 (81 FR 23311, April 20, 2016).

recommendation to Congress for the reauthorized program (AGDUFA III), 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 abbreviated new animal drug applications (ANADAs) to be central to the Agency's mission to protect and promote human and animal health. Prior to 2009, the timeliness and predictability of the generic new animal drug review program was a concern. The Animal Generic Drug User Fee Act enacted in 2008 (Pub. L. 110–316; hereinafter referred to as ''AGDUFA I'') amended the FD&C Act to authorize the FDA's first-ever generic animal drug user fee program. AGDUFA I provided FDA with additional funds to enhance the performance and predictability of the generic new animal drug review process. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic new animal drug products are safe and effective.

Under AGDUFA I, FDA agreed to meet review performance goals for certain submissions over 5 years from fiscal year (FY) 2009 through FY 2013. The purpose of establishing these review performance goals was to ensure the timely review of ANADAs and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions, and as a result FDA has been able to reduce the time for the application review process for generic new animal drugs without compromising the quality of the Agency's review.

AGDUFA I established increasingly stringent review performance goals over a 5-year period from FY 2009 through FY 2013. Based on those performance goals, in the final year of AGDUFA I (FY 2013) FDA agreed to review and act on 90 percent of the following submission types within the specified time frames:

- Original ANADAs and reactivations within 270 days after the submission date.
- Administrative ANADAs within 100 days after the submission date.
- Manufacturing supplemental ANADAs and reactivations within 270 days after the submission date.
- JINAD study submissions within 270 days after the submission date.
- JINAD protocol submissions within 100 days after submission date.

With the reauthorization of AGDUFA for an additional 5 years under AGDUFA II (FY 2014 to FY 2018), FDA agreed to further enhance and improve the review process.

The AGDUFA II reauthorization enhancements included developing Question Based Review Process for Bioequivalence Submissions and shortening review time for key submission types. Additionally, there were chemistry, manufacturing, and controls (CMC) enhancements, including: Permitting 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 a JINAD file; and developing guidance for a two-phased CMC technical section submission and review process under the JINAD file. Finally, the proportion of revenue collected from user fees was redistributed as follows: Application fees from 30 percent to 25 percent; product fees from 35 percent to 37.5 percent; and sponsor fees from 35 percent to 37.5 percent.

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

II. Topics for Discussion at the Public Meeting

In preparing the proposed recommendations to Congress for AGDUFA reauthorization (AGDUFA III), we have conducted discussions with the regulated industry, and we have consulted with stakeholders as required by the law. We began the AGDUFA reauthorization process with a public meeting held on May 16, 2016 (81 FR 23311, April 20, 2016). Following the May 2016 public meeting, FDA conducted negotiations with regulated industry and continued regular consultations with public stakeholders from August 2016 through January 2017. As directed by Congress, FDA posted minutes of these discussions on its Web site at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm*. The proposed enhancements from AGDUFA III 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 AGDUFA III Performance Goals and Procedures Letter. FDA intends to publish in the **Federal Register** the full text of the proposed AGDUFA III Performance Goals and Procedures Letter and a summary of proposed statutory changes, as well as post them at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.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/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.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 12:30 p.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 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: AGDUFA III Public Meeting. Event address for attendees: *https://fda.webex.com/fda/onstage/g.php?MTID=ec1c356734bcf010b59e0b885726ccad0*. Date and time: Thursday, November 2, 2017, 1 p.m. Eastern Daylight Time (New York, GMT–4). Duration: 3 hours. Event number: 817 527 611. 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: 817 527 611.

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/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm*.

Dated: September 29, 2017.

Anna K. Abram,

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

[FR Doc. 2017–21438 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–2017–N–5017]

Health Canada and United States Food and Drug Administration Joint Public Consultation on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public Meeting and Webcast

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and webcast; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a regional public meeting entitled ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).'' The purpose of this public meeting is to provide information and solicit public input on the current activities of ICH as well as the upcoming ICH Assembly Meeting and the Expert Working Group Meetings in Geneva, Switzerland, scheduled for November 11 through 16, 2017. The topics to be discussed are the topics for discussion at the forthcoming ICH Assembly Meeting in Geneva.

DATES: The public meeting will be held on October 19, 2017, from 9 a.m. to 12 noon Eastern Time. Submit either electronic or written comments on this public meeting by October 26, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information. Registration to attend the meeting and requests for oral presentations must be received by October 16, 2017; see the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting.

ADDRESSES: The public meeting will be held at the Sir Frederick G. Banting Research Centre, 251 Sir Frederick Banting Dr., Ottawa, ON K1Y 0M1, Canada. It will also be broadcast on the web allowing participants to join in person OR via the Web.

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 October 26, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 27, 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 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–2017–N–5017 for ''Health Canada and U.S. Food and Drug Administration Joint Public Consultation on International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; Public