



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) is announcing a public meeting on the Animal Generic Drug User Fee Act (AGDUFA). FDA invites public comment on the AGDUFA program and suggestions regarding the features FDA should propose for the next AGDUFA program.

DATES: The meeting will be held on May 16, 2016, from 1 p.m. to 4 p.m. In order to be taken into consideration before the public meeting, submit either electronic or written comments to the docket by May 4, 2016. To permit the widest possible opportunity to obtain comments on all aspects of the public meeting, the docket will remain open for comment through December 1, 2017. In addition to being publicly viewable at <http://www.regulations.gov>, comments received by June 16, 2016, suggesting changes to the program, will also be published on <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm>. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The meeting will be held at the Food and Drug Administration, 7519 Standish Pl., 3rd floor, rm. A, Rockville, MD 20855.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management 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 <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: Cassie Ravo, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6866, FAX: 240-276-9744, Cassie.Ravo@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

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 generic new animal drug review process. Prior to beginning negotiations with the regulated industry on AGDUFA reauthorization, section 740A(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-13(d)(2)) requires FDA to: (1) Publish a notice in the Federal Register requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization including specific suggestions for changes to the goals referred in section 740A(a) of FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA’s Web site. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of AGDUFA. FDA is interested in

responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the AGDUFA program thus far?
2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of AGDUFA and its current status.

II. Background

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 FDA’s first ever generic new animal drug user fee program. AGDUFA I provided FDA with additional funds to enhance the performance 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, and enabled FDA’s continued support for lower-cost alternatives to brand drugs for consumers. Under AGDUFA I, FDA agreed to meet review performance goals for certain submissions over 5 years from fiscal year (FY) 2009 through FY 2013. These review performance goals strive to expedite the review of abbreviated new animal drug applications (ANADAs) and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions.

Under AGDUFA I, the industry agreed to pay user fees that are available to FDA, in addition to appropriated funds, to spend on the generic new animal drug review process. Moreover, FDA’s authority to collect user fees is contingent on a certain level of spending from appropriated funds, as adjusted for inflation.

AGDUFA I established increasingly stringent review performance goals over a 5-year period from FY 2009 through FY 2013. By the 5th and final year of AGDUFA I, FDA agreed to review and act on 90 percent of the following submission types within the specified timeframes:

- Original ANADAs and reactivations within 270 days of the submission date.
- Administrative ANADAs (ANADAs submitted after all scientific decisions have been made during the JINAD process, i.e., prior to the submission of the original 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. JINAD protocol submissions consist of protocols without substantial data that FDA and the sponsor consider to be an essential part of the basis to make the decision to approve or not approve an ANADA or supplemental ANADA.

The additional resources provided under AGDUFA I enabled FDA to completely eliminate the backlog of ANADA and JINAD submissions by August 2010.

In 2013, before AGDUFA I expired, Congress passed the Animal Generic Drug User Fee Amendments of 2013 (Pub. L. 113-14; hereinafter referred to as “AGDUFA II”) which included an extension of AGDUFA for an additional 5 years (FY 2014 to FY 2018). AGDUFA II is maintaining the AGDUFA I performance goals regarding work queue procedures, timely meetings with industry, review of administrative ANADAs, review of protocols without substantial data, and amending similar applications and submissions. In addition, FDA agreed to the following program enhancements to further improve review processes:

- Developing a shortened review time process for certain ANADA and JINAD submissions.
- Permitting certain prior approval manufacturing supplements to be resubmitted as “Supplement-Changes Being Effected in 30 days”.
- Developing guidance for a two-phased Chemistry Manufacturing and Controls technical section submission and review process under the JINAD file.
- Permitting comparability protocols to be submitted as protocols without substantial data in a JINAD file.
- Improving timeliness and predictability of foreign pre-approval inspections.
- Developing and implementing a question-based review process for the bioequivalence submissions.

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 and plans can be found at:
<http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>.

III. Meeting Information

A. Meeting Format

In general, the meeting format will include presentations by FDA followed by an open public comment period. Registered speakers for the open public comments will be grouped and scheduled in advance of the meeting based on their affiliation (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry) and timing of their registration. FDA presentations are planned from 1 p.m. until 2

p.m. The open public comment portion of the meeting for registered and scheduled speakers is planned to begin at 2 p.m. An opportunity for additional open public comments from meeting attendees will commence following the registered presentations, if time permits.

FDA policy issues are beyond the scope of these reauthorization discussions. Accordingly, the presentations should focus on process enhancements and funding issues, not on policy issues.

B. Meeting Questions

Please consider the following questions for this meeting:

1. What is your assessment of the overall performance of the AGDUFA program thus far?
2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

C. Registration

If you wish to attend and/or present at the meeting, please register by email to cvmagdufa@fda.hhs.gov by May 4, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. 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 available on a first-come, first-served basis. Early registration is recommended since seating is limited. FDA may limit the number of participants from each organization based on space constraints. Registrants will receive confirmation once their registrations are accepted. Onsite registration on the day of the public meeting will be based on space availability. FDA

will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you need special accommodations due to a disability, please contact Cassie Ravo (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

D. Transcripts

Please be advised that as soon as the transcript is available, it will be accessible at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm270232.htm>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be made available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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