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, email, 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.

[FR Doc. 2016–09150 Filed 4–19–16; 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) is announcing a public meeting on the Animal Drug User Fee Act (ADUFA). FDA invites public comment on the ADUFA program and suggestions regarding the features FDA should propose for the next ADUFA program.

DATES: The meeting will be held on May 16, 2016, from 9 a.m. to 12 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 throughout the reauthorization of ADUFA, until 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/AnimalDrugUserFeeActADUFA/ucm042891.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–0656 for the ''Animal Drug User Fee Act; Public Meeting.'' 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 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. Prior to beginning negotiations with the regulated industry on ADUFA 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 ADUFA. 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 ADUFA program thus far?

2. What aspects of ADUFA 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 ADUFA and its current status.

II. Background

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 that were dedicated to expediting the review of animal drug applications in accordance with certain performance goals. The implementation of ADUFA I provided a significant funding increase for new animal drug application review process, and enabled FDA to increase the number of staff dedicated to the new animal drug application review process by 30 percent from 2003 through 2008.

Under ADUFA I, the industry agreed to pay user fees that are available to FDA, in addition to appropriated funds, to spend on the new animal drug application 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.

As part of ADUFA I, FDA established review performance goals that have been phased in over a 5-year period. These performance goals set from FY 2004 to FY 2008 were intended to achieve progressive, yearly improvements in the time for review of new animal drug applications. By the 5th and final year of ADUFA ending on September 30, 2008, FDA agreed to review and act on 90 percent of the following submission types within the specified timeframes:

- New animal drug applications (NADAs) and reactivations of such applications within 180 days after submission date.
- Nonmanufacturing supplemental NADAs (that is supplemental NADAs for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.
- Manufacturing supplemental NADAs and reactivations of such supplemental applications within 120 days after submission date.
- Investigational new animal drug (INAD) study submissions within 180 days after submission date.
- INAD submissions consisting of protocols, that FDA and the sponsor consider to be an essential part of making the decision to approve or not approve a NADA or supplemental NADA, without substantial data, within 60 days after submission date.
- Administrative NADAs submitted after all scientific decisions have been made in the INAD process (that is, prior to submission of the animal drug application) within 60 days after submission date.

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 (FY 2009 to FY 2013). ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA agreed to the following program enhancements to reduce review cycles and improve communications during reviews:

- Incorporating an ''end-review amendment'' process to amend pending submissions to achieve a complete review decision sooner and reduce the number of review cycles.
- Developing an electronic submission tool that allows industry to submit drug applications electronically.
- Participating with industry in public workshops on mutually agreed upon topics.
- Improving communications by enhancing the timeliness and predictability of foreign pre-approval inspections.

In 2013, before ADUFA II expired, Congress passed the Animal Drug User Fee Amendments of 2013 (Pub. L. 113–14; hereinafter referred to as ''ADUFA III'') which included an extension of ADUFA for an additional 5 years (FY 2014 to FY 2018). ADUFA III is maintaining the ADUFA II performance goals regarding work queue procedures, timely meetings with industry, preapproval foreign inspections, and review of NADAs (including administrative NADAs), supplemental NADAs, INAD protocol submissions, and INAD study submissions. In addition, FDA agreed to the following program enhancements to further improve the review process:

- Discontinuing the end-review amendment procedures and replacing them with a shorter review time process for sponsors providing certain NADA and INAD submissions through the eSubmitter electronic submission tool.
- Implementing a new sentinel submission type and decreasing review time for certain labeling supplements.
- Decreasing the review time for microbial food safety hazard characterization submissions.
- Developing guidance for a two-phased Chemistry, Manufacturing, and Controls technical section submission and review process under the INAD file.

• Permitting certain prior approval manufacturing supplements to be resubmitted as ''Supplement—Changes Being Effected in 30 days.''

• Permitting comparability protocols to be submitted as protocols without substantial data in an INAD file.

• Developing a process where supporting information for pre-submission conferences and INAD protocols without data submissions can be submitted early.

• Exploring the feasibility of pursuing statutory revisions that may modify the current requirements that the use of multiple new animal drugs in the same medicated feed be subject to an approved application.

• Exploring the feasibility of pursuing statutory revisions that may expand the use of conditional approvals to other appropriate categories of new animal drug applications.

FDA has published a number of reports that provide useful background on ADUFA I, ADUFA II, and ADUFA III. ADUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports and plans can be found at: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/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 registration. FDA presentations are planned from 9 a.m. until 10 a.m. The open public comment portion of the meeting for registered and scheduled speakers is planned to begin at 10 a.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 ADUFA III program thus far?

2. What aspects of ADUFA 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 *cvmadufa@fda.hhs.gov* by May 4, 2016. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email, and phone 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/AnimalDrugUserFeeActADUFA/ucm042891.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 *www.fda.gov.*

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09148 Filed 4–19–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our Web site at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding.

The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR