C. Registration

If you wish to attend and/or present at the meeting, please register by email to cvmagnudufa@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/AnimalGenericDrugUserFeeActAGDUFARovm270232.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]
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.
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

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 scheduled from 9 a.m. until 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.

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D. Transcripts

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