C. How do you register for the meeting or submit comments?

If you wish to attend and/or present at the meeting, please register by e-mail to *AGDUFAReauthorization@fda.hhs.gov* by October 26, 2011. Your e-mail should contain complete contact information for each attendee—name, title, affiliation, address, e-mail, and phone number. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patient and consumer advocacy groups; or the regulated industry. Registration is free and will be 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, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

In addition, interested persons may submit either electronic or written comments to the Division of Dockets Management (see *Comments*). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration before the public meeting, all comments must be received by October 26, 2011.

D. Will meeting transcripts be available?

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 *Comments*). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24083 Filed 9–19–11; 8:45 am]

BILLING CODE 4160–01–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.

Date and Time: The meeting will be held on November 7, 2011, from 9 a.m. to 12 noon.

Location: The meeting will be held at the Food and Drug Administration, 7519 Standish Pl., 3d floor, Rm. A, Rockville, MD 20855. If you require special accommodations, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

Contact Person: Donal Parks, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240–276–8688, FAX: 240–276–9744, *Donal.Parks@fda.hhs.gov,* or Patricia Arnwine, Food and Drug Administration, Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855, 240–276–9724, FAX: 240–276–9744, *Patricia.Arnwine@fda.hhs.gov.*

Comments: Regardless of attendance at the meeting, interested persons may submit either electronic or written comments regarding this document. Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. Comments received by October 26, 2011, will be taken into consideration before the public meeting.

Transcripts: Transcripts of the meeting will be available for review at the Division of Dockets Management and on the Internet at *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/ucm042891.htm* approximately 30 days after the meeting.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to hold a public meeting on ADUFA. The authority for ADUFA expires September 30, 2013. 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) 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 to in section 740A(a) of the 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. What is ADUFA? What does it do?

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 to be 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 the 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 since 2003.

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 specified times:

- New animal drug applications and reactivations of such applications within 180 days after submission date.
- Nonmanufacturing supplemental new animal drug applications (that is, supplemental new animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.
- Manufacturing supplemental new animal drug applications and reactivations of such supplemental applications within 120 days after submission date.
- Investigational new animal drug study submissions within 180 days after submission date.
- Investigational new animal drug 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 new animal drug application or supplemental new animal drug application, without substantial data, within 60 days after submission date.
- Administrative new animal drug applications submitted after all scientific decisions have been made in the investigational new animal drug 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 time frames. In addition, FDA agreed to the following program enhancements to reduce review cycles and improve communications during reviews:

- Incorporating an ''end-review amendment'' (ERA) 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.

FDA has published a number of reports that provide useful background on ADUFA I and ADUFA II. 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. What information should you know about the meeting?

A. When and where will the meeting occur? What format will FDA use?

Throughout this document, FDA has been announcing a public meeting to hear stakeholders' views on what FDA should consider for the ADUFA III program. FDA will conduct the meeting on November 7, 2011, at 7519 Standish Pl., 3rd floor, Rm. A, Rockville, MD 20855. (see *Comments*). 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 invited to speak in the order of their affiliation and time of registration (scientific and academic experts/veterinary professionals, representatives of consumer advocacy groups, and the regulated industry). FDA presentations are planned from 9 a.m. until 10 a.m. The open public comment portion of the meeting for registered speakers is planned to begin at 10 a.m. An opportunity for 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.

The docket will remain open for either electronic or written comments through December 7, 2011.

B. What questions would FDA like the public to consider?

Please consider the following questions for this meeting:

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

C. How do you register for the meeting or submit comments?

If you wish to attend and/or present at the meeting, please register by email to *ADUFAReauthorization@fda.hhs.gov* by October 26, 2011. Your e-mail should contain complete contact information for each attendee—name, title, affiliation, address, e-mail, and phone number. Also, please self-identify as a member of one of the following stakeholder categories: Scientific or academic experts; veterinary professionals; patient and consumer advocacy groups; or the regulated industry. Registration is free and will be 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, please contact Patricia Arnwine (see *Contact Person*) at least 7 days before the meeting.

In addition, interested persons may submit either electronic or written comments to the Division of Dockets Management (see *Comments*). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. To ensure consideration before the public meeting, all comments must be received by October 26, 2011.

D. Will meeting transcripts be available?

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 *Comments*). A transcript will also be made available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: September 13, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24082 Filed 9–19–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0640]

Magnetic Resonance Imaging Safety; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled: ''Magnetic Resonance Imaging (MRI) Safety Public Workshop.'' The purpose of the public workshop is to discuss factors affecting the safe use of magnetic resonance imaging (MRI) and approaches to mitigate risks. The overall goal is to discuss strategies to minimize patient and staff risk in the MRI environment.

DATES: The public workshop will be held on October 25, 2011, from 8:30 a.m. to 5 p.m. EDT and on October 26, 2011, from 8:30 a.m. to 5 p.m. EDT.

ADDRESSES: The public workshop will be held in the Great Room at the FDA White Oak Conference Center, Bldg 31, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD, 20993.

FOR FURTHER INFORMATION CONTACT: Carol Krueger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5437, Silver Spring, MD 20993, 301–796–3241, FAX: 301–847–8510, or e-mail: *Carol.Krueger@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and on a first-come, first-served basis. Persons interested in attending this workshop must register online by 5 p.m. on October 4, 2011. Early registration is recommended because facilities are limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, on-site registration on the day of the public workshop will be provided beginning at 7:30 a.m. If you need special accommodations due to a disability, please contact Cynthia Garris, e-mail: *Cynthia.Garris@fda.hhs.gov* or phone: 301 796–5861 no later than October 11, 2011.

To register for the public workshop, please visit the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm270720.htm* (or go the ''FDA Medical Devices News & Events—Workshops and Conferences'' calendar and select this public workshop from the posted events list). Please provide complete contact information for each attendee, including name, title, affiliation, address, e-mail, and telephone number. For those without Internet access, please call the Contact Person to register. Registrants will receive confirmation once they have been accepted. You will be notified if you are on a waitlist.

Streaming Webcast of the Public Workshop: This workshop will also be webcast. Persons interested in viewing the webcast must register online by 5 p.m. on October 4, 2011. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants, but view using one connection per location. Webcast participants will be sent technical system requirements after registration, and will be sent connection access information after October 20, 2011. If you have never attended a Connect Pro event before, test your connection at: *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit: *http://www.adobe.com/go/connectpro_overview.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Requests for Oral Presentations: This workshop includes public comment and topic-focused roundtable sessions. During on-line registration you may indicate if you wish to present during a public comment session or participate in a roundtable session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment and participate in the roundtable sessions. 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 roundtable. Following the close of registration, FDA 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 roundtable participants. All requests to make oral presentations must be received by the close of registration on October 4, 2011. If selected for presentation, any presentation materials must be sent by email to the Contact Person no later than October 11, 2011. No commercial promotional material will be permitted to be presented or distributed at the workshop.

Comments: FDA is holding this public workshop to obtain information on a number of questions regarding factors affecting MRI safe use. The deadline for submitting written comments related to this public workshop is November 22, 2011. Regardless of attendance at the public workshop, interested persons may submit written or electronic comments. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.* It is necessary to send only one set of comments. Please identify written comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at *http://www.regulations.gov.*

I. Background

The number of MRI procedures performed each year continues to rise. At the same time, MRI technology, implanted medical devices and medical device accessories (non-implanted) are becoming more complex. There is increasing demand to scan patients with implanted or accessory medical devices, and the presence of these devices are becoming commonplace in the MRI suite during imaging procedures. While MRI procedures are relatively safe, there are hazards inherent to the MRI environment that must be considered to ensure the safety of patients, healthcare providers, and others who enter the MRI suite. The Agency recognizes the need to work with stakeholders to identify