the Tobacco Control Act for achieving each of the communication goals. The information collected from the study will help inform the Agency's efforts to implement the mandatory graphic health warnings required by the Tobacco Control Act.

The experimental study data will be collected from participants of an Internet panel of approximately 43,000 people. Participation in the experimental study is voluntary.

In the **Federal Register** of March 27, 2012 (77 FR 18250), FDA published a 60-day notice requesting public comment on its proposed collection of information. FDA received eight comments that were not PRA-related and that were outside the scope of this collection of information. FDA also received a comment that asked FDA to provide more detail about the design of the proposed consumer research study to allow for meaningful public comments. The commenter also encouraged FDA to provide additional information for public comment, including details of the protocol, screen, questionnaire, and actual graphic warnings images to be used with study participants to enhance the quality, utility, and clarity of the information to be collected and further the goals of the PRA to ensure the greatest possible public benefit from and maximize the utility of the information. FDA notes in response to this comment that the study and copies of the instruments used to collect this information are described in detail as part of the overall package submitted to OMB for review. The study and copies of the instrument were made available to the public during the original information collection period. They will also be available to the public at *www.reginfo.gov* once OMB receives the package for review.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	60	1	60	0.5 (30 minutes) ..	30
Screener	15,000	1	15,000	0.016 (1 minute) ..	240
Experimental Survey	5,400	1	5,400	0.5 (30 minutes) ..	2,700
Total					2,970

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 15,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.016 hours), for a total of 240 hours. Fifty-four hundred respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 2,700 hours. The total estimated burden is 2,970 hours (30 hours plus 240 hours plus 2,700 hours).

Dated: November 29, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29321 Filed 12–4–12; 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 meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following meeting: Animal Drug User Fee Act. The topic to be discussed is proposed recommendations for the reauthorization of the Animal Drug User Fee Act (ADUFA III).

Date and Time: The meeting will be held on December 18, 2012, from 9 a.m. to 12 p.m.

Location: The meeting will be held at FDA's Metro Park North Campus, 7519 Standish Pl., third floor, Meeting Room A, Rockville, MD 20855. There is parking near the building.

Contact: Jacqueline Farmer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8695, FAX: 240–276–9744, email: *ADUFAReauthorization@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by December 11, 2012.

If you need special accommodations due to a disability, please contact Jacqueline Farmer at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Comments: Interested persons may submit either written comments regarding this meeting to the Division of Dockets Management (see Transcripts) or electronic comments to *http://www.regulations.gov*. It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov*. So that FDA can consider comments and revise the recommendations as necessary, we request that comments be submitted to the docket by January 4, 2013.

SUPPLEMENTARY INFORMATION:

I. The ADUFA Program

A. What is ADUFA? What does it do?

FDA considers the timely review of the safety and effectiveness of new animal drug applications (NADAs) to be central to the Agency's mission to protect and promote the public health. Prior to 2004, the timeliness and predictability of the new animal drug review program was a concern. 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 new animal drug applications in accordance with certain performance goals and to expand and modernize the new animal drug review program. The Agency agreed, under this new Act, to meet a comprehensive set of performance goals established to show significant improvement in the timeliness and predictability of the new animal drug review process. The implementation of ADUFA I provided a significant funding increase that enabled FDA to increase the number of staff dedicated to the new animal drug application review process by 30 percent since 2003.

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—fiscal year (FY) 2009 to FY 2013. ADUFA II performance goals were established based on ADUFA I FY 2008 review timeframes. In addition, FDA provided program enhancements to reduce review cycles and improve communications during reviews. The ADUFA programs have enabled FDA to speed up the application review process for new animal drugs without compromising the quality of the Agency's review.

B. ADUFA Achievements

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

- New animal drug applications and reactivations of such applications within 180 days after submission date.
- Non-manufacturing supplemental new animal drug applications 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 without substantial data within 60 days after submission date.
- Administrative new animal drug applications within 60 days after submission date.

With the reauthorization of ADUFA for an additional 5 years under ADUFA II (FY 2009 to FY 2013), FDA agreed to enhance and further improve the review process via the following changes.

A key improvement under ADUFA II is the ''end-review amendment'' (ERA) process that allows FDA reviewers to work with the drug sponsor to amend certain pending submissions. The ERA process allows us to decrease the number of review cycles, which ultimately leads to a shorter time to approval. Improved communication early in the process has the greatest potential of reducing review cycles. The greatest impact of this new tool in the first 3 years under ADUFA II has been with submissions of investigational new animal drug (INAD) studies and study protocols, which are the earliest review processes impacted by ADUFA performance goals.

The development of an electronic submission tool has enabled sponsors to submit applications and submissions electronically, and has provided FDA reviewers with the ability to evaluate submissions online.

The joint participation of FDA and the regulated industry in 10 public workshops by the end of FY 2013 on mutually agreed-upon topics has enhanced communication and transparency on topics critical to the animal drug review and approval process. To date, FDA and the regulated industry have participated in eight workshops with the final two planned for FY 2013.

FDA is committed to improving the animal drug review and business processes to facilitate the timely scheduling and conducting of foreign preapproval inspections. Because of processes developed under ADUFA II, sponsors are now able to voluntarily submit an annual facilities list and notification 30 days prior to submitting an NADA, a supplemental NADA, or an INAD submission to inform FDA that the application or submission includes a foreign manufacturing facility.

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 can be found at: *http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm.*

II. Proposed ADUFA III Recommendations

A. Enhancing the Process for Premarket Review

We are proposing changes to the performance goals that ADUFA II established to further enhance the process for review of animal drug applications.

The ERA procedure implemented as part of ADUFA II resulted in an increase in the number of one-cycle reviews; however, certain challenges associated with the process restricted its full utilization. We are proposing, among other changes, to further improve the review process by replacing the ERA with shorter review times for certain resubmissions and reactivations. To allow time for the programming and system changes required to make this and other changes, we are proposing to maintain the ADUFA II ERA process and associated review performance goals for FY 2014 for non-administrative animal drug applications, non-manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug submissions consisting of protocols without substantial data.

Starting on October 1, 2014 (for FYs 2015 to 2018), we are proposing to discontinue the ERA procedures and replace them with the process for shorter review times for reactivations and resubmissions. The performance goals listed below for the shorter reactivation and resubmission times only apply when the sponsor provides submissions for the NADA and the INAD through the use of the eSubmitter electronic submission tool.

The Agency will review and act on 90 percent of non-administrative NADAs within 180 days after the submission date. An application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the application and reach a decision on the issue(s) presented in the application.

The Agency will review and act on 90 percent of reactivated applications:

• Within 180 days after the reactivated NADA submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;

• Within 135 days after the reactivated NADA submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the NADA reactivation must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and

• Within 180 days after the reactivated NADA submission date if the NADA reactivation is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the reactivated application.

The Agency will review and act on 90 percent of non-manufacturing supplemental animal drug applications (*i.e.,* supplemental animal drug applications for which safety or effectiveness data are required) within 180 days after the submission date. A supplemental application is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the supplement and reach a decision on the issue(s) presented in the supplement.

• The Agency will review and act on 90 percent of reactivated supplements:

• Within 180 days after the resubmission date if the Agency determines and notifies the sponsor that the deficiencies are substantial.

• Within 135 days after the resubmission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the resubmission to the supplemental application must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and

• Within 180 days after the resubmission date if the resubmission to the supplemental application is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the resubmission.

The Agency will review and act on 90 percent of INAD study submissions within 180 days after the submission date. An INAD study submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission.

The Agency will review and act on 90 percent of resubmitted INAD study submissions:

• Within 180 days after the resubmitted INAD study submission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;

• Within 60 days after the resubmitted INAD study submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the resubmission must be submitted no more than 120 days after the Agency's dated incomplete letter to qualify for the shorter review time; and

• Within 180 days after the resubmitted INAD study submission date if the resubmission is submitted after 120 days of the Agency's dated incomplete letter or new substantial information is provided in the resubmission.

The Agency will review and act on 90 percent of INAD submissions consisting of protocols without data that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application within 50 days after the submission date. An INAD protocol without data submission is incomplete if it would require additional information to enable the Agency to complete a comprehensive review of the protocol and reach a decision on the issue(s) presented in the protocol.

The Agency will review and act on 90 percent of resubmitted INAD protocol without data submissions:

• Within 50 days after the resubmission date if the Agency determines and notifies the sponsor that the deficiencies are substantial;

• Within 20 days after the resubmitted INAD protocol without data submission date if the Agency determines and notifies the sponsor that the deficiencies are not substantial; and the resubmission must be submitted no more than 120 days after the Agency's dated nonconcurrence letter to qualify for the shorter review time; and

• Within 50 days after the resubmission date if the resubmission is submitted after 120 days of the Agency's dated nonconcurrence letter or new substantial information is provided in the resubmission.

B. Additional Review Enhancements Proposal for FYs 2015 to 2018

The Agency will review and act on 90 percent of microbial food safety hazard characterization submissions within 100 days after the submission date.

The Agency will review and act on 90 percent of qualifying labeling supplements as described in 21 CFR 514.8(c)(2)(i)(A) and (D) within 60 days after the submission date. Qualifying labeling supplements are defined as those submitted through the use of the eSubmitter electronic submission tool, for which the sponsor provides and certifies a complete list of label changes made in the application and that CVM can determine upon initial review do not decrease the safety of drug use.

The Agency will review and act on 90 percent of non-qualifying supplemental applications within 180 days after the submission date.

C. Performance Goals Proposal Affecting All Fiscal Years of ADUFA III (2014 to 2018)

The Agency will maintain the ADUFA II goals regarding work queue procedures, timely meetings with industry, review of administrative NADAs, and preapproval foreign inspections.

The Agency will review and act on 90 percent of manufacturing supplemental animal drug applications within 120 days after the submission date. A submission is incomplete if it would require additional data or information to enable the Agency to complete a comprehensive review of the submission and reach a decision on the issue(s) presented in the submission.

• If the Agency determines and notifies the sponsor that the deficiencies are not substantial for manufacturing supplements requiring prior approval according to § 514.8(b), the Agency will permit the manufacturing supplements to be resubmitted as ''Supplement—Changes Being Effected in 30 Days'' as described in § 514.8(b)(3).

• If the Agency determines and notifies the sponsor that the deficiencies are substantial or new substantial information is provided in the resubmission, the Agency will review and act on 90 percent of reactivated manufacturing supplements within 120 days after the resubmission date.

The Agency will permit comparability protocols as described in § 514.8(b)(2)(v) to be submitted as protocols without substantial data in an INAD file. The Agency will review and act on 90 percent of INAD submissions consisting of protocols without substantial data within 50 days after the submission date of the protocol.

The Agency will develop guidance for a two-phased Chemistry, Manufacturing, and Controls (CMC) technical section submission and review process under the INAD file by the end of FY 2014.

The Agency and the regulated industry agree that data and/or information which uniquely describes

the general attributes of the new animal drug (*e.g.,* the known characteristics of the drug that can impact safety, effectiveness, and/or quality) needs to be submitted early in the new animal drug development process in order to enable the parties to reach agreement at a presubmission conference or to begin review of a protocol. Predicated on submission of this information:

- The Agency will allow short justifications within INAD protocols without data submissions that are limited in scope.
- The Agency will allow for the concurrent submission of supporting data and protocols provided that the protocol is not submitted until the supporting data has been in the Agency's queue for at least 50 days.

The Agency will allow for the inclusion of this data and/or information in presubmission conferences, however it would not preclude holding a presubmission conference without such data. Presubmission conferences will be held approximately 100 days after the submission of the data supporting the request.

The Agency and the regulated industry agree that dosage characterization is part of the effectiveness technical section of an investigational new animal drug file. In instances where data and/or information about the dosage is integral to the review of a protocol, the Agency and the regulated industry agree that this data and/or information should be submitted as supporting data well in advance of the protocol submission.

The Agency agrees to explore the feasibility of pursuing statutory revisions, consistent with the Agency's mission to protect and promote the public health, that may expand the use of conditional approvals to other appropriate categories of new animal drug applications and that may modify the current requirement that the use of multiple new animal drugs in the same medicated feed be subject to an approved application.

D. ADUFA III Enhancements for a Modified Inflation Adjuster and Workload Adjuster

ADUFA III financial enhancements include a new statutory inflation adjuster provision that accounts for changes in FDA's costs related to payroll compensation and benefits as well as changes in nonpayroll costs through use of the Consumer Price Index. ADUFA III also modifies the base years for calculating the workload adjuster, as specified in the ADUFA III performance goals letter, to ensure that it adequately captures changes in FDA's workload during ADUFA III.

E. Impact of ADUFA III Enhancements on User Fee Revenue

The following table summarizes the FY 2014 baseline and added funding to support ADUFA III program:

Financial baseline	Dollars
FY 2014 Base Revenue [1]	21,600,000
One-Time Information Technology (IT) Funding	2,000,000
Total Statutory Revenue for FY 2014	23,600,000

[1] For each year in FY 2015 to FY 2018, the annual fee revenue will be further adjusted according to the new statutory provision for the inflation adjuster and may be further adjusted by the workload adjuster. In fiscal years 2016 to 2018, if applicable, the annual fee revenue is subject to a number of possible adjustments, including for inflation and collection shortfalls.

The statutory revenue for 2009, the first year of ADUFA II, was $15,260,000. The statutory revenue for the first year of ADUFA III will be $23,600,000, which includes one-time IT funding in the amount of $2,000,000 for FY 2014. The statute specifies annual revenue of $21,600,000 for each of the FY 2015 through FY 2018, however this amount is subject to a number of possible adjustments, including for inflation and collection shortfalls.

Additionally, ADUFA III offers the following financial recommendations:

- A new provision for recovering collection shortfalls is being offered to ensure adequate funding for the animal drug review process. For example, when FDA sets fees for FY 2016, it may add to the fee revenue the amount of any shortfall in fees collected in FY 2014. This process would follow in subsequent years through the final year adjustment, as specified in the statute.
- FDA has modified the fee revenue distribution from 25 percent for each fee type in ADUFA II to 20 percent in application, 27 percent in product, 27 percent in sponsor, and 26 percent in establishment fees in ADUFA III. The purpose of changing the fee distribution is to increase the revenue stream stability, reduce application fee costs, and minimize the potential for collection shortfalls.

III. What information should you know about the meeting?

We will convene a public meeting to hear the public's views on the proposed recommendations for reauthorization of the ADUFA program. We will conduct the meeting on December 18, 2012, at FDA's Metro Park North Campus (see *Location*). The meeting will include a presentation by FDA and we will provide an opportunity for other organizations and individuals to make presentations at the meeting or to submit written comments to the docket. So that FDA can consider comments and revise the recommendations as necessary, we request that comments be submitted to the docket by January 4, 2013.

Dated: December 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–29498 Filed 12–3–12; 4:15 pm]

BILLING CODE 4160–01–P

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 meeting; request for comments.

The Food and Drug Administration (FDA) is announcing the following meeting: 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 II).

Date and Time: The meeting will be held on December 18, 2012, from 1 p.m. to 4 p.m.

Location: The meeting will be held at FDA's Metro Park North Campus, 7519 Standish Pl., third floor, Meeting Room A, Rockville, MD 20855. There is parking near the building.

Contact: Jacqueline Farmer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–8695, FAX: 240–276–9744, email: *AGDUFAReauthorization@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by December 11, 2012.

If you need special accommodations due to a disability, please contact Jacqueline Farmer at least 7 days in advance.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed