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

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 AGDUFA Program

### *A. What is AGDUFA? What does it do?*

FDA considers the timely review of abbreviated new animal drug applications (ANADAs) to be central to the Agency's mission to protect and promote the public health. Prior to 2009, the timeliness and predictability of the generic animal drug review program was a concern. The Animal Generic Drug User Fee Act enacted in 2008 (Pub. L. 110–316; hereinafter referred to as ''AGDUFA I'') amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to authorize the FDA's first-ever generic animal drug user fee program. AGDUFA I provides FDA with additional funds to enhance the performance of the generic animal drug review process. Furthermore, the authorization of AGDUFA I enabled FDA's continued assurance that generic animal drug products are safe and effective, and enabled FDA's continued support for lower cost alternatives to brand name 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. The purpose of establishing these review performance goals was to expedite the review of ANADAs and reactivations, supplemental ANADAs, and generic investigational new animal drug (JINAD) submissions and to enable FDA to speed up the application review process for generic new animal drugs without compromising the quality of the Agency's review.

### *B. AGDUFA Achievements*

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

- Original ANADAs and reactivations within 270 days after the submission date.
- Administrative 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.

In the 3 years of AGDUFA I review performance evaluated to date (FY 2009 to FY 2011) FDA has exceeded all performance goals for ANADAs, manufacturing supplements, JINAD data submissions, and administrative ANADAs. FDA did not meet the FY 2009 performance goal for JINAD protocol submissions, with 86 percent reviewed by the goal for that year but has exceeded the performance goal for JINAD protocol submissions in FY 2010 and FY 2011. The additional resources provided under AGDUFA I enabled FDA to completely eliminate the backlog of ANADA and JINAD submissions by August 2010.

FDA has published a number of reports that provide useful background on AGDUFA I. AGDUFA-related **Federal Register** notices, guidances, legislation, performance reports, and financial reports can be found at: *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeAct AGDUFA/default.htm.*

## II. Proposed AGDUFA II Recommendations

### *A. Enhancing the Process for Premarket Review*

We are proposing to maintain the AGDUFA I 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. We are proposing the following changes to the performance goals that AGDUFA I established to further enhance the process for review of generic animal drug applications.

The Agency will review and act on 90 percent of non-administrative ANADAs within 270 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 190 days after the reactivated ANADA submission date if the Agency determines that the deficiencies are not substantial;
- Within 270 days after the reactivated ANADA submission date if the Agency determines that the deficiencies are substantial or new substantial information is provided.

The Agency will review and act on 90 percent of manufacturing supplemental ANADAs within 270 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 that the deficiencies are not substantial for manufacturing supplements requiring prior approval according to 21 CFR 514.8(b), the Agency will permit the manufacturing supplements to be resubmitted as ''Supplement-Changes Being Effected in 30 Days'' as described in 21 CFR 514.8(b)(3).
- If the Agency determines 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 270 days after the resubmission date.

The Agency will review and act on 90 percent of JINAD study submissions within 270 days after the submission date. A JINAD 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 JINAD study submissions:

- Within 90 days after the JINAD study resubmission date if the Agency determines that the deficiencies are not substantial;
- Within 270 days after the JINAD study resubmission date if the Agency

determines that the deficiencies are substantial or new substantial information is provided in the resubmission.

The Agency will permit comparability protocols as described in 21 CFR 514.8(b)(2)(v) to be submitted as protocols without substantial data in a JINAD file. The Agency will continue to review and act on 90 percent of JINAD submissions consisting of protocols without substantial data within 100 days after the submission date.

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

The Agency will develop and implement a question based review process for bioequivalence submissions by the end of FY 2016. At its discretion, the Agency may extend the timeline for completion if necessary, depending on available resources.

To improve the timeliness and predictability of foreign preapproval inspections (PAIs), sponsors may voluntarily submit, at the beginning of the calendar year, a list of foreign manufacturing facilities that are included in abbreviated animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and may be subject to foreign PAIs for the following fiscal year.

If such a list is voluntarily submitted, the sponsor should submit a notification 30 days prior to submitting an abbreviated animal drug application, an abbreviated supplemental animal drug application, or generic investigational animal drug submission that informs the Agency that the application includes a foreign manufacturing facility. Should any changes to the annual list occur after its submission to the Agency, the sponsor may provide the updated information to the Agency.

*B. AGDUFA II Enhancements for a Modified Inflation Adjuster and Workload Adjuster*

Similar to AGDUFA I, we agreed to a fixed inflation adjuster over the 5-year period that results in the statutory revenues specified in sections 741(b) and 741(g)(3) of FD&C Act (21 U.S.C. 379j–21(b) and 379–21(g)(3)).

AGDUFA II also modifies the base years for calculating the workload adjuster, as specified in the AGDUFA II performance goals letter, to ensure that it adequately captures changes in FDA's workload during AGDUFA II.

*C. Impact of AGDUFA II Enhancements on User Fee Revenue*

The following table summarizes FY 2014 baseline and added funding to support AGDUFA II program, as well as the AGDUFA II total 5-year revenue:

| Financial baseline | Dollars |
|---|---|
| FY 2014 Base Revenue [1] | 6,478,000 |
| One-Time Information Technology (IT) Funding | 850,000 |
| Total Statutory Revenue for FY 2014 | 7,328,000 |
| Total Financial Funding | |
| Total 5-Year Revenue | 38,100,000 |

[1] For each year in FY 2015 to FY 2018, the annual statutory revenue amounts established in section 741(b) of the FD&C Act may be further adjusted by the workload adjuster for FY 2015 to FY 2018 user fee revenues.

The total 5-year revenue for AGDUFA I was $27,100,000. The total 5-year revenue for AGDUFA II will be $38,100,000, which also includes one-time IT funding in the amount of $850,000 for FY 2014.

Additionally, the fee revenue distribution has been modified from 30 percent in application fees, 35 percent in product fees, and 35 percent in sponsor fees under AGDUFA I to 25 percent in application fees, 37.5 percent in product fees, and 37.5 percent in sponsor fees under AGDUFA II. The purpose of changing the fee distribution is to increase the revenue stream stability and reduce application fee costs.

## 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 AGDUFA I. The public meeting will be held on December 18, 2012, at FDA's Metro Park North Campus (see *Location*). The meeting will include a presentation by FDA, and we will also 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. 2012–29499 Filed 11–26–12; 4:15 pm]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

**SUMMARY:** As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*).

**DATES:** Comments must be submitted within 30-days after publication of this notice in the **Federal Register**.

**ADDRESSES:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Brandie K. Taylor, MA, Strategic Planning and Evaluation Branch, Office of Strategic Planning and Initiative Development, NIAID, NIH, 6610 Rockledge Drive, Room 2502, MSC, 6620, Bethesda, MD 20892, by phone at (301) 451–3068 or Email your request, including your address to: *taylorbr@niaid.nih.gov*.

**SUPPLEMENTARY INFORMATION:**

*Title:* Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIAID) .

*Abstract:* The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into