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

customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide the NIAID's projected average estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of activities: 25.

Respondents: 28,000.

Annual responses: 28,000.

Frequency of Response: Once per request.

Average minutes per response: Ranges from 15 minutes to 120 minutes.

Burden hours: 16,100 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: November 27, 2012.

Shamay D. Knox,

NIAID Project Clearance Liaison.

[FR Doc. 2012–29403 Filed 12–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: AIDS and AIDS Related Research.

Date: December 12, 2012.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, *walkermc@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel Member Conflict: AIDS Clinical Studies and Epidemiology Study Section.

Date: December 13, 2012.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, *rubertm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Biobehavioral Mechanisms of Emotion, Stress and Health.

Date: January 4, 2013.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Melissa Gerald, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3172, MSC 7848, Bethesda, MD 20892, (301) 408–9107, *geraldmel@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 28, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–29304 Filed 12–4–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of Career Development Award.

Date: December 18, 2012.

Time: 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).