APPENDIX B

Process for Information Sharing

While recognizing that the overall purpose of this MOU is to facilitate information sharing, pursuant to Section 4 of this MOU, any Federal partner may decide not to share information or expertise in response to a particular request for information, or to limit the scope of information and expertise sharing in response to a particular request. Nothing in the process described below changes Section 4.

When, under the current MOU, staff at the FDA or the appropriate USDA agency request from the other agency information that may contain confidential material, the request should be in writing, which includes an informal email, and need only identify the subject for which information is requested. Although a more specific description of the information requested may be helpful, it would not be required for purposes of making a request. However, the following language should be included in the request:

> "Information that is shared under this request will be under the FDA-AMS-FSA-FNS Memorandum of Understanding. We agree not to disclose any shared information in any manner without your written permission or as required by law with advance notice to the originating agency." With the inclusion of this statement, requestors would not have to use a particular format or include other pre-specified text.

A response to a request should also be in writing, but it, too, can be an informal email that acknowledges transmission of information in response to the request. Although identifying each piece of information/document provided may be helpful, it would not be required for purposes of responding to a request. However, the following language should be included in the response:

> "Pursuant to the FDA-AMS-FSA-FNS Memorandum of Understanding, this communication may contain privileged and/or confidential information exempt from public disclosure. It may not be disclosed or shared in any manner without our express written consent or as required by law with advance notice to the originating agency." With the inclusion of this statement, responders would not have to use a particular format or include other pre-specified text.

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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

AGENCY: Office of the Director (OD), National Institutes of Health.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, OD 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 in FR.

ADDRESSES: Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to *OIRA_submission@omb.eop.gov,* or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Mikia P. Currie, Program Analyst, Office of policy for Extramural Research Administration, 6705 Rockledge Drive Suite 350, Bethesda, MD 20892–7974, or Email your request, including your address to *curriem@od.nih.gov.*

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

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.

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

Below we provide OD'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: 30.

Respondents: 253,000.

Annual Responses: 253,000.

Frequency of Response: Once per request.

Average Minutes per Response: 10.

Burden Hours: 49,358.

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 22, 2011.

Mikia P. Currie,

Program Analyst, Office of policy for Extramural Research Administration, Office of the Director.

[FR Doc. 2011–30904 Filed 11–30–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Laboratory Animal Welfare: Adoption and Implementation of the Eighth Edition of the Guide for the Care and Use of Laboratory Animals

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) has analyzed public comments received regarding adoption and implementation of the 8th Edition of the *Guide for the Care and Use of Laboratory Animals (Guide)* and has determined to adopt the 8th Edition of the *Guide.* (The comments, received by NIH from February 24 to May 24, 2011, may be viewed at *http://grants.nih.gov/grants/olaw/2011guidecomments/web_listing.htm.*) In NIH's judgment, the 8th Edition of the *Guide* empowers continued advancement in the humane care and use of vertebrate animals in research, research training, and biological testing.

Effective January 1, 2012, institutions that receive Public Health Service (PHS) support for animal activities must base their animal care and use programs on the 8th Edition of the *Guide* and must complete at least one semiannual program review and facilities inspection using the 8th Edition of the *Guide* as the basis for evaluation by December 31, 2012. It is not required that all necessary changes be completed by December 31, 2012, but rather that an evaluation must be conducted and a plan and schedule for implementation of the standards in the 8th Edition of the *Guide* must be developed by December 31, 2012. Institutions must verify to the Office of Laboratory Animal Welfare (OLAW), the organizational component of NIH that provides guidance and interpretation of the PHS Policy on Humane Care and Use of Laboratory Animals, that they have met the required schedule. This will be done through the Annual Report to OLAW covering the 2012 reporting period due January 31, 2013. In addition, institutions must document the implementation of the 8th Edition of the *Guide* in their next Animal Welfare Assurance renewal.

OLAW has developed Position Statements located at *http://grants.nih.gov/grants/olaw/2011positionstatement.htm.* The Position Statements clarify the ways in which NIH expects Assured institutions to implement the 8th Edition of the *Guide* by addressing the following concerns: cost of implementing the 8th Edition of the *Guide;* animal housing specifications; use of nonpharmaceutical-grade compounds; food and fluid restrictions; multiple surgical procedures; and application of the 8th Edition of the *Guide* to agricultural animals used in biomedical research. In addition, there is a summary of OLAW's position on performance standards and practice standards. The public is invited to submit comments on their understanding of the Position Statements for a period of 60 days from December 1, 2011, to January 29, 2012. In response, OLAW may further clarify the Position Statements.

DATES: Written comments on the public's understanding of the Position Statements must be received by NIH on or before January 29, 2012, to be considered.

ADDRESSES: Public comments on the Position Statements may be entered at *http://grants.nih.gov/grants/olaw/2011positionstatement.htm.* Comments will be made publicly available. Personally identifiable information (except organizational affiliations) will be removed prior to making comments publicly available.

FOR FURTHER INFORMATION CONTACT: Office of Laboratory Animal Welfare, Office of Extramural Research, National Institutes of Health, RKL1, Suite 360, 6705 Rockledge Drive, Bethesda, MD 20892–7982; or *telephone:* (301) 496–7163.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1985, the PHS Policy on Humane Care and Use of Laboratory Animals, authorized by Public Law 99–