

requests for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, the issuance shall clearly state the percentage and dollar amount of the total costs of the program or project to be financed with Federal money and the percentage and dollar amount of the total costs of the project or program to be financed by non-governmental sources.

3. Reporting Requirements

The applicant must provide HHS with an original, plus two hard copies, as well as an electronic copy of the following reports in English:

1. A quarterly progress report, due no less than 30 days after the end of each quarter of the budget period. The quarterly progress report must contain the following elements:

- a. Activities and Objectives for the Current Budget Period;
- b. Financial Progress for the Current Budget Period;
- c. Proposed Activity Objectives for the New Budget Period;
- d. Budget;
- e. Measures of Effectiveness; and
- f. Additional Requested Information.

2. A progress report, due 90 days after the end of the budget period, which must contain a detailed summary of the elements required in the quarterly progress report;

3. A final performance report, due no more than 90 days after the end of the project period; and

4. A Financial Status Report (FSR) SF-269 is due 90 days after the close of the 12-month budget period.

Recipients must mail the reports to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For program technical assistance, contact: Craig Carlson, MPH, Office of Public Health Emergency Preparedness, Department of Health and Human Services, Telephone: 202-205-5228, E-mail: craig.carlson@hhs.gov.

For financial, grants management, or budget assistance, contact: DeWayne Wynn, Grants Management Specialist, Office of Grants Management, Office of Public Health and Science, Department of Health and Human Services, 1101 Wootten Parkway, Suite 550, Rockville, MD 20857, Telephone: (240) 453-8822, E-Mail Address:

DeWayne.Wynn.os@hhs.gov.

Dated: September 6, 2006.

W. Craig Vanderwagen,

Assistant Secretary for Public Health Emergency Preparedness, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the proposed information collection project: "Eisenberg Center Voluntary Customer Survey Generic Clearance for the Agency for Healthcare Research and Quality." In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on July 5, 2006 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 12, 2006.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room #5036, Rockville, MD 20850. Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

"Eisenberg Center Voluntary Customer Survey Generic Clearance for the Agency for Healthcare Research and Quality".

AHRQ's newly-established Eisenberg Center is an innovative effort aimed at improving communication of findings to a variety of audiences ("customers"), including consumers, clinicians, payers, and health care policy makers. The Eisenberg Center, one of three components of AHRQ's Effective Health Care Program announced in September 2005, is directed through a contract by the Oregon Health and Science University, Department of Medicine, located in Portland, Oregon. The Eisenberg Center intends to employ the latest survey research techniques to (1) determine how well its products and services are meeting customers' current and anticipated needs; (2) identify problem areas with existing products and services and determine what improvements should be made to improve these products and services; and (3) identify and develop new products and services.

To address customer requirements and to evaluate current and future AHRQ products and services, the Eisenberg Center must periodically determine how well the Eisenberg Center products and services are meeting customers' current and anticipated needs. Work conducted under this clearance will improve the products and services the Center develops for AHRQ for a three year period. The health care environment changes rapidly and requires a quick response from AHRQ to provide appropriately refined products and services. A generic clearance for this work will facilitate AHRQ's timely response to customers' needs.

Methods of Collection

Participation in survey testing will be fully voluntary and non-participation will have no affect on eligibility for, or receipt of, future AHRQ health services research support, on future opportunities to participate in research or to obtain informative research results. Specific estimation procedures, when used, will be described when we notify OMB as to actual studies conducted under the clearance.

Estimated Annual Respondent Burden

Type of survey	Number of respondents	Average hours per response	Total hours
Focus groups for needs assessment	30	1	30
Individual interviews for needs assessment	50	.75	37.5

Type of survey	Number of respondents	Average hours per response	Total hours
Formative focus groups for information tools	120	1	120
Cognitive testing of information tools	500	1	500
Clinician interviews for information tools	160	.75	120
Decision aid laboratory testing	100	1	100
Formative focus groups for decision aids	60	1	60
Automated/web-based surveys for product evaluation	600	.163	98
Telephone interviews for product evaluation	100	1	100
Focus groups for product evaluation	20	1	20
Totals	1,740	NA	1,186

Estimated Costs to the Federal Government

The maximum cost to the Federal Government is \$750,000 annually for FY 2007, FY 2008, and FY 2009. Most of the work will be carried out through contracts. The costs were estimated at \$200 for each face-to-face interview, \$100 for each telephone interview, \$5,000 for each focus group, \$10,000 for Web-based surveys, and \$20,000 for each laboratory testing module. Any deviation from these limits will be noted in reports made to OMB with respect to a particular study or studies conducted under the clearance.

Request for Comments

In accordance with the above-cited legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of health care information dissemination functions of AHRQ, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: August 31, 2006.

Carolyn M. Clancy,

Director.

[FR Doc. 06-7585 Filed 9-11-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D-0344]

Draft Guidance for Industry on Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling." This document is intended to provide recommendations to sponsors of new drug applications (NDAs), and biologic license applications (BLAs) for therapeutic biologics (drugs) on carrying out in vitro or in vivo drug-drug interaction studies. The draft guidance reflects the current view that the metabolism and transport of a new drug should be defined during drug development and that its interactions with other drugs should be explored as part of an adequate assessment of the safety and effectiveness of the drug.

DATES: Submit written or electronic comments on the draft guidance by November 13, 2006. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance 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.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Shiew-Mei Huang, Center for Drug Evaluation and Research (HFD-850), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4550, Silver Spring, MD 20993-0002, 301-796-1541, or
Toni Stifano, Center for Biologics Evaluation and Research (HFM-600), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-6190.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Drug Interaction Studies—Study Design, Data Analysis, and Implications for Dosing and Labeling." FDA previously published two guidance documents on the use of in vitro and in vivo approaches to study metabolism and metabolic drug-drug interactions entitled "Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies in Vitro" and "In Vivo Drug Metabolism/Drug Interaction Studies—Study Design, Data Analysis, and Recommendations for Dosing and Labeling." The draft guidance, when finalized, will replace these guidance documents. This draft guidance discusses study design, choice of interacting drugs, data analysis, and provides recommendations for dosing and labeling.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking