

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori J. Churchyard, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled “Investigating and Reporting Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR part 1271” dated February 2015. The draft guidance document is intended provide manufacturers of HCT/Ps, with recommendations for complying with the requirements for investigating and reporting adverse reactions involving communicable disease in recipients of HCT/Ps that are regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 (361 HCT/Ps).

The draft guidance, when finalized, is intended to supplement section XXII of FDA’s guidance entitled “Guidance for Industry: Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated December 2011 by providing additional recommendations specific to the responsibilities to investigate complaints of adverse reactions concerning 361 HCT/Ps under §§ 1271.160(b)(2), 1271.320 and 1271.350(a)(1).

The draft guidance, when finalized, is intended to supersede the guidance

entitled “Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated November 2005. The guidance will provide updated information specific to reporting adverse reactions related to HCT/Ps to supplement the general instructions accompanying the MedWatch mandatory reporting form, Form FDA 3500A.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 1271 have been approved under OMB control number 0910-0543 and OMB control number 0910-0291.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). 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>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than April 21, 2015.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail to the HRSA Information Collection Clearance Officer, Room 10-29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Radiation Exposure Screening and Education Program OMB No. 0915-xxxx—New.

Abstract: The Radiation Exposure Screening and Education Program (RESEP) is authorized by section 417C of the Public Health Service Act (42 U.S.C. 285a-9). The purpose of RESEP is to assist individuals who live (or lived) in areas where U.S. nuclear weapons testing occurred and who are

diagnosed with cancer and other radiogenic diseases caused by exposure to nuclear fallout or nuclear materials such as uranium. RESEP funds support eligible health care organizations in implementing cancer screening programs; developing education programs; disseminating information on radiogenic diseases and the importance of early detection; screening eligible individuals for cancer and other radiogenic diseases; providing appropriate referrals for medical treatment; and facilitating documentation of Radiation Exposure Compensation Act (RECA) claims.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L.

103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy, including: (a) Demographics for the RESEP program medical user patient population; (b) medical screening activities for cancers and other radiogenic diseases; (c) exposure and presentation types for eligible radiogenic malignant and non-malignant diseases; (d) referrals for appropriate medical treatment; (e) eligibility counseling and referral assistance for the RECA and Energy Employees Occupational Illness Compensation Act programs; and (f) program outreach and education activities. These measures will speak to the Office's progress toward meeting the goals set.

Likely Respondents: Radiation Exposure Screening and Education Program award recipients.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to: (1) Review instructions; (2) develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; (3) train personnel and to be able to respond to a collection of information; (4) search data sources; to complete and review the collection of information; and (5) transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Radiation Exposure Screening and Education Program Performance Measures	50	1	50	24	1,200
Total	50	1	50	24	1,200

HRSA specifically requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jackie Painter,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than March 23, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children's Public Health

System Assessment Surveys OMB No. 0906–xxxx—New.

Abstract: The purpose of the public health system assessment surveys is to inform the Secretary's Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee) on the ability to add newborn screening for particular conditions within a state, including the feasibility, readiness, and overall capacity to screen for a new condition.

The Committee was established under the Public Health Service Act, 42 U.S.C. 217a: Advisory Councils or Committees. This Committee fulfills the functions previously undertaken by the former Secretary's Advisory Committee on Heritable Disorders in Newborns and Children, established under section 1111 of the Public Health Service Act (PHS), 42 U.S.C. 300b–10, as amended in the Newborn Screening Saves Lives Act of 2008. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The purpose of the Committee is to provide the Secretary with recommendations, advice, and technical information regarding the most appropriate application of technologies, policies,