

effectiveness of messages for intended audiences.

Data collection methods proposed for HMTS includes intercept interviews, telephone interviews, focus groups, online surveys, and cognitive interviews. In almost all instances, data will be collected by outside organizations under contract with CDC.

For many years CDC programs have used HMTS to test and refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences. Having this generic clearance available has enabled them to test their information and get critical health information out to the public quickly. Over the last three years, more than 20 messages have been tested using this clearance. For example: *Evaluation of Emergency Preparedness Materials for Limited English Proficient Spanish Speakers*. Risk communication is a top priority in CDC's anthrax preparedness activities. The Anthrax Management Team developed materials to provide LEP Spanish-speakers with information

needed to increase the chances for survival in the event that bioterrorists attacked the U.S. using anthrax. Once refined, based on participant feedback, these materials will be used in creating additional public education materials to be utilized during an anthrax emergency. The lessons learned about communication with vulnerable populations have application to others who are seeking to improve communication during a domestic or global public health emergency.

The Division of Diabetes Translation obtained OMB approval through HMTS for *Testing of Brand Concepts, Messages and Materials* for CDC's National Diabetes Prevention Program (National DPP). Materials testing was conducted with multiple audiences, and provided the detailed level of feedback needed to make materials that resonate with each audience. Findings have also been used to inform the development and testing of a new brand for the National DPP which will be launched in 2015.

The National Institute for Occupational Safety and Health

(NIOSH) conducted a field study, *Spanish Trench Safety CD-ROM*, to determine the most effective way to disseminate trench safety information to Latino immigrant workers using computer-based training. Using results of this study, NIOSH produced the CD-ROM and are preparing to field test the product. As part of this project, a tutorial was also created for workers with limited computer literacy teaching them how to use the computer. The tutorial has been field tested and the English and Spanish versions will become NIOSH numbered publications.

Over 12,000 respondents were queried and over 5,500 burden hours used during this time period. Because the availability of this ICR has been so critical to programs in disseminating their materials and information to the public in a timely manner, OADC is requesting a three year extension of this information collection.

There is no cost to the respondents other than their time. The total estimated annualized burden hours are 2,470.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Professionals, Health Care Providers, State and Local Public Health Officials, Emergency Responders, General Public.	Moderator's Guides, Eligibility Screeners, Interview Guides, Opinion Surveys, Consent Forms.	18, 525	1	8/60

Leroy A. Richardson,
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 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care Development Fund (CCDF)—Reporting Improper Payments—Instructions for States.
OMB No.: 0970-0323.

Description: Section 2 of the Improper Payments Act of 2002 provides for estimates and reports of improper payments by Federal agencies. Subpart K of 45 CFR, Part 98 will require States to prepare and submit a report of errors

occurring in the administration of CCDF grant funds once every three years.

The Office of Child Care (OCC) is completing the third 3-year cycle of case record reviews to meet the requirements for reporting under IPIA. The current forms and instructions expire September 30, 2015. OCC is submitting the information collection for renewal clearance with minor changes. Responders will now have additional guidance and clarification in the instructions and errors have been corrected. New language incorporates requirements from the 2014 Child Care and Development Fund Block Grant Act passed in November 2014.

Respondents: State grantees, the District of Columbia, and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Sampling Decisions and Fieldwork Preparation Plan	17	1	106	1802
Record Review Worksheet	17	276	6.33	29,700.36

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Improper Authorizations for Payment Report	17	1	639	10,863
Corrective Action Plan	8	1	156	1248

Estimated Total Annual Burden Hours: 43,613.36.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0973]

Complicated Intra-Abdominal Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated intra-abdominal infections (cIAs). Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment of cIAs, including clinical trial designs to support approval of drugs. This guidance finalizes the draft guidance of the same name issued October 1, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Complicated Intra-Abdominal Infections: Developing Drugs for Treatment." The purpose of this guidance is to assist sponsors in the development of drugs for the treatment of cIAs.

Intra-abdominal infections including cIAs are common in clinical practice and comprise a wide variety of clinical presentations and differing sources of infection. Different bacterial pathogens are responsible for cIAI, including Gram-negative aerobic bacteria, Gram-positive bacteria, and anaerobic bacteria, including mixed infections. This guidance describes the efficacy endpoint of clinical success as resolution of the baseline signs and symptoms attributable to cIAI. The guidance provides a scientific justification for a noninferiority margin.

This guidance finalizes the draft guidance of the same name issued October 1, 2012. After consideration of comments received in response to the draft guidance, FDA updated the guidance to include clarifications about the primary efficacy endpoint and the use of prior nontrial antibacterial drugs. In addition, issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804 of the Food and Drug Safety and Innovation Act of 2012 (Pub. L. 112-144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency'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 requirements of the applicable statutes and regulations.