

348) establishes a premarket approval requirement for "food additives;" section 201(s) of the act (21 U.S.C. 321) provides an exemption from the definition of "food additive" and thus from the premarket approval requirement, for uses of substances that are Generally Recognized as Safe (GRAS) by qualified experts. In April 1997, FDA proposed a voluntary procedure whereby manufacturers would notify FDA about a view that a particular use (or uses) of a substance is not subject to the statutory premarket

approval requirements based on a determination that such use is GRAS (62 FR 18938, April 17, 1997). Proposed §§ 170.36 and 570.36 provide a standard format for the voluntary submission of a notice. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the subject of the GRAS notice, and the agency's response to the notice, available in a publicly

accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act and other Federal disclosure statutes.

*Description of Respondents:* Manufacturers of Substances Used in Food and Feed.

In the **Federal Register** of February 11, 2009 (74 FR 6894), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.36	25	1	25	150	3,750
570.36	5	1	5	150	750
Total					4,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
170.36(c)(v)	25	1	25	15	375
570.36(c)(v)	5	1	5	15	75
Total					450

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In the proposed rule, FDA estimated that the Center for Food Safety and Applied Nutrition (CFSAN) would receive approximately 50 GRAS notices per year and that the Center for Veterinary Medicine (CVM) would receive approximately 10 GRAS notices per year. Although FDA requested comment on this estimate, the comments did not provide useful information regarding this issue. Therefore, FDA evaluated the number of notices received by CFSAN to date. CFSAN received 274 GRAS notices during the 11-year period from 1998 through 2008, for an average of approximately 25 GRAS notices per year. Based on this experience, FDA is revising its estimate of the annual number of GRAS notices submitted to CFSAN to be 25 or less. FDA also is revising its estimate of the annual number of GRAS notices submitted to CVM to be 5 or less.

Dated: May 4, 2009.

**Jeffrey Shuren**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-09-0733]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and

instruments, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited 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) 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

#### Proposed Project

CDC Early Hearing Detection and Intervention Hearing Screening and Follow-up Survey, OMB #0920-0733—

Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The National Center on Birth Defects and Developmental Disabilities at CDC promotes the health of babies, children, and adults with disabilities. As part of these efforts the Center is actively involved in addressing hearing loss (HL) among newborns and infants. HL is a common birth defect that affects approximately 12,000 infants each year and, when left undetected, can result in developmental delays. As awareness about infant HL increases, so does the demand for accurate information about rates of screening, referral, loss to follow-up, and incidence. This information is important for helping to ensure infants and children are

receiving recommended screening and follow-up services, documenting the occurrence and etiology of differing degrees of HL among infants, and determining the overall impact of infant HL on future outcomes, such as cognitive development, and family dynamics. These data will also assist state Early Hearing Detection and Intervention (EHDI) programs with quality improvement activities and provide information that will be helpful in assessing the impact of federal initiatives. The public will be able to access this information via the CDC EHDI Web site (<http://www.cdc.gov/ncbddd/ehdi/data.htm>).

Given the lack of a standardized and readily accessible source of data, the CDC EHDI program developed a survey to be used annually that utilizes uniform definitions to collect aggregate, standardized EHDI data from states and

territories. The request to complete this survey is planned to be disseminated to respondents via an e-mail, which will include a summary of the request and other relevant information. Minor changes to this survey, based on respondent feedback, are planned in order to make the survey easier to complete and further improve data quality. These changes include splitting the previously combined questions about the number of infants that died and parents refused into two separate questions, adding a question about how many infants with hearing loss are receiving only monitoring services, simplifying the table for reporting type and severity of hearing loss data, and expanding the maternal race categories in the demographic section.

There are no costs to the respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
State and territory EHDI Program Coordinators .....	53	1	4	212

Dated: May 5, 2009.

**Marilyn S. Radke,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[30Day-09-08BL]

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov). Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

**Proposed Project**

Multi-site HIV Testing in Community Mental Health Settings Serving African Americans—New—National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

People with severe mental illness, including those with substance use disorders, are at increased risk of infection with human immunodeficiency virus (HIV) when compared with the general population. However, not enough is known about the risk behaviors, willingness to be tested for HIV, and prevalence of HIV among persons with severe mental illness. In addition, the interrelations among diagnosis of HIV, compliance with medical care, subsequent risk behaviors, and the course of mental illness have not been well-described. Mental health clinics are an important setting for testing and promoting prevention efforts against the transmission of HIV.

The objectives of this project are to (1) demonstrate improved access to HIV testing and linkage to care in participating mental health care settings and (2) describe the relationship between mental illness, HIV risk behaviors, and access to testing and

services, in order to inform the development of optimal prevention interventions for persons with severe mental illness. Staff at selected implementation sites will offer testing for HIV to clients and administer a brief survey to assess risk behaviors, previous access to similar testing services, and mental health symptoms. This project will collect data from clients using brief surveys administered on a voluntary basis. Collection of data will provide information on client demographics; current behaviors that may facilitate HIV transmission, including sexual and drug-use behaviors; current psychiatric symptoms, determined using brief rating scales; access and barriers to HIV testing, prevention, and treatment services; and adherence to psychiatric and medical treatment regimens. CDC is requesting approval for a 2-year clearance for data collection. Data will be collected in 6 sites which provide mental health services.

The goal will be to approach 716 persons annually for participation in the study and interview a total of 600 persons. Based on the University of Pennsylvania's prior experience working in mental health settings, it is estimated that of the 716 approached for participation in the study, the response rate will be approximately 90%. Of the 644 persons approached who agree to be