

those who have not responded to the mailings.

As part of this process, for large respondents reflecting high burdens, such as State employers and large firms, AHCPR will, if needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats.

#### Data

*Type of review:* Regular Submission.

*Affected Public:* Employers.

*Estimated Annual Number of Respondents:* 38,500.

*Estimated Time Per Respondent:* .83.

*Estimated Total Annual Burden Hours:* 32,000.

*Estimated Annual Total Costs to Government:* \$5,700,000.

#### Request for Comments

Comments are invited on: (a) the necessity of the proposed collection; (b) the accuracy of the Agency's estimate of burden (including hours and cost) 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 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/or included in the request for OMB approval of this information collection and they will become a matter of public record.

Copies of these proposed collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above).

Dated: December 2, 1996.

Clifton R. Gaus,

Administrator.

[FR Doc. 96-31255 Filed 12-9-96; 8:45 am]

BILLING CODE 4160-90-M

## Centers for Disease Control and Prevention

### Announcement of Workshop

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the Cystic Fibrosis Foundation, and the University of Washington announce the following workshop.

*Name:* Newborn Screening for Cystic Fibrosis: A Paradigm for Public Health Genetics Policy Development.

*Times and Dates:* 8 a.m.-5:30 p.m., January 13, 1997. 8 a.m.-4 p.m., January 14, 1997.

*Place:* CDC, Auditorium B, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

*Status:* Open to the public, limited only by the space available.

*Purpose:* The Workshop will enable academic and public health professionals to discuss and clarify issues and to provide individual input to develop guidance on population-based newborn screening for cystic fibrosis. This workshop will bring together leaders from the fields of cystic fibrosis research, clinical practice, public health, and newborn screening for an updated discussion of the benefits and risks of newborn screening for cystic fibrosis. Nationally, a wide range of newborn screening tests are now widely accepted and used. Since the immunotrypsinogen test for cystic fibrosis has been available, experts have been discussing adding this test to the newborn screening panel. Previous symposiums, held in 1983 and 1991, concluded that routine newborn screening for cystic fibrosis should not be more widely implemented until newborn diagnosis has been demonstrated to lead to significant clinical benefits. Recently, the discovery of the Cystic Fibrosis Transmembrane Conductive Regulator (CFTR) gene renewed interest in this possibility, as the sensitivity and specificity of testing could be improved. Since cystic fibrosis is a genetic disease of public health importance, public awareness of cystic fibrosis is generating increased interest in health policies related to newborn screening.

*Matters to be discussed:* The Workshop will include sessions on the following: (1) decision making in newborn screening for Cystic Fibrosis (CF), (2) laboratory considerations in newborn screening for CF, (3) progress in newborn screening and

interventions for CF, (4) ethics and health policy of newborn screening for CF, (5) update on international newborn screening programs, followed by break-out group discussions and final conclusions.

Agenda items are subject to change as priorities dictate.

*For Further Information Contact:* Dwight Jones, Division of Birth Defects and Developmental Disabilities, NCEH, CDC, 4770 Buford Highway, NE, Atlanta, Georgia, 30341, telephone 770/488-7160, FAX 770/488-7197. Registration is not required. A limited number of hotel rooms are reserved for the "Cystic Fibrosis Workshop" until December 20, 1996, at the Emory Inn, 1634 Clifton Road, Atlanta, Georgia 30333, telephone 404/712-6700.

Dated: December 4, 1996.

Nancy C. Hirsch,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 96-31325 Filed 12-9-96; 8:45 am]

BILLING CODE 4163-18-M

## Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* The Office of Child Support Enforcement OCSE-156, Child Support Enforcement Program Quarterly Report and OCSE-158, Child Support Enforcement Program Annual Data Summary Report.

*OMB No.:* 0970-0057.

*Description:* The authority to collect and report the information requested on these forms is found in sections 452(a)(4), 452(a)(5), 452(a)(10), 469 of the Social Security Act. These data are highly aggregated and used in a management function to establish the effectiveness and efficiency of State child support programs. The Federal Office of Child Support Enforcement will use the data to carry out its oversight role and submit the Annual Report to Congress.

*Respondents:* State governments, District of Columbia, Guam, Virgin Islands and Puerto Rico.

### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-156 .....	54	4	3.7	799.2
OCSE-158 .....	54	1	1.2	64.8

Estimated Total Annual Burden Hours: 864.0

**Additional Information:**

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

**OMB Comment:**

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: October 21, 1996

Doug Godesky,

Reports Clearance Officer.

[FR Doc. 96-31258 Filed 12-9-96; 8:45 am]

BILLING CODE 4184-01-M

**Food and Drug Administration**

[Docket No. 96N-0433]

**Agency Information Collection  
Activities: Proposed Collection;  
Comment Request; Extension**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for exemption from the food additive listing requirements that are submitted under § 170.39 (21 CFR 170.39).

**DATES:** Submit written comments on the collection of information by February 10, 1996.

**ADDRESSES:** Submit written comments on the collection of information to the

Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Threshold of Regulation for Substances Used in Food-Contact Articles—**  
§ 170.39—(OMB Control Number 0910-0298)—Extension

Under section 409(a) of the act (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless it either conforms to the terms of a regulation prescribing its use or to an exemption for investigational use. Consequently,

the safety of the substance under its intended conditions of use must be established, and a food additive regulation issued, before the substance can be used in food. In accordance with section 409 of the act, manufacturers of all components of a food-contact article (e.g., food packaging or food processing equipment) whose use meets the food additive definition in 201(s) of the act (21 U.S.C. 321(s)) must submit a petition establishing the safe conditions of use before such food-contact articles may be marketed, unless they are the subject of an exemption for investigational use under section 409(i) of the act.

Section 170.39 establishes a process that provides a manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation (Federal Register of July 17, 1995 (60 FR 36582)). The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration is at or below 0.5 part per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

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