manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB Control No. 0910-0116. The recordkeeping burden is based on the number of lots released (6,446), the number of recalls made (1,176), and the total number of AER reports received (16,900) for FY 99. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
600.12	111	58.1	6,446	32	206,272
600.12(b)(2)	343	3.4	1,176	24	28,224
600.80(i)	79	213.92	16,900	1	16,900
Total					251,396

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32783 Filed 12–22–00; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1501]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by January 25, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulation for Substances used in Food-Contact Articles--21 CFR 170.39 (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless: (1) It conforms to an exemption for investigational use under 409(j); (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

In the **Federal Register** of July 17, 1995 (60 FR 36582), § 170.39 (21 CFR 170.39) established a process that provides the 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 or an effective notification. 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 would be at or below 0.5 parts 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.

In the **Federal Register** of September 19, 2000 (65 FR 56585), the agency requested comments on the proposed collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
170.39	6	1	6	48	288

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The above annual reporting estimate is based on information received from representatives of the food packaging and processing industries and on agency records. In the past, FDA has typically received 60 threshold of regulation exemption requests per year.

However, it is estimated that up to 90 percent of the requests that would have previously been submitted under § 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the act.

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32784 Filed 12–22–00; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; Evaluation of a Public Education Campaign on Drinking During Pregnancy

SUMMARY: Under the provisions of Section 3507(a)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 18, 2000, page 56316 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. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Evaluation of a Public Education Campaign on Drinking During Pregnancy.

Type of Information Collection Request: New Collection.

Need and Use of Information Collection: The evaluation is being conducted to determine whether the public education campaign on alcohol consumption during pregnancy raises awareness and attentiveness to the problems of drinking during pregnancy among the target audience of African American women ages 21–29 residing in Washington, DC. The public education campaign, funded by NIAAA, is in response to a need for increased awareness among African American women of childbearing age about the consequences of drinking during pregnancy, the most severe of which is Fetal Alcohol Syndrome (FAS). The two-year campaign will be launched during the spring of 2001, and will serve as a pilot program for possible replication in other communities across the country.

The information from the evaluation of the public information campaign is to be used by NIAAA to inform policy and practice related to public education efforts targeted toward preventing drinking during pregnancy. The collection of information will take place at two points (pretest and posttest): (1) In the spring, 2001, prior to commencement of the public education campaign, to gather baseline data on knowledge of the effects of drinking during pregnancy; and (2) in the winter, 2003, immediately following the conclusion of the public education campaign, to determine whether the message to the target audience had its intended effect. The data collected will be analyzed to: (1) Increase understanding about the extent of African American women's knowledge of the risks of drinking during pregnancy; (2) evaluate whether a public education campaign targeted towards African American women is effective in increasing awareness; and (3) assess the campaign's strengths and weaknesses in order to provide guidance to other similar public education campaigns.

The public education campaign and evaluation are new efforts that will continue for approximately two years.

Frequency of Response: Once per respondent. Potential respondents will be screened to avoid including individuals in both the pre- and post-test invervals as well as including individuals multiple times in a single test interval.

Affected Public: Individuals.

Type of Respondents: Adults. The annual reporting burden is as follows:

Estimated Number of Respondents: 400 at each of the two data collection points, for a total of 800 respondents.

Estimated Number of Responses per Respondent: One response per respondent.

Average Burden Hours per Response: 5-minute response per individual, for a total respondent burden of 4045 minutes, including pilot test responses.

Estimated Total Annual Burden Hours Requested: 67.4 hours. There are no Costs to Respondents to report. There are no Capital Costs to report. There are no Operating or Maintenance costs to report.

Request for Comments

Written comments and suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions; (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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection