ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
Web site Users	400,000	1	6/60	40,000

Dated: December 2, 2005.

Joan F. Karr,

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

[FR Doc. E5–7039 Filed 12–7–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-06–05BF)

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) 639–4766 or send an e-mail to *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

Human Smoking Behavior—New—National Center for Chronic Disease and Public Health Promotion (NCDDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), in a joint venture with the National Center for Environmental Health (NCEH), proposes to conduct a 2-year laboratory-based study of human smoking behavior among established current smokers of the major styles and varieties of cigarettes consumed in the United States. This study will compare how different categories of cigarettes deliver toxic chemicals to smokers in order to further investigate the link between tobacco use and disease.

The major objective of this study is to better understand how human and cigarette variables influence the delivered dose of harmful chemicals in smoke to identify risk factors that result in adverse health effects from smoking. The smoking behavior and biomarkers of 360 smokers will be ascertained. Participants will attend two sessions on consecutive days. Solanesol levels in cigarette filter butts; carbon monoxide boost in breath; carcinogens and nicotine and its metabolites in urine; cotinine in saliva; vent-blocking (as measured by filter stain pattern and visualization of lip and finger placement on the rod using fluorescent markers); smoking topography; and breathing patterns (inhalation and exhalation volume, breath velocity and duration prior to smoking, during smoking and after smoking) will be used to measure dose based on the number of cigarettes smoked, amount of each cigarette smoked, filter vent blocking behavior, smoking behavior and puff characteristics.

Another objective of this study is to define average or ''composite'' smoking patterns across several of the most popular cigarette categories (ultralight, light, full-flavored menthol and full-flavored non-menthol) from the quantitative and observational data. All current smoking machine methodologies are ''one size fits all'' approaches to generating cigarette smoke. The composite conditions can be used to establish human behavior-based smoking machine methods for laboratory studies that require cigarette smoke for chemical or toxicological testing. Currently, laboratory scientists rely on automated smoking machines to generate cigarette smoke for chemical and toxicological testing.

Funding for this study will come from both NCCDPHP and NCEH. The Centers will share responsibilities, with administrative and technical assistance coming from NCCDPHP and laboratory support coming from NCEH.

This is a two-year study, and an estimated 500 respondents will be screened by telephone to yield 360 eligible respondents who complete both visits over the two-year study period. The total burden for each respondent who completes screening, visit 1 and visit 2 will be two hours and five minutes. The CATI screening will take five minutes. Visit 1 will take one hour, which includes a short screening item, the informed consent process, biologic sample collection (urine, saliva, and breath carbon monoxide), smoking topography, ventilation hole blocking procedure and breath measurements. Visit 2 will also take approximately one hour, which includes compensation, discussion of quit opportunities if requested, collection of cigarette butts, biologic sample collection (urine, saliva, and breath carbon monoxide), smoking topography, ventilation hole blocking procedure and breath measurements.

The following table summarizes burden on an annualized basis for 500 telephone interviews and 180 eligible respondents (one-half of the total respondents). The 180 eligible respondents estimated to complete visit 2 are the same respondents estimated to complete visit 1.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 402.

ESTIMATED ANNUALIZED BURDEN TABLE

Respondents	Procedure	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Smokers	CATI Screening	500	1	42
Eligible Smokers	Visit 1, (Day 1)	180	1	180
Eligible Smokers	Visit 2, (Day 2)	180	1	180

Dated: December 1, 2005.

Joan Karr,

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

[FR Doc. E5–7040 Filed 12–7–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0186]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''State Enforcement Notifications'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 14, 2005 (70 FR 54393), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0275. The approval expires on November 30, 2008. A copy of the supporting statement for this information collection is available on the Internet at ''*http://www.fda.gov/ohrms/dockets*''.

Dated: November 30, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23744 Filed 12–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0457]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notice of a Claim for Generally Recognized as Safe Exemption Based on a Generally Recognized as Safe Determination

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 (the PRA), 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 the procedures used for submitting a Generally Recognized as Safe (GRAS) notice stating that a particular use of a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written or electronic comments on the collection of information by February 6, 2006.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (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 PRA (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 set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.

Notice of a Claim for GRAS Exemption Based on a GRAS Determination—21 CFR 170.36 and 570.36 (OMB Control Number 0910–0342)—Extension

Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for ''food additives;'' section 201(s) of the act (21 U.S.C. 321(s)) provides an exemption from the definition of ''food additive'' and thus from the premarket approval requirement, for uses of substances that are GRAS by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. 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 GRAS claim, 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.