

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE-75 .....	36	1	60	2,160

Estimated Total Annual Burden Hours: 2,160.

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto: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 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.

Dated: October 28, 2009.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. E9-26315 Filed 10-30-09; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0360]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Public Health Notification Readership Survey (Formerly Known as "Safety Alert/Public Health Advisory Readership Survey")

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

**ACTION:** Notice.

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

**DATES:** Fax written comments on the collection of information by December 2, 2009.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0341. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**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.

#### FDA Public Health Notification Readership Survey (formerly known as Safety Alert/Public Health Advisory Readership Survey) (PHS Act, Section 1701(a)(4)); (OMB Control Number 0910-0341—Extension)

Section 705(b) of the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 375(b)) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH), communicates these risks to user communities through two publications: (1) The Public Health Notification (PHN) and (2) the Preliminary Public Health Notification (PPHN). The PHN is published when CDRH has information or a message to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type, and that information may not be readily available to the affected target audience in the health care community. CDRH can make recommendations that will help the health care practitioner mitigate or avoid the risk.

The PPHN is also published when CDRH has information to convey to health care practitioners that they would want to know in order to make informed clinical decisions about the use of a device or device type. However, two additional conditions exist that make the use of this type of notification preferable: (1) CDRH's understanding of the problem, its cause(s), and the scope of the risk that is still evolving, so that in order to minimize the risk, the center believes that health care practitioners needs the information they can provide, however incomplete, as soon as possible and (2) the problem is actively being investigated by the center, private industry, another agency or some other reliable entity, so that the center expects to be able to update the PPHN when definitive new information becomes available. Notifications are sent to organizations affected by risks discussed in the notification, such as hospitals, nursing homes, hospices, home health care agencies, retail pharmacies, and other health care providers. Through a process for identifying and addressing postmarket safety issues related to

regulated products, CDRH determines when to publish notifications.

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)), authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address

how clearly notifications for reducing risks are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of the information in the alert. Subjects will also be asked whether they wish to receive future notifications electronically, as well as how the PHN program might be improved.

The information collected will be used to shape FDA's editorial policy for the PHN and PPHN. Understanding how

target audiences view these publications will aid in deciding what changes should be considered in their content and format, and method of dissemination.

In the **Federal Register** of August 24, 2009 (74 FR 42674), 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>

PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Section 1701(a)(4)	308	3	924	.17	157

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

Based on the history of the PHN program, it is estimated that an average of three collections will be conducted a year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey and through discussions with the contacts in trade organizations.

Dated: October 19, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-26307 Filed 10-30-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0497]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

**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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork associated with abbreviated new animal drug

applications submitted to the Center for Veterinary Medicine, FDA.

**DATES:** Submit written or electronic comments on the collection of information by January 4, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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:** Denver Presley, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**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, 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.

#### Abbreviated New Animal Drug Applications—FD&C Act/Section 512(n)(1) (OMB Control Number 0910-NEW)

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Public Law 100-670). Under Section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to