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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

NOV 27 1999

[Docket No. 99N-4933]

Agency Information Collection Activities: Proposed Collection; Comment Request; FDA Safety Alert/Public Health Advisory Readership Survey

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for FDA Safety Alert/Public Health Advisory Readership Survey.

DATES: Submit written comments on the collection of information by *(insert date 60 days after date of publication in the Federal Register.)*

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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 Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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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: (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.

**FDA Safety Alert/Public Health Advisory Readership Survey (OMB No. 0910–0341B—
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 FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health

care providers. Subjects of previous alerts included spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

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

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

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

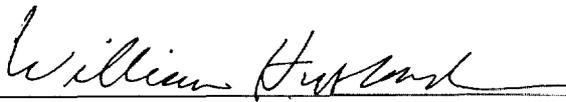
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	1.7	157

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

Based on the history of the safety alert and public health advisory 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: November 19, 1999



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

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