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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-4933]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Safety Alert/Public Health Advisory Readership Survey**

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

**ACTION:** Notice.

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**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 [*insert date 30 days after date of publication in the Federal Register*].

**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.

oc99346

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## **FDA Safety Alert/Public Health Advisory Readership Survey (OMB Control No. 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 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.

In the **Federal Register** of November 26, 1999 (64 FR 66479), the agency requested comments on the proposed collections of information. No significant comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17 <sup>2</sup>	157

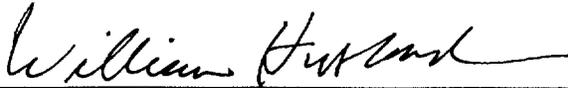
<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Due to a clerical error, the reporting burden hours for "Hours per Response" that appeared in the FEDERAL REGISTER of November 26, 1999 (64 FR 66480) were incorrect. Table 1 of this document contains the correct information.

Based on the history of the safety alert and the 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: March 15, 2000



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

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