TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
540	1	540	20/60	180
900	1	900	25/60	375
200	1	200	25/60	83
Total				638

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

The burden chart reflects up to 3 pretests of 180 individuals each, 900 participants in the main study, and 200 participants in the followup study involving electronic administration.

Dated: December 8, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–31388 Filed 12–14–10; 8:45 am]

BILLING CODE 4160–01–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 the 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 January 14, 2011.

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:* 202–395–7285, or e-mailed to *oira_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, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 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.

Food and Drug Administration Public Health Notification Readership Survey (Formerly Known as the Safety Alert/ Public Health Advisory Readership Survey)—(OMB Control Number 0910–0341)—Reinstatement

Section 705(b) of the Federal Food, Drug, and Cosmetic 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 in order for them to make informed clinical decisions about the use of a device or device type when 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 in order for them to make informed clinical decisions about the use of a device or device type. However, two additional conditions exist that make use of this type of notification preferable: (1) CDRH's understanding of the problem, its cause(s), and the scope of the risk; the Center believes that health care practitioners need 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 risks 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 the format and method of dissemination.

In the **Federal Register** of August 24, 2009 (74 FR 42674), FDA published a 60-day notice requesting comments. No comments were received. However, FDA is republishing this 30-day notice for public comment, due to the amount of time that has passed for submission of this information collection request to OMB.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Public Health Service Act section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1701(a)(4)	308	3	924	0.17	157

[1] 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: December 8, 2010.

Leslie Kux,

Acting Assistant, Commissioner for Policy.

[FR Doc. 2010–31387 Filed 12–14–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Proposed Collection; Comment Request; Voluntary Cosmetic Registration Program

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 collection of information associated with the Agency's Voluntary Cosmetic Registration Program (VCRP).

DATES: Submit either electronic or written comments on the collection of information by February 14, 2011.

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, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 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, 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.

Voluntary Cosmetic Registration Program—21 CFR Parts 710 and 720 (OMB Control Number 0910–0027)—Revision

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) provides FDA with the authority to regulate cosmetic products in the United States. Cosmetic products that are adulterated under section 601 of the FD&C Act (21 U.S.C. 361) or misbranded under section 602 of the FD&C Act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, the Agency has developed the VCRP.

In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the Agency on Form FDA 2511 entitled "Registration of Cosmetic Product Establishment." The term "Form FDA 2511" refers to both the paper and electronic versions of the form. The electronic version of Form FDA 2511 is available on FDA's VCRP Web site at *http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/VoluntaryCosmeticsRegistrationProgramVCRP/OnlineRegistration/default.htm.* FDA's online registration system, intended to make it easier to participate in the VCRP, was made available industrywide on December 1, 2005. The Agency strongly encourages electronic registration of Form FDA 2511 because it is faster and more convenient. A registering facility will receive confirmation of electronic registration, including a registration number, by e-mail, usually within 7 business days. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the