

Catina Conner,
Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0019]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

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 August 11, 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 0910-0360. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794, *Jonnalynn.Capezzuto@fda.hhs.gov*.

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.

Customer/Partner Service Surveys (OMB Control Number 0910-0360)-Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive Order 12862, entitled, "Setting Customer Service Standard," directs Federal agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." FDA is seeking OMB clearance to conduct a

series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers "partner" (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per year, each requiring an average of 15 minutes for review and completion. We estimate respondents to these surveys to be between 100 and 10,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

In the **Federal Register** of January 13, 2011 (76 FR 2395), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Type of survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Mail, telephone, web-based	20,000	1	20,000	0.25 (15 min.)	5,000

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

Dated: July 6, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
 [FR Doc. 2011-17416 Filed 7-11-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0494]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Communications To Educate Consumers on How To Safely Purchase Drugs Online

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 a generic clearance on "Data to Support Communications to Educate Consumers on How to Safely Purchase Drugs Online." This data collection will obtain baseline knowledge of the Internet users' knowledge, attitudes, and practices with regard to online pharmacies, and then will collect ongoing data for tracking changes in knowledge, attitudes, and practices as a

function of an integrated public outreach campaign FDA will roll out to educate consumers on how to safely purchase drugs online.

DATES: Submit either electronic or written comments on the collection of information by September 12, 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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150-400B, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

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.

Data To Support Communications To Educate Consumers on How To Safely Purchase Drugs Online—(OMB Control Number 0910—New)

FDA has planned an integrated public outreach campaign to improve the safe use of online pharmacies for drug purchases. In order to effectively

evaluate this campaign, FDA must understand individuals' knowledge, attitudes, and practices with regard to online pharmacies both at the start of the campaign and on an ongoing basis. This will enable FDA to gauge progress toward educating the public on safely purchasing from online pharmacies. An online survey panel will be employed to collect this information, which serves the need for direct and quantitative measurement of our target population, and which, as a quantitative research tool has some major benefits:

- To focus on our target population of adults who use the Internet.
- To collect data quickly and efficiently with minimal cost to the government.
- To reduce burden to the public by providing a means to complete the survey at a time and place of their choosing.

FDA will use online data collection to establish a baseline and evaluate the success of its messages and distribution methods for its outreach campaign, which educates consumers about how to safely purchase drugs online. Additionally, FDA will use this method to help tailor messages and communications vehicles to have both a more powerful and desired impact on target audiences. The data will not be used for the purposes of making policy or regulatory decisions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Survey Study	5,000	1	5,000	.33 (20 min.)	1,650

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

Annually, FDA projects one survey study. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: July 6, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0476]

Draft Guidance for Industry and Food and Drug Administration Staff; Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance

entitled "Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices." This document describes FDA's intent with regard to enforcement of premarket notification (510(k)) requirements for certain in vitro diagnostic and radiology devices under the regulations. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 11, 2011.