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.

[FR Doc. 2011–17415 Filed 7–11–11; 8:45 am]

BILLING CODE 4160–01–P

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.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5543, Silver Spring, MD 20993–0002, 301–796–6217.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has identified certain Class I and Class II in vitro diagnostic and radiology devices that have established safety and effectiveness profiles and for which it believes 510(k) review is not necessary to assure safety and effectiveness. While FDA intends to exempt these devices from the 510(k) requirement through rulemaking that would reclassify the Class II devices and amend the classification regulations of the Class I devices, FDA no longer believes it is necessary to review premarket notification (510(k)) submissions for these devices before they enter the market. FDA is issuing a draft guidance concerning a policy of exercising enforcement discretion with regard to the 510(k) requirement for such devices. The draft guidance lists the devices for which, when the guidance is finalized, FDA intends to exercise enforcement discretion with regard to premarket notification requirements, subject to the limitations to the exemption criteria found in 21 CFR 862.9, 21 CFR 864.9, 21 CFR 866.9, and 21 CFR 892.9. FDA intends to continue to enforce all other applicable requirements under the FD&C Act, including, but not limited to: Registration and listing (21 CFR part 807); labeling (21 CFR part 801 and 21 CFR 809.10); good manufacturing practice requirements as set forth in the Quality System regulation (21 CFR part 820); and Medical Device Reporting requirements (21 CFR part 803).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Enforcement Policy for Premarket Notification Requirements for Certain In Vitro Diagnostic and Radiology Devices.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Premarket Notification Enforcement Discretion for Certain In Vitro Diagnostic and Radiology Devices,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1752 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 807, subparts B and C have been approved under OMB control number 0910–0387; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 6, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–17352 Filed 7–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; Training (2012/01).

Date: October 27, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Palomar Arlington, 1121 North 19th Street, Arlington, VA 22209.

Contact Person: Ruth Grossman, DDS, Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Boulevard, Room 960, Bethesda, MD 20892, 301–496–8775, *grossmanrs@mail.nih.gov.*