CALENDAR OF REPORTING DATES FOR CALIFORNIA SPECIAL ELECTION—Continued

Report	Close of books [1]	Reg./Cert. & overnight mailing date	Filing date
Post-Runoff & July Quarterly [3]	06/30/06	07/15/06	07/15/06 [2]
Committees Involved *Only* In The Special Runoff (06/06/06) Must File:			
Pre-Runoff	05/17/06	05/22/06	05/25/06
Post-Runoff & July Quarterly [3]	06/30/06	07/15/06	07/15/06 [2]

[1] The period begins with the close of books of the last report filed by the committee. If the committee has filed no previous reports, the period begins with the date of the committee's first activity.
[2] Notice that this deadline falls on a holiday or a weekend. Filing dates are not extended when they fall on nonworking days.
[3] Committees should file a consolidated Post-Runoff and July Quarterly Report by the filing date of the July Quarterly Report.

Dated: December 29, 2005.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. E6–42 Filed 1–6–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0508]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Healthcare Practitioners Regarding Their Preferences for Public Health Notifications

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 survey of healthcare practitioners' preferences regarding public health notifications (PHNs).

DATES: Submit written or electronic comments on the collection of information by March 10, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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.

Survey of Healthcare Practitioners Regarding Their Preferences for PHNs

The PHN is one of the tools that the Center for Devices and Radiological Health (CDRH) uses to get an important message to the user community about risks associated with use of medical devices. This particular tool is meant to serve a specific purpose not served by the other communication tools at our disposal—to be a source of information for healthcare practitioners, immediately recognizable as a statement from FDA, about a device risk with information on how to avoid or mitigate the risk. The purpose of this project is to evaluate the current notification format and distribution process for CDRH, with the goal of determining what is necessary to assure that the notifications reach, and are acted upon by, the target audience. The center needs to know that it is using the most effective approach to formatting and to disseminating PHNs to assure that they are received, recognized, understood, and acted upon quickly and effectively by medical practitioners and institutions. Considerations include, but are not limited to, design, terminology, nomenclature, distribution, utility of standardization, relationship with other medical product notifications (e.g., recalls), use of electronic transmission, and use of plain language.

The intent of this project is to determine the preferences of the healthcare community for learning from FDA about risks associated with medical devices and to compare the current process against the approach identified by the research to be ''preferred'' with the intent of improving our format and process.

CDRH will conduct a survey of a sample of healthcare providers who receive a new PHN from FDA. Most recently, FDA has been using intermediary organizations, such as professional associations, to help us distribute notifications to the appropriate target audiences and we are

assuming that any new PHN will be disseminated in this way, using the appropriate association to distribute the PHN to their members. Generally, the PHN is distributed to the target audience electronically, either as a link embedded in a news article or sent directly via e-mail from either the professional association or FDA using the e-mail listing provided by the professional association. As part of the notification, we will provide a link to a Web-based questionnaire that will collect information related to the healthcare providers' preferences for learning about risks associated with medical devices.

The information collected in this survey will help FDA identify the most effective format(s) and distribution method(s) for CDRH PHNs.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey of healthcare providers in relevant specialty	300	1	300	.1666	50
Survey of healthcare providers in another relevant specialty	300	1	300	.1666	50
Total					100

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

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including the time for reviewing instructions and completing the questionnaire.

Dated: January 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–72 Filed 1–6–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0507]

Agency Emergency Processing Under Office of Management and Budget Review; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA believes, and is preparing a guidance document explaining, that it is possible in certain circumstances for In Vitro Diagnostic (IVD) device studies to be conducted using leftover specimens obtained without informed consent while protecting the human subjects who are the source of such specimens. This notice solicits comments on the proposed collection of information associated with the guidance document entitled ''Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable.''

DATES: Fax written comments on the collection of information by February 8, 2006. FDA is requesting approval of this emergency processing by January 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–26, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. The Center for Devices and Radiological Health (CDRH) intends to issue a guidance document that addresses an immediate need of the research community. CDRH's guidance will identify the circumstances when the agency intends to exercise enforcement discretion regarding the informed consent requirements. These requirements normally apply to all FDA-regulated clinical studies, including studies using only leftover human specimens that are not individually identifiable. The agency intends to issue this guidance because the existing requirements are bringing a halt to a class of very valuable research that can produce new diagnostic tests, without appreciably adding protection for human subjects.

With respect to the following proposed collection of information, FDA invites comments on the following 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.

Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product