

Parties seeking to nominate themselves as potential panelists in the workshop must notify the FTC in writing of their interest in participating on or before Wednesday, April 12, 2006. Requests to participate as workshop panelists should refer to "Mortgage Workshop—Panelist Participation Request." A request to participate filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Mortgage Workshop, c/o Julie Bush, FTC, 601 New Jersey Avenue, NW., Mail Stop NJ-3158, Washington, DC 20580. If the request to participate contains any material for which confidential treatment is requested, it must be filed in paper (rather than electronic) form, and the first page of the document must be clearly labeled "Confidential."<sup>1</sup> The FTC prefers that any request to participate filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area is subject to delay due to heightened security precautions. Please include an original and two copies of each document submitted in paper form.

In the alternative, parties may e-mail requests to participate as workshop panelists (except requests containing any confidential material) to [mortgageworkshop@ftc.gov](mailto:mortgageworkshop@ftc.gov) and should caption them: "Mortgage Workshop—Panelist Participation Request."

Requests to participate as workshop panelists should include the following information:

- (1) A brief biographical description, including name and affiliation;
- (2) A statement setting forth the potential panelist's expertise in or knowledge of one or more issues likely to be addressed by the workshop;
- (3) A list of the topic(s) that the potential panelist would like to address, and a one-paragraph summary of the potential panelist's unique perspective or knowledge of each such topic; and
- (4) Contact information, including a daytime telephone number, facsimile number, and e-mail address (if available).

Parties filing requests to participate as workshop panelists will be notified

<sup>1</sup> Commission Rule 4.2(d), 16 CFR 4.2(d). The request to participate must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the request to participate to be withheld from the public record. The request for confidential treatment will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. See Commission Rule 4.9(c), 16 CFR 4.9(c).

whether they have been invited on or before Wednesday, April 26, 2006.

The FTC Act and other laws the Commission administers permit the collection of requests to participate as workshop panelists, to consider and use in this proceeding as appropriate. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at <http://www.ftc.gov/ftc/privacy/htm>.

#### General Participation

The event is open to the public and there is no fee for attendance. For admittance to the workshop, all attendees will be required to show a valid form of photo identification, such as a driver's license.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. E6-4439 Filed 3-27-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0395]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Product

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Product" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 24, 2006 (71 FR 3858), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0429. The approval expires on March 31, 2009. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 20, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-4424 Filed 3-27-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0507]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; 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 collection of information entitled "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 9, 2006 (71 FR 1429), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0582. The approval expires on September 30, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 20, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-4425 Filed 3-27-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0484]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting

**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 April 27, 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:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**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.

#### Medical Device Reporting: Manufacturer Reporting, Importer Reporting, User Facility Reporting, and Distributor Reporting—21 CFR Part 803 (OMB Control Number 0910-0437)—Extension

Section 519(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act

(the act) (21 U.S.C. 360i(a), (b), and (c)) requires user facilities, manufacturers, and importers of medical devices to report adverse events involving medical devices to FDA. On December 11, 1995 (60 FR 63578 at 63597), FDA issued part 803 (21 CFR part 803) that implemented section 519 of the act. The regulation was amended to conform to the changes reflected in the FDA Modernization Act of 1997.

Information from these reports will be used to evaluate risks associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

Respondents to this collection of information are businesses or other for profit and nonprofit organizations including user facilities, manufacturers, and importers of medical devices.

In the **Federal Register** of December 23, 2005 (70 FR 76318), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
803.19	55	4	220	3	660
803.30	700	5	3,500	1	3,500
803.33, FDA Form 3419	700	1	700	1	700
803.40	40	17	680	1	680
803.50	1,465	57	83,505	1	83,505
803.55, FDA Form 3417	700	5	3,500	1	3,500
Total					92,545

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
803.17	220	1	220	3.3	726
803.18(c) and (d)	30,000	1	30,000	1.5	45,000
Total					45,726

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

Part 803 requires user facilities to report to the device manufacturer, and to FDA in the case of a death, incidents

where a medical device caused or contributed to a death or serious injury. Manufacturers of medical devices are

required to report to FDA when they become aware of information indicating that one of their devices may have