

recordkeeping burden of 2,800 hours (700 x 4 = 2,800). FDA estimates that the cost of developing standard operating procedures for each recordkeeper is \$300 (6 hours of work at \$50/hour (h)). This results in a total cost to industry of \$210,000 (\$300 x 700 recordkeepers). FDA estimates that operating costs for collecting this information is \$300 per

recordkeeper (6 hours of work at \$50/h). This results in a total operational and maintenance cost to industry of \$210,000 (\$300 x 700 recordkeepers). The total cost of this recordkeeping, capital plus operational and maintenance cost is estimated to be \$420,000.

In the **Federal Register** of October 20, 2009 (74 FR 53749), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Section of the Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
520(g)	700	1	700	4	2,800

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. Due to a clerical error, the capital costs and operating and maintenance costs that appeared in a notice issued in the **FEDERAL REGISTER** of October 20, 2009 (74 FR 53749 at 53750) were incorrect. The costs were actually salary costs; Table 1 of this document contains the correct cost burden.

Dated: January 12, 2010.

**David Dorsey,**  
*Acting Deputy Commissioner for Policy,  
Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0480]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational Device Exemptions Reports and Records

**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 February 18, 2010.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0078. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.

#### Investigational Device Exemptions Reports and Records—21 CFR Part 812 (OMB Control Number 0910-0078)—Extension

Section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) establishes the statutory authority to collect information regarding investigational devices, and establishes rules under which new medical devices may be tested using human subjects in a clinical setting. The Food and Drug Administration Modernization Act of 1997 added section 520(g)(6) to the act and permitted changes to be made to either the investigational device or to the clinical protocol without FDA approval of an investigational device exemption (IDE) supplement. An IDE allows a device, which would otherwise be subject to provisions of the act, such as premarket notification or premarket approval, to be used in investigations involving human subjects in which the safety and effectiveness of the device is being studied. The purpose of part 812 (21 CFR part 812) is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use. The IDE regulation is designed to encourage the development of useful medical devices, and allow investigators the maximum freedom

possible, without jeopardizing the health and safety of the public or violating ethical standards. To do this, the regulation provides for different levels of regulatory control depending on the level of potential risk the investigational device presents to human subjects. Investigations of significant risk devices, ones that present a potential for serious harm to the rights, safety or welfare of human subjects, are subject to the full requirements of the IDE regulation. Non-significant risk device investigations, ones that do not present a potential for serious harm, are subject to the reduced burden of the abbreviated requirements. The regulation also includes provisions for treatment IDEs. The purpose of these provisions is to facilitate the availability, as early in the device development process as possible, of promising new devices to patients with life-threatening or serious conditions for which no comparable or satisfactory alternative therapy is available. Section 812.10 of the act, permits the sponsor of the IDE to request a waiver to all of the requirements of part 812. This information is needed for FDA to determine if waiver of the requirements of part 812 will impact the public's health and safety. Sections 812.20, 812.25, and 812.27 consist of the information necessary to file an IDE application with FDA. The submission of an IDE application to FDA is required only for significant risk device investigations.

Section 812.20 lists the data requirements for the original IDE application; § 812.25 lists the contents of the investigational plan; and § 812.27 lists the data relating to previous investigations or testing. The information in the original IDE application is evaluated by the Center for Devices and Radiological Health to

determine whether the proposed investigation will reasonably protect the public health and safety, and for FDA to make a determination to approve the IDE. Upon approval of an IDE application by FDA, a sponsor must submit certain requests and reports. Under § 812.35, a sponsor who wishes to make a change in the investigation which affects the scientific soundness of the study or the rights, safety, or welfare of the subjects, is required to submit a request for the change to FDA. Section 812.150 requires a sponsor to submit reports to FDA. These requests and reports are submitted to FDA as supplemental applications. This information is needed for FDA to assure protection of human subjects and to allow review of the study's progress. Section 812.36(c) identifies the information necessary to file a treatment IDE application. FDA uses this

information to determine if wider distribution of the device is in the interests of the public health. Section 812.36(f) identifies the reports required to allow FDA to monitor the size and scope of the treatment IDE, to assess the sponsor's due diligence in obtaining marketing clearance of the device and to ensure the integrity of the controlled clinical trials. Section 812.140 lists the recordkeeping requirements for investigators and sponsors. FDA requires this information for tracking and oversight purposes. Investigators are required to maintain records, including correspondence and reports concerning the study, records of receipt, use or disposition of devices, records of each subject's case history and exposure to the device, informed consent documentation, study protocol and documentation of any deviation from the protocol. Sponsors are required to

maintain records including correspondence and reports concerning the study, records of shipment and disposition, signed investigator agreements, adverse device effects information and for a non-significant risk device study, an explanation of the non-significant risk determination, records of device name and intended use, study objectives, investigator information, investigational review board information, and statement on the extent that good manufacturing practices will be followed.

In the **Federal Register** of October 23, 2009 (74 FR 54824), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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
812.10	1	1	1	1	1
812.20, 812.25, and 812.27	465	0.5	233	80	18,640
812.35 and 812.150 (reports for significant risk studies)	465	7.8	3,627	6	21,762
812.150 (reports for non-significant risk studies)	465	0.017	8	6	48
812.36(c)	1	1	1	120	120
812.36(f)	1	2	2	20	40
Total					40,611

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. Due to a reevaluation of the burden, the burden hours and annual responses which appeared in a notice issued in the FEDERAL REGISTER of October 23, 2009 (74 FR 54824) have been adjusted.

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

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
812.140 Original	465	0.5	233	10	2,330
812.140 Supplemental	465	7	3,255	1	3,255
812.140 Non-significant	465	1	465	6	2,790
Total					8,375

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information. The estimate of the burden is based on the number of IDEs received in the last 3 years.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0474]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

**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 February 18, 2010.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0510. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.

#### Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—(OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph “g” to

section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program. FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled “Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.”

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

In the **Federal Register** of October 22, 2009 (74 FR 54570), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

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

Section of the Act	Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
704(g)	Request for Accreditation	3	1	3	80	240
Total Hours						240

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

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy,  
Planning and Budget.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0475]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

**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 February 18, 2010.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0114. Also

include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.

#### Administrative Detention and Banned Medical Devices—(OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.