

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

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
571.1(c) moderate category	1	1	1	3,000	3,000
571.1(c) complex category	1	1	1	10,000	10,000
571.6 amendment of petition	2	2	4	1300	5,200
Total Hours					18,200

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

*571.1(c) moderate category:* For food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. An average of one petitions of this type is received on an annual basis, resulting in a burden of 3,000 hours.

*571.1(c) complex category:* For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. An average of one petition of this type is received on an annual basis, resulting in a burden of 10,000 hours.

*571.6:* For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. An average of four petitions of this type is received on an annual basis, resulting in a burden of 5,200 hours.

Thus, the estimated total annual burden for this information collection is 18,200 hours.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-783 Filed 1-15-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0487]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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 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 0910-0582. 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.

#### Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—(OMB Control Number 0910-0582)—Extension

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 development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations

addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1; 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level one guidance document issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total

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