submitted for an application with the actual submitted application by using a unique number tracking system. The information collected is used by FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new medical device applications and supplemental applications. The total number of annual responses is based on the number of cover sheet submissions received by FDA in fiscal year (FY) 2008. CDRH received approximately 5,095 annual responses that included the following submissions: 16 premarket approval applications (PMAs) (PDP, PMR, and BLA),[1] 3,625 premarket notifications, 8 modular premarket applications, 9 panel track supplements, 201 real-time supplements, 173 180-day supplements, 633 30-day notices, 93 513(g) requests, and 337 annual fees for periodic reporting.

CBER received approximately 97 annual responses that included the following submissions: 2 PMAs, 1 BLA efficacy supplement, 50 premarket notifications, 3 180-day supplements, 2 real-time supplements, 20 30-day notices, 3 513(g) requests, and 16 annual fees for periodic reporting. The number of received annual responses in FY 2008 included the cover sheets for applications that were qualified for small businesses and fee waivers or reductions. The estimated hours per response are based on past FDA experience with the various cover sheet submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Medical Device Manufacturers	3601	5,192	1	5,192	18/60	1,558

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

In the **Federal Register** of October 15, 2009 (74 FR 52965), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

Dated: January 12, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–790 Filed 1–15–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Additive Petitions

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 *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0546. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3793.

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.

Food Additive Petitions (OMB Control Number 0910–0546)—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by regulation for investigational use. Section 409(b) of the act specifies the information that must be submitted by a petition in order to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provision of section 409 of the act, procedural regulations have been issued under part 571 (21 CFR part 571). These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the law. The regulations add no substantive requirements to those indicated in the law, but seek to explain the requirements and provide a standard format for submission of petitions, that when implemented, will speed up the time for processing. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 573, 582, and 584 of the act. The labeling regulations are considered by FDA to be cross referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

In the **Federal Register** of October 6, 2009 (74 FR 51287), 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:

[1] PDP means product development protocol, PMR means postmarketing requirements, and BLA means biologics license applications.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

[1]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]

BILLING CODE 4160–01–S

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 *oira_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 Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@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