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—(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 21 CFR part 812, Investigational Device Exemptions, under 21 CFR 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 1 guidance document, entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,'' 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 the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours ($700 \times 4 = 2,800$).

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Federal Food, Drug, and Cosmetic Act section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
520(g) (21 U.S.C. 360j(g))	700	1	700	4	2,800

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

Dated: June 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14228 Filed 6–11–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0294]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Contact Substance Notification Program

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 July 12, 2012.

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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0495. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 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 Contact Substance Notification Program—21 CFR 170.101, 170.106, and 171.1 (Control Number 0910–0495)—Extension

Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(h)) establishes a premarket notification process for food contact substances. Section 409(h)(6) of the FD&C Act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the FD&C Act requires that the notification process be used for authorizing the marketing of food contact substances except when: (1) FDA determines that the submission and premarket review of a food additive petition (FAP) under section 409(b) of the FD&C Act is necessary to provide adequate assurance of safety or (2) FDA and the manufacturer or supplier agree

that an FAP should be submitted. Section 409(h)(1) of the FD&C Act requires that a notification include: (1) Information on the identity and the intended use of the food contact substance and (2) the basis for the manufacturer's or supplier's determination that the food contact substance is safe under the intended conditions of use.

Sections 170.101 and 170.106 of FDA's regulations (21 CFR 170.101 and 170.106) specify the information that a notification must contain and require that: (1) A food contact substance notification (FCN) include a completed and signed Form FDA 3480 and (2) a notification for a food contact substance formulation include a completed and signed Form FDA 3479. These forms serve to summarize pertinent information in the notification. The forms facilitate both preparation and review of notifications because the forms serve to organize information necessary to support the safety of the use of the food contact substance. The burden of filling out the appropriate form has been included in the burden estimate for the notification.

Currently, interested persons transmit an FCN submission to the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3480 whether it is submitted in electronic or paper format. FDA recently made minor revisions to Form FDA 3480 to better enable its use for electronic submission and to prompt FCN submitters to include certain information in a standard format. FDA estimates that the revisions to Form FDA 3480 will not change the amount of time necessary to complete the form.

In addition to its required use with FCNs, revised Form FDA 3480 is recommended to be used to organize information within a Pre-notification Consultation or Master File submitted in support of an FCN according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the Agency, thus minimizing paperwork burden for food contact substance authorizations. FDA estimates that the amount of time for respondents to complete the revised Form FDA 3480 for these types of submissions will be 0.5 hours.

FDA has recently developed a new form, which the Agency recommends be used with each submission of additional information (i.e. amendment) to an FCN submission currently under Agency review, as well as be used to submit an amendment to a Pre-notification Consultation, or for an amendment to Master File in support of an FCN, whether submitted in electronic format or paper format. New Form FDA 3480A is entitled ''Amendment to an Existing Food Contact Substance Notification, a Pre-Notification Consultation, or a Food Master File.'' The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format. Form FDA 3480A helps the respondent organize their submission to focus on the information needed for FDA's safety review. FDA estimates that the amount of time for respondents to complete the new Form FDA 3480A will be 0.5 hours because the new form, used solely for transmitting an amendment, is much shorter than Form FDA 3480. Amendments include the following information on new Form FDA 3480A and in attachments to the form:

- Date of submission;
- Whether the notifier has determined that all files provided in an electronic transmission are free of computer viruses;
- Whether the submission is an amendment to an FCN submission, a Pre-Notification Consultation, or a Master File;
- The format of the submission (i.e., Electronic Submissions Gateway (ESG), transmission on electronic physical media such as CD–ROM or DVD, or paper);
- The name of and contact information for the submitter, including the identity of the contact person and the company name (if applicable);
- The name of and contact information for any agent or attorney who is authorized to act on behalf of the notifier; and
- A brief description of the information provided and the purpose(s) of the amendment.

Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to: (1) Establish that the proposed use of an indirect food additive is safe and (2) secure the publication of an indirect food additive regulation in parts 175 through 178 (21 CFR parts 175 through 178). Parts 175 through 178 describe the conditions under which the additive may be safely used.

In addition, FDA's guidance document entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations'' provides assistance to manufacturers of food packaging in evaluating processes for producing packaging from post-consumer recycled plastic. The recommendations in the guidance address the process by which manufacturers certify to FDA that their plastic products are safe for food contact.

Description of Respondents: The respondents to this information collection are manufacturers of food contact substances.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section or other category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
170.106 [2] (Category A)	FDA 3479	5	1	5	2	10
170.101 [3, 7] (Category B)	FDA 3480	5	1	5	25	125
170.101 [4, 7] (Category C)	FDA 3480	5	2	10	120	1,200
170.101 [5, 7] (Category D)	FDA 3480	33	2	66	150	9,900
170.101 [6, 7] (Category E)	FDA 3480	30	1	30	150	4,500
Pre-notification Consultation or Master File (concerning a food contact substance).[8]	FDA 3480	60	1	60	0.5	30

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section or other category	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Amendment to an existing notification (170.101), amendment to a Pre-notification Consultation, or amendment to a Master File (concerning a food contact substance).[9]	FDA 3480A	50	1	50	0.5	25
171.1 Indirect Food Additive Petitions.	N/A	1	1	1	10,995	10,995
Use of Recycled Plastics in Food Packaging: Chemistry Considerations.	N/A	10	1	10	25	250
Total	.....	.....	.....	.....	.....	27,035

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Notifications for food contact substance formulations and food contact articles. These notifications require the submission of Form FDA 3479 (''Notification for a Food Contact Substance Formulation'') only.
[3] Duplicate notifications for uses of food contact substances.
[4] Notifications for uses that are the subject of exemptions under 21 CFR 170.39 and very simple food additive petitions.
[5] Notifications for uses that are the subject of moderately complex food additive petitions.
[6] Notifications for uses that are the subject of very complex food additive petitions.
[7] These notifications require the submission of Form FDA 3480.
[8] These notifications recommend the submission of Form FDA 3480.
[9] These notifications recommend the submission of Form FDA 3480A.

The forms in table 1 of this document, and elements that would be prepared as attachments to the forms, may be submitted in electronic format through the ESG; email, if appropriate; or may be submitted in paper format, or as electronic files on physical media with paper signature page. FDA expects that most if not all businesses filing these submissions in the next 3 years will choose to take advantage of the option of electronic submission. Thus, the burden estimates in Table 1 of this document are based on the expectation of 100 percent participation in the electronic submission process. The opportunity to provide the information in electronic format could reduce the Agency's previous estimates for the time to prepare each submission. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the revised or new forms and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission.

These estimates are based on FDA's experience with the food contact substance notification program. Based on input from industry sources, FDA estimates that approximately five respondents will submit one notification annually for food contact substance formulations (Form FDA 3479), for a total of five responses. FDA estimates the reporting burden to be 2 hours per response, for a total burden of 10 hours. FDA also has included five expected duplicate submissions in the second row of table 1 of this document. FDA expects that the burden for preparing these notifications primarily will consist of the manufacturer or supplier filling out Form FDA 3480, verifying that a previous notification is effective, and preparing necessary documentation. Thus, FDA estimates that five respondents will submit one such submission annually, for a total of five responses. FDA estimates the reporting burden to be 25 hours per response, for a total burden of 125 hours.

Based on the submissions received, FDA identified three other tiers of FCNs that represent escalating levels of burden required to collect information (denoted as Categories C, D, and E in the third, fourth, and fifth rows of table 1 of this document). FDA estimated the median number of hours necessary for collecting information for each type of notification within each of the three tiers based on input from industry sources. FDA estimates that 5 respondents will submit two Category C submissions annually, for a total of 10 responses. FDA estimates the reporting burden to be 120 hours per response, for a total burden of 1,200 hours. FDA estimates that 33 respondents will submit two Category D submissions annually, for a total of 66 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 9,900 hours. FDA estimates that 30 respondents will submit one Category E submission annually, for a total of 30 responses. FDA estimates the reporting burden to be 150 hours per response, for a total burden of 4,500 hours.

Based on the submissions received, FDA estimates that 60 respondents will submit information to a Pre-notification Consultation or a Master File in support of FCN submission using Form FDA 3480. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 30 hours.

Based on the submissions received, FDA estimates that 50 respondents will submit an amendment (Form FDA 3480A) to a substantive or non-substantive request of additional information to an incomplete FCN submission, for an amendment to a Pre-notification Consultation, or for an amendment to a Master File in support of an FCN. FDA estimates the reporting burden to be 0.5 hours per response, for a total burden of 25 hours.

Based on the submissions received, FDA estimates that one respondent will submit one indirect food additive petition under § 171.1, for a total of one response. FDA estimates the reporting burden to be 10,995 hours per response, for a total burden of 10,995 hours.

FDA estimates that 10 respondents will utilize the recommendations in the guidance document entitled ''Use of Recycled Plastics in Food Packaging: Chemistry Considerations,'' to develop the additional information for one such submission annually, for a total of 10 responses. FDA estimates the reporting

burden to be 25 hours per response, for a total burden of 250 hours.

As noted, FDA estimates that all of the future Forms FDA 3479, 3480, and 3480A submissions will be made electronically through the ESG. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: June 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14227 Filed 6–11–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0835]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The draft guidance discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. The draft guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either written or electronic comments on the draft guidance by August 13, 2012.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Bridget Foltz, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg, 32, Rm. 5174, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The draft guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. In particular, the draft guidance discusses eight steps to be considered when transferring oversight of a previously approved clinical investigation between two IRBs. These include: Identifying those studies for which IRB oversight is being transferred; ensuring availability and retention of pertinent records; establishing an effective date for the transfer; conducting a review of research by the receiving IRB, where appropriate; confirming or establishing the date for the next continuing review; determining whether the consent form needs to be revised; notifying the key parties; and updating IRB registration information. This list is not meant to be exhaustive as the circumstances involved in the transfer may vary.

To enhance human subject protections and reduce regulatory burden, FDA and the Office for Human Research Protections (OHRP) have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subjects research. This draft guidance document was developed as a part of these efforts. OHRP has simultaneously published in this same issue of the **Federal Register** a draft guidance document entitled ''Considerations in Transferring a Previously Approved Research Project to a New IRB or Research Institution'' that is similar to FDA's draft document.

FDA and OHRP recognize that the two documents may appear somewhat different as there are minor variations in formatting and some necessary variations due to differences in the regulated entities under FDA's and OHRP's jurisdiction. The Agencies wish to stress, however, that our intent was to provide harmonized guidance to IRBs, sponsors, institutions, investigators, and other entities involved in the study oversight transfer process. FDA and OHRP will continue to work closely in the development of final guidance and appreciate comments from interested parties.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collections provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this draft guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, which include the requirements for records related to informed consent, have been approved under OMB control number 0910–0130; the collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 812 have been approved under