information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information From U.S. Processors That Export to the European Community (OMB Control Number 0910–0320)—Extension

The EC is a group of 27 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed in this document, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, animal casings, and gelatin) to the EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to the EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to the EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the lists are subject to detention and possible refusal at the port. FDA requests the following information from each processor seeking to be included on the lists:

1. Business name and address;
2. Name and telephone number of person designated as business contact;
3. Lists of products presently being shipped to the EC and those intended to be shipped in the next 6 months;
4. Name and address of manufacturing plants for each product; and
5. Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier such as plant number, and last date of inspection.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	10	1	10	0.25	3
Dairy	120	1	120	0.25	30
Game Meat and Meat Products	5	1	5	0.25	1
Animal Casings	5	1	5	0.25	1
Gelatin	3	1	3	0.25	1
Collagen	3	1	3	0.25	1
Total					37

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

FDA bases its estimate on the responses received over the past 3 years. We estimate that the annual reporting burden would be approximately 37 hours. The time to respond to the questions should take approximately 15 minutes using any of the technologies available to transmit the information. All of the information asked for should be readily available. No record retention is required. In previous years, FDA estimated that the agency's communication with trade associations and states resulted in a reporting burden of 520 hours. FDA no longer receives information from trade associations and states under this program. Accordingly, the proposed annual burden for this information collection has been reduced by 520 hours. Therefore, the proposed annual burden for this information collection is 37 hours.

Dated: June 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11980 Filed 6–20–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0227]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for ''Medical Devices Third-Party Review under the Food and Drug Administration Modernization Act of 1997 (FDAMA).''

DATES: Submit written or electronic comments on the collection of information by August 20, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act--Section 523, Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0375)—Extension

Section 210 of FDAMA established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) of the act (21 U.S.C. 360) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited person review program established by FDAMA and improve the efficiency of 510(k) review for low- to moderate-risk devices.

Respondents to this information collection are businesses or other for-profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 523 of the Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	14	24	336	40	13,440
Totals					13,464

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section 523 of the Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
510(k) reviews by third-party reviewers	14	24	336	10	3,600

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

I. Reporting

A. Requests for Accreditation

FDA now has approximately 8 years of experience with third-party reviews under section 523 of the act. Currently there are 11 active accredited third parties. FDA does not expect to receive more than 1 application for accreditation per year for a total of 14 accredited third parties, who will be conducting third-party reviews.

B. 510(k) Reviews Conducted by Accredited Third Parties

FDA has received 784 510(k)s with a third-party review since 2004. FDA estimates that over the next 3 years, they will accredit 1 third-party reviewer per year for a total of 14 third parties. Each third-party reviewer expects to review a total of 24 510(k) submissions per year for an annual total of 336 applications.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. At the end of 3 years, the agency expects to have 14 accredited persons for review with each third party reviewing on average 24 510(k) applications per year. The agency anticipates approximately 336 annual submissions of 510(k)s for third-party review.

Dated: June 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11981 Filed 6–20–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0223]

Draft Guidance for Industry on Use of the Computer Crossmatch; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: ''Computer Crossmatch'' (Electronic Based testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)'' dated June 2007. The draft guidance document provides recommendations to blood establishments consistent with current good manufacturing practice (CGMP) for the use of a ''computer crossmatch,'' also called an ''electronic crossmatch.'' The computer crossmatch is an alternative to serologic crossmatch and may be used to demonstrate incompatibility between the donor's red blood cell type and the recipient's serum or plasma type.

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 written or electronic comments on the draft guidance by September 19, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: ''Computer Crossmatch'' (Electronic Based Testing for the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)'' dated June 2007. The draft guidance document provides recommendations consistent with CGMP for use of a ''computer crossmatch'' also called an ''electronic crossmatch''. The computer crossmatch is an alternative to serologic crossmatch and may be used to demonstrate incompatibility between the donor's red blood cell type and the recipient's serum or plasma type.

A final rule published in the **Federal Register** on August 6, 2001 (66 FR 40886) revised § 606.151(c) (21 CFR 606.151(c)) to allow either a serologic crossmatch or a computer crossmatch. Prior to September 5, 2001, a blood establishment could only use a computer crossmatch if FDA gave its written approval for the use of a computer crossmatch as an alternate procedure under § 640.120 (21 CFR 640.120). With this revision to § 606.151(c), an application to FDA to permit use of computer crossmatch as an alternative procedure under § 640.120 is no longer necessary. Licensed establishments that change procedures to implement computer crossmatch remain subject to § 601.12 (21 CFR 601.12).

This 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 in 21 CFR 606.100(b) and 606.160 have been approved under OMB control number 0910–0116. The collections of information under § 601.12 have been approved under OMB control number 0910–0338. The collections of information under 21 CFR 606.171 have been approved under OMB control number 0910–0458.

III. Comments

The draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.