(§ 123.6(g)) or otherwise fails to meet any of the requirements of the fish and fishery products regulations (part 123).

FDA published the first edition of the guidance in September 1996 (about 1 year before the fish and fishery products regulations became effective), issued the second edition in January 1998, and issued the third edition in June 2001. In February 2008, FDA updated the third edition to include ciguatera fish poisoning guidance for northern Gulf of Mexico processors and seafood processors that purchase grouper, amberjack, and related predatory reef species captured from the northern Gulf of Mexico. On January 4, 2011, the President signed into law the FDA Food Safety Modernization Act (FSMA) (Pub. L 111–353). Section 103(h) of FSMA requires FDA to update the Fish and Fisheries Products Hazard and Control Guidance within 180 days to take into account advances in technology. This updated guidance satisfies the requirements of section 103(h). The guidance provides current information relating to: (1) Potential hazards associated with the known commercial species of vertebrate and invertebrate seafood, (2) potential hazards associated with certain processing operations, (3) HACCP strategies that may be used to control the potential hazards, and (4) other information related to food safety.

There are a number of important changes to this edition of the HACCP guidance. For example, a new chapter has been added containing guidance for the control of pathogen survival through processes designed to retain raw product characteristics; food safety hazards are identified for additional species; new control recommendations are listed for the natural toxin action level for diarrhetic shellfish poisoning; and tolerances for additional chemical hazards are listed.

The guidance represents the Agency's current thinking on fish and fishery products hazards and controls. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The 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 123.6(a), (b), (c), (c)(5), and (c)(7), 123.7(d), 123.8(a)(1), (c), and (d), 123.11(c), 123.12(a)(2), (a)(2)(ii), and (c) have been approved under OMB control number 0910–0354.

III. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/UCM251970.pdf* or *http://www.regulations.gov.* Always access an FDA document by using the FDA Web site listed previously to find the most current version of the guidance.

Dated: April 22, 2011,

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10234 Filed 4–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0019 (formerly Docket No. 2007D–0223)]

Guidance for Industry: "Computer Crossmatch" (Computerized Analysis of the Compatibility Between the Donor's Cell Type and the Recipient's Serum or Plasma Type); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: 'Computer Crossmatch' (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)" dated April 2011. The guidance document provides blood establishments that perform compatibility testing using a computer crossmatch system to perform computerized matching of blood with recommendations consistent with current good manufacturing practice (CGMP) requirements. Blood establishments are required to have standard operating procedures to demonstrate incompatibility between the donor's cell type and the recipient's serum or plasma type. The guidance describes practices that we believe satisfy those requirements to help ensure detection of an incompatible crossmatch when using a computerized system for matching a donor's cell type with a recipient's serum or plasma type. The guidance announced in this notice finalizes the draft guidance 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.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to 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. Send one self-addressed adhesive label to assist the office in processing your requests. The 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 guidance document.

Submit electronic comments on the 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.

FOR FURTHER INFORMATION CONTACT: Melissa Reisman, 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 document entitled "Guidance for Industry: 'Computer Crossmatch' (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type)" dated April 2011. The guidance document provides blood establishments that perform compatibility testing using a computer crossmatch system to perform computerized matching of blood with recommendations consistent with

CGMP requirements in 21 CFR Parts 210, 211, and 606.

In the **Federal Register** of August 6, 2001 (66 FR 40886), FDA issued a final rule that revised 21 CFR 606.151(c) to allow for the use of either a serologic crossmatch or a computer crossmatch as an acceptable method of establishing the compatibility between the donor's cell type and recipient's serum or plasma type (*i.e.,* major crossmatch). Prior to the issuance of the final rule, a blood establishment could only use a computer crossmatch if FDA gave its written approval for the use of a computer crossmatch as an alternative procedure under 21 CFR 640.120. With this revision to 21 CFR 606.151(c), establishments are no longer required to submit an application to FDA to permit use of a computer crossmatch as an alterative procedure. The guidance does not apply to those circumstances where the donor's blood has not been screened for agglutinating, coating and hemolytic antibodies. In such cases, 21 CFR 606.151(d) requires that "* * * the recipient's cells shall be tested with the donor's serum (minor crossmatch) by a method that will so demonstrate."

The guidance document describes the practices that FDA believes satisfy the requirements in 21 CFR 606.151(c) to help ensure detection of an incompatible crossmatch when using a computerized system for matching a donor's cell type with a recipient's serum or plasma type. We consider computer crossmatch an acceptable method of compatibility analysis when it is properly designed, validated, implemented, and monitored. In addition, the guidance contains recommendations for blood establishments performing compatibility testing that intend to implement a computer crossmatch procedure. For licensed establishments, the guidance also describes how to report this manufacturing change to FDA under 21 CFR 601.12.

In the **Federal Register** of June 21, 2007 (72 FR 34259), FDA announced the availability of the draft guidance 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. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated June 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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. Paperwork Reduction Act of 1995

The 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 211.68(a) and (b) and 211.100(a) have been approved under OMB control number 0910–0139. The collections of information in 21 CFR 606.100(b), 606.121, 606.151, and 606.160 have been approved under OMB control number 0910–0116. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 22, 2011,

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10221 Filed 4–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Study Methodologies for Diagnostics in the Postmarket Setting; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Study Methodologies for Diagnostics in the Postmarket Setting." The purpose of the public workshop is to provide a forum for discussion among FDA, governmental Agencies, academia, physicians, and various stakeholders with expertise in epidemiology, statistics, diagnostics, and biomedical research to advance the methodologies for diagnostics in the postmarket setting.

Date and Time: The public workshop will be held on May 12, 2011, from 8:30 a.m. to 5:15 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the workshop. Sign-in will be required.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

The public workshop with also be available to be viewed via online Web-cast (see *Registration*).

Contact Person: Hui-Lee Wong, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4611, Silver Spring, MD 20993–0002, 301–796–6234, e-mail: *hui-lee.wong@fda.hhs.gov;* or Xueying Sharon Liang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993–0002, 301–796–9601, e-mail: *XueyingSharon.Liang@fda.hhs.gov.*

Registration: In-person and Web-cast registration and information are available at the following Web site: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/*