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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Screener	20,000	1	20,000	2/60	667
Pretests	1,200	1	1,200	20/60	400
Study 1	4,000	1	4,000	25/60	1,667
Study 2	2,000	1	2,000	25/60	834
Study 3	3,600	1	3,600	25/60	1,500
Total					5,068

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

I. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Macias, W. and L. Stavchansky Lewis, "How Well Do Direct-to-Consumer (DTC) Prescription Drug Web Sites Meet FDA Guidelines and Public Policy Concerns?" *Health Marketing Quarterly,* vol. 22, pp. 45–71, 2005.
2. Hicks, K. E., M. S. Wogalter, and W. J. Vigilante, Jr., "Placement of Benefits and Risks in Prescription Drug Manufacturers' Web Sites and Information Source Expectations," *Drug Information Journal,* vol. 39, pp. 267–278, 2005.
3. Huh, J. and B. J. Cude, "Is the Information 'Fair and Balanced' in Direct-to-Consumer Prescription Drug Web Sites?" *Journal of Health Communication,* vol. 9, pp. 529–540, 2004.
4. Sheehan, K. B., "Direct-to-Consumer (DTC) Branded Drug Web Sites Risk Presentation and Implications for Public Policy," *Journal of Advertising,* vol. 36, pp. 123–135, 2007.
5. Davis, J. J., E. Cross, and J. Crowley, "Pharmaceutical Web Sites and the Communication of Risk Information," *Journal of Health Communication,* vol. 12, pp. 29–39, 2007.
6. Naik, S. and S. P. Desselle, "An Evaluation of Cues, Inducements, and Readability of Information on Drug-Specific Web Sites," *Journal of Pharmaceutical Marketing and Management,* vol. 17, pp. 61–81, 2007.
7. Vigilante, Jr., W. J., and M. S. Wogalter, "Assessing Risk and Benefit Communication in Direct-to-Consumer Medication Web Site Advertising," *Drug Information Journal,* vol. 39, pp. 3–12, 2005.

Dated: April 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10253 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–D–0287]

Guidance for Industry on Fish and Fishery Products Hazards and Controls, Fourth Edition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition." The updated guidance supports and complements FDA's regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point (HACCP) methods.

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

ADDRESSES: Contact the Florida Sea Grant, IFAS–Extension Bookstore, University of Florida, P.O. Box 110011, Gainesville, FL 32611–0011, 1–800–226–1764, for single copies of this guidance. *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: Bruce F. Wilson, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the guidance for industry entitled "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition." This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the updated information in this guidance will significantly enhance the seafood industry's ability to protect the public health and will provide important recommendations for conducting a hazard analysis and implementing a HACCP plan. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

This guidance provides industry with information that will assist processors of seafood products in identifying the likelihood that a food safety hazard may occur in their product and will guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur. A summary of the changes from the third edition is included in the discussion section of the guidance.

Under FDA's fish and fishery products regulations (part 123 (21 CFR part 123)), processors of fish and fishery products are required to operate preventive control systems under the principles of HACCP. Fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)) if a processor fails to have and implement a HACCP plan when one is necessary

(§ 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