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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response (in hours)</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screener</td>
<td>20,000</td>
<td>1</td>
<td>20,000</td>
<td>2/60</td>
<td>667</td>
</tr>
<tr>
<td>Pretests</td>
<td>1,200</td>
<td>1</td>
<td>1,200</td>
<td>20/60</td>
<td>400</td>
</tr>
<tr>
<td>Study 1</td>
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<td>1</td>
<td>4,000</td>
<td>25/60</td>
<td>1,667</td>
</tr>
<tr>
<td>Study 2</td>
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<td>1</td>
<td>2,000</td>
<td>25/60</td>
<td>834</td>
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<tr>
<td>Study 3</td>
<td>3,600</td>
<td>1</td>
<td>3,600</td>
<td>25/60</td>
<td>1,500</td>
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<tr>
<td>Total</td>
<td></td>
<td></td>
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<td></td>
<td>5,068</td>
</tr>
</tbody>
</table>

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.


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

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.” This 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:

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(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)(i), 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

Dated: April 22, 2011,
Leslie Kux,
Acting Assistant Commissioner for Policy.

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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 computerized 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 compatibility 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.


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 computerized matching of blood with recommendations consistent with