

in the spread of these pathogens. Pathogens that can cause diseases after an infected person handles food are the following:

Noroviruses.

Hepatitis A virus.

Salmonella Typhi.*

Shigella species.

Staphylococcus aureus.

Streptococcus pyogenes.

II. Pathogens Occasionally Transmitted by Food Contaminated by Infected Persons Who Handle Food, But Usually Transmitted by Contamination at the Source or in Food Processing or by Non-foodborne Routes

Other pathogens are occasionally transmitted by infected persons who handle food, but usually cause disease when food is intrinsically contaminated or cross-contaminated during processing or preparation. Bacterial pathogens in this category often require a period of temperature abuse to permit their multiplication to an infectious dose before they will cause disease in consumers. Preventing food contact by persons who have an acute diarrheal illness will decrease the risk of transmitting the following pathogens:

Campylobacter jejuni.

Cryptosporidium parvum.

Entamoeba histolytica.

Enterohemorrhagic Escherichia coli.

Enterotoxigenic Escherichia coli.

Giardia lamblia.

Nontyphoidal Salmonella.

Sapoviruses.

Taenia solium.

Vibrio cholerae.

Yersinia enterocolitica.

References

1. World Health Organization. Health surveillance and management procedures for food-handling personnel: report of a WHO consultation. World Health Organization technical report series; 785. Geneva: World Health Organization, 1989.
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3. Bennett JV, Holmberg SD, Rogers MF, Solomon SL. Infectious and parasitic diseases. In: Amler RW, Dull HB, eds. *Closing the gap: the burden of unnecessary illness*. New York: Oxford University Press, 1987:102–114.
4. Centers for Disease Control and Prevention. Locally acquired neurocysticercosis—North Carolina, Massachusetts, and South Carolina, 1989–1991. MMWR 1992; 41:1–4.

5. Centers for Disease Control and Prevention. Foodborne Outbreak of Cryptosporidiosis—Spokane, Washington, 1997. MMWR 1998; 47:27.

6. Noel JS, Humphrey CD, Rodriguez EM, et al., Parkville virus: A novel genetic variant of human calicivirus in the sapporo virus clade, associated with an outbreak of gastroenteritis in adults. J. Med. Virol. 52:173–178, 1997.

Dated: September 15, 2006.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0044]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications; Availability

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 October 26, 2006.

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: 202–395–6974.

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

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.

Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Clinical Laboratory Improvement Amendments (CLIA) of 1988 Waiver Applications; Availability

Congress passed the CLIA (Public Law 100–578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary) before accepting materials derived from human body for laboratory tests (42 U.S.C. 263a(b)).

Laboratories that perform only tests that are “simple” and that have an “insignificant risk of an erroneous result” may obtain a certificate of waiver (42 U.S.C. 263a (c)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are “simple” and have “an insignificant risk of an erroneous result” under CLIA (69 FR 22849, April 27, 2004). This guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets CLIA standards (CLIA waiver application).

The guidance recommends that CLIA waiver applications include a description of the features of the device that make it “simple”: A report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanism and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate accuracy of the test in the hands of intended operators; and statistical analysis of clinical study results. The guidance also make recommendations concerning labeling of “waived tests.” The burden associated with most of these labeling recommendations is approved under OMB control number 0910–0485.

Only new information collections not already approved, are included in the estimate in this document. Recommendations for quick reference instructions are written in simple language that can be posted. The guidance also notes that “waived tests” remain subject to applicable reporting and recordkeeping requirements under 21 CFR part 803. The burden associated

* Kauffmann-White scheme for designation of *Salmonella* serotypes.

with this provision is approved under OMB control number 0910-0437.

Respondents to this collection of information are manufacturers of in vitro diagnostic devices.

In the **Federal Register** of September 7, 2005 (70 FR 53231), FDA solicited comments on the collection of information requirements. No comments were received in response to this notice.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
40	1	40	780	31,200	\$5,500

¹There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

No. of Recordkeepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record	Total Hours	Total Operating & Maintenance Costs
40	1	40	2,800	112,000	\$60,700

¹There are no capital costs associated with this collection of information.

Based on previous years of experience, with CLIA waiver applications, FDA expects 40 manufacturers to apply for one CLIA waiver per year. The annual reporting burden to respondents is estimated to be 31,200 hours and the recordkeeping burden for respondents is estimated to be 112,00 hours. FDA based the reporting and recordkeeping burden on agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests.

The total operating and maintenance costs associated with the implementation of this draft guidance is estimated to be \$66,200. The cost consists of specimen collections for the clinical study (estimated at \$23,500); laboratory supplies, reference testing, and study oversight (estimated at \$26,700); shipping and office supplies (estimated at \$6,000); and educational materials, including quick reference instructions (estimated at \$10,000).

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0357]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products

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 extending OMB approval on the existing reporting and recordkeeping requirements for processors and importers of fish and fishery products.

DATES: Submit written or electronic comments on the collection of information by November 27, 2006.

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:

Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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