

**ACTION:** Notice of annual update of list of infectious and communicable diseases that are transmitted through handling the food supply and the methods by which such diseases are transmitted.

**SUMMARY:** Section 103(d) of the Americans with Disabilities Act of 1990, Public Law 101-336, requires the Secretary to publish a list of infectious and communicable diseases that are transmitted through handling the food supply and to review and update the list annually. The Centers for Disease Control and Prevention (CDC) published a final list on August 16, 1991 (56 FR 40897) and updates on September 8, 1992 (57 FR 40917); January 13, 1994 (59 FR 1949); August 15, 1996 (61 FR 42426); September 22, 1997 (62 FR 49518-9); September 15, 1998 (63 FR 49359); September 21, 1999 (64 FR 51127); September 27, 2000 (65 FR 58088); September 10, 2001 (66 FR 47030); and September 27, 2002 (67 FR 61109). The final list has been reviewed in light of new information and has been revised as set forth below.

**DATES:** *Effective Date:* November 17, 2008.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donald Sharp, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE., Mailstop G-24, Atlanta, Georgia 30333; Telephone: (404) 639-2213.

**SUPPLEMENTARY INFORMATION:** Section 103(d) of the Americans with Disabilities Act of 1990, 42 U.S.C. 12113 (d), requires the Secretary of Health and Human Services to:

1. Review all infectious and communicable diseases which may be transmitted through handling the food supply;
2. Publish a list of infectious and communicable diseases which are transmitted through handling the food supply;
3. Publish the methods by which such diseases are transmitted; and,
4. Widely disseminate such information regarding the list of diseases and their modes of transmissibility to the general public.

Additionally, the list is to be updated annually.

Since the last publication of the list on September 26, 2006 (67 FR 61109), no information has been added.

#### **I. Pathogens Often Transmitted by Food Contaminated by Infected Persons Who Handle Food, and Modes of Transmission of Such Pathogens**

The contamination of raw ingredients from infected food-producing animals

and cross-contamination during processing are more prevalent causes of foodborne disease than is contamination of foods by persons with infectious or contagious diseases. However, some pathogens are frequently transmitted by food contaminated by infected persons. The presence of any one of the following signs or symptoms in persons who handle food may indicate infection by a pathogen that could be transmitted to others through handling the food supply: Diarrhea, vomiting, open skin sores, boils, fever, dark urine, or jaundice. The failure of food-handlers to wash hands (in situations such as after using the toilet, handling raw meat, cleaning spills, or carrying garbage, for example), wear clean gloves, or use clean utensils is responsible for the foodborne transmission of these pathogens. Non-foodborne routes of transmission, such as from one person to another, are also major contributors 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.
2. Frank JF, Barnhart HM. Food and dairy sanitation. In: Last JM, ed. Maxcy-Rosenau public health and preventive medicine, 12th edition. New York: Appleton-Century-Crofts, 1986: 765-806.
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: November 6, 2008.

**James D. Seligman**,

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

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Administration for Children and Families**

##### **Proposed Information Collection Activity; Comment Request**

###### *Proposed Projects:*

*Title:* Court Improvement Program.  
*OMB No.:* 0970-0245.

*Description:* The Court Improvement Program provides grants to State court systems to conduct assessments of their foster care and adoption laws and judicial processes and to develop and implement a plan for system improvement. ACF proposes to collect information from the States about this program (applications, program reports) by way of a Program Instruction, which (1) describes the requirements for States under the reauthorization of the Court Improvement Program; (2) outlines the programmatic and fiscal provisions and reporting requirements of the program; (3) specifies the application submittal and approval procedures for the program for Fiscal Years 2007 through

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

2011; and (4) identifies technical resources for use by State courts during the course of the program. This Program Instruction contains information collection requirements pursuant to receiving a grant award that are found

in Public Law 103-66, as amended by Public Law 105-89, Public Law 107-133, Public Law 109-239, and Public Law 109-288. The agency will use the information received to ensure compliance with the statute and provide

training and technical assistance to the grantees.

*Respondents:* State Courts.

*Annual Burden Estimates.*

| Instrument                  | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Application .....           | 52                    | 1                                  | 40                                | 2,080              |
| Annual program report ..... | 52                    | 1                                  | 36                                | 1,872              |

*Estimated Total Annual Burden Hours:* 3,952.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn: ACF Reports Clearance Officer.* E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

*The Department specifically requests comments on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 12, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0571]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Compliance With the Medical Device User Fee and Modernization Act of 2002, as Amended; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices (formerly "Reprocessed Single-Use Device Labeling")

**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 reprocessed single-use device labeling.

**DATES:** Submit written or electronic comments on the collection of information by January 16, 2009.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.regulations.gov>. 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 Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

**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.