

performance; (2) Development of a standardized test protocol for measuring the efficacy of a decontamination procedure for FFR; (3) Measure the survivability of a virus simulant trapped on FFR; (4) Measurement of the re-aerosolization of a trapped virus simulant on FFR; (5) Assess the efficacy of various decontamination methods suitable for FFR; (6) Determine the effects of decontamination on the FFR fit; and (7) produce a final report that could be used to issue guidance documents on FFR reuse.

FOR FURTHER INFORMATION CONTACT:

Jonathan Szalajda, telephone 412-386-6627, or e-mail zfx1@cdc.gov.

Dated: September 19, 2006.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E6-15706 Filed 9-25-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Portfolio on the Disability and Health Team of the Division of Human Development and Disability

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Portfolio on the Disability and Health Team of the Division of Human Development and Disability.

Times and Dates:

6 p.m.–8 p.m., October 22, 2006 (Closed).

8 a.m.–5 p.m., October 23, 2006 (Closed).

8 a.m.–3 p.m., October 24, 2006 (Closed).

Place: National Center on Birth Defects and Developmental Disabilities, CDC, 12 Executive Park Drive, Atlanta, Georgia 30329, Telephone Number 404.498.3013.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

Matters To Be Discussed: The meeting will include expert review of science and programs of the Disability and Health Team.

Contact Person for More Information: Esther Sumartojo, Associate Director for Science, National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE., Mailstop E-87, Atlanta, GA 30333, Telephone Number 404.498.3072.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 18, 2006.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E6-15719 Filed 9-25-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Diseases Transmitted Through the Food Supply

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

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.

EFFECTIVE DATE: September 26, 2006.

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 October 4, 2004 (67 FR 61109), new information has been reviewed and added. Norwalk and Norwalk-like viruses, previously listed in Part I, are now identified as Noroviruses so as to conform with current scientific nomenclature. Sapoviruses have been added to Part II.

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.

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

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).

[FR Doc. E6–15712 Filed 9–25–06; 8:45 am]

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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