the list published in the **Federal Register** on November 6, 2003.

### 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*
*Taenia solium*
*Vibrio cholerae* 01
*Yersinia enterocolitica*

[*] Kauffmann-White scheme for designation of Salmonella serotypes

### 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.

Dated: September 24, 2004.

**James D. Seligman,**

*Associate Director for Program Services, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 04–22260 Filed 10–1–04; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee*: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

*General Function of the Subcommittee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on November 3, 2004, from 8 a.m. to 5:30 p.m., and on November 4, 2004, from 8 a.m. to 1:30 p.m.

*Location*: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person*: Hilda Scharen, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, e-mail: *SCHARENH@cder.fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On November 3, 2004, the subcommittee will: (1) Receive topic updates for ongoing FDA activities previously presented to the subcommittee; (2) discuss and provide comments on the evidence for updating labels of approved drugs to include integrating pharmacogenetic, pharmacokinetic, and prognostic biomarkers for the purpose of optimizing therapeutic response and reducing risks of toxicity; and (3) discuss and provide comments on metabolism- and transporter-based drug-drug interactions included as recommendations in a draft guidance for industry being prepared by FDA. On November 4, 2004, the subcommittee will discuss and provide comments on a new critical path project related to general aspects of the transition of biomarkers to surrogate endpoints, with a focus on planning and process, rather than on specific biomarkers or surrogate endpoints.

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 25, 2004. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m. on November 3, 2004, and between 1 p.m. and 1:30 p.m. on November 4, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and

addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Hilda Scharen at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 24, 2004.

**Sheila Dearybury Walcoff,**

*Associate Commissioner for External Relations.*

[FR Doc. 04–22214 Filed 10–1–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0431]**

### Draft Guidance for Industry and the Food and Drug Administration; Current Good Manufacturing Practices for Combination Products; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practices for Combination Products.'' Once finalized, this guidance will provide guidance to industry and FDA staff on the applicability of current good manufacturing practices (CGMP) for combination products.

**DATES:** Submit written or electronic comments on the draft guidance by December 3, 2004. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Combination Products (HFG–3), 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Patricia Y. Love, Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–427–1934, FAX 301–427–1935, e-mail: *patricia.love@oc.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Current Good Manufacturing Practices for Combination Products.'' Combination products are defined under 21 CFR 3.2(e). This draft guidance document makes recommendations for achieving compliance with applicable CGMPs for the drug, device, or biological product constituent parts of a combination product. In addition, the draft guidance document makes recommendations for achieving compliance with applicable CGMPs for combination products where the constituent parts of a combination product are joined together. The applicable regulations include the CGMP regulations for finished pharmaceuticals, or drug products, and most biological products (21 CFR parts 210 and 211); the biological product regulations for biological products (21 CFR parts 600–680); and the quality system regulations for devices (21 CFR part 820).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on CGMP for combination products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either *http://www.fda.gov/oc/combination/default.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: September 28, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–22205 Filed 9–29–04; 1:51 pm]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0440]**

### Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Computerized Systems Used in Clinical Trials.'' This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999.

**DATES:** Submit written or electronic comments on the draft recommendations by January 3, 2005. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Training and Communications, Division of Communications Management, Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857; to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; to the Office of Health and Industry Programs,