

in Spanish and English. Some volunteers are fluent in different Chinese dialects and in English. The shelter works with community groups to access interpreters in the several Chinese dialects that they encounter. Shelter staff trains the community volunteers in the sensitivities of domestic violence intake and counseling. Volunteers sign confidentiality agreements. The shelter is looking for a grant to increase its language capabilities despite its tiny budget. These actions constitute strong evidence of compliance.

(3) A small childcare center has three LEP parents (two who speak Mandarin and one speaks Spanish) whose English-speaking children attend its childcare center on a regular basis. The center has a staff of six, and has limited financial resources to afford to hire bilingual staff, contract with a professional interpreter service, or translate written documents. To accommodate the language needs of their LEP parents, the Center made arrangements with a Chinese and a Hispanic community organization for trained and competent volunteer interpreters in the appropriate language, and with a telephone interpreter language line, to interpret during parent meetings and to orally translate written documents. There have been no client complaints of inordinate delays or other service related problems with respect to LEP clients. The assistance that the childcare center is providing will probably be considered appropriate, given the center's resources, the size of staff, and the size of the LEP population. Thus, OCR would consider this strong evidence of compliance.

(4) A county social service program that administers the State's welfare and health programs has a large budget. Their service area encompasses an eligible service population of 500,000. Thirty-five hundred individuals in the serviced population are LEP and speak a Chinese dialect; 4,000 individuals in the serviced population are LEP and speak Spanish; 2000 individuals in the serviced population are LEP and speak Vietnamese; and 400 individuals are LEP and speak Vietnamese. The county has translated vital documents, *i.e.*, applications and program brochures, into Chinese, Spanish, and Vietnamese. Therefore, with regard to translation of vital documents, OCR would consider this strong evidence of compliance, consistent with the safe harbor provision in GSA's guidance. Additionally, the county should adequately address and provide needed interpretation services to their LEP clients (*i.e.*, hiring bilingual staff or

contracting with a language service provider).

*Permanent Versus Seasonal Populations.* In many communities, resident populations change over time or season. For example, in some resort communities, populations swell during peak vacation periods, many times exceeding the number of permanent residents of the jurisdiction. In other communities, primarily agricultural areas, transient populations of workers may require increased services during the relevant harvest season. This dynamic demographic ebb and flow can also dramatically change the size and nature of the LEP community likely to come into contact with the recipient. Thus, recipients should not limit their analysis to numbers and percentages of permanent residents. In assessing factor one—the number or proportion of LEP individuals—emergency service providers should consider any significant but temporary changes in a jurisdiction's demographics.

[FR Doc. 03-18658 Filed 7-22-03; 8:45 am]

BILLING CODE 6820-34-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Notice of Meeting of a Health Care Policy and Research Special Emphasis Panel

In accordance with section 10(d) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), announcement is made of a Health Care Policy and Research Special Emphasis Panel (SEP) meeting.

The Health Care Policy and Research Special Emphasis Panel is a group of experts in fields related to health care research who are invited by the Agency for Healthcare Research and Quality (AHRQ), and agree to be available, to conduct on an as needed basis, scientific reviews of applications for AHRQ support. Individual members of the Panel do not attend regularly-scheduled meetings and do not serve for fixed terms or long periods of time. Rather, they are asked to participate in particular review meetings which require their type of expertise.

Substantial segments of the upcoming SEP meeting listed below will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b(c)(6). Grant applications for AHRQ Partnerships for Quality Competing Continuation (R18)

Awards are to be reviewed and discussed at this meeting. These discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure under the above-cited statutes.

*SEP Meeting on:* AHRQ Partnerships for Quality Competing Continuation (R18) Awards.

*Date:* August 5, 2003 (open on August 5 from 11 a.m. to 11:10 a.m. and closed for the remainder of the Teleconference).

*Place:* John M. Eisenberg, M.D. Building, 540 Gaither Road, Room 2020, Rockville, Maryland 20850.

*Contact Person:* Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of this meeting should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Research Review, Education and Policy, AHRQ, 540 Gaither Road, Room 2038, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for this meeting are subject to change as priorities dictate.

Dated: July 14, 2003.

Carolyn M. Clancy,  
*Director.*

[FR Doc. 03-18718 Filed 7-22-03; 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: Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003-N-00872; Correction

**SUMMARY:** This notice was published in the **Federal Register** on July 8, 2003, Volume 68, Number 130, Page 40676. The meeting date, time and location have been revised.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 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): Collection of Specimen Panels for Validation for Incidence Assays, Contract Solicitation Number 2003-N-00872.

*Action:* The meeting times and dates have been revised as follows:

*Times and Dates:* 12:30 p.m.–1 p.m., July 25, 2003 (Open); 1 p.m.–3:30 p.m., July 25, 2003 (Closed).

*Action:* The meeting place has been revised as follows:

*Place:* Teleconference Number: 1–888–677–1828 passcode 5772091 for the Open portion of the meeting and 1–888–829–8669 for the Closed portion of the meeting.

*Status:* Portions of 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 Pub. L. 92–463.

*Matters to be Discussed:* The meeting will include the review, discussion, and evaluation of applications received in response to Contract Solicitation Number 2003–N–00872.

*For Further Information Contact:* Esther Sumartojo, Ph.D., Deputy Associate Director for Science, National Center for HIV, STD, and TB Prevention, CDC, 1600 Clifton Road, NE, MS–E07, Atlanta, GA 30333, Telephone 404.639.8006.

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: July 17, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 03–18793 Filed 7–22–03; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N–0084]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Electronic Records; Electronic Signatures

**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:** Submit written comments on the collection of information by August 22, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**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.

#### Electronic Records; Electronic Signatures—21 CFR Part 11 (OMB Control No. 0910–0303)—Extension

The FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records,

electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided that the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA required records.

The respondents will be businesses and other for-profit organizations, state or local governments, Federal agencies, and nonprofit institutions.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 11.100         | 4,500              | 1                             | 4,500                  | 1                  | 4,500       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

| 21 CFR Section | No. of Recordkeepers | Annual Frequency of Recordkeeping | Total Annual Records | Hours per Recordkeeper | Total Hours |
|----------------|----------------------|-----------------------------------|----------------------|------------------------|-------------|
| 11.10          | 2,500                | 1                                 | 2,500                | 20                     | 45,000      |