ESTIMATED ANNUALIZED BURDEN HOURS—Continued

| Form | Number of respondents | Number of responses per respondents | Avg. burden/ response (in hours) | Total burden (hours) |
|---|---|---|---|---|
| Health and QOL questionnaire Final | 3000 | 2 | 20/60 | 2000 |
| Total | | | | 2184 |

Dated: July 21, 2006.

**Joan F. Karr,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. E6–12025 Filed 7–26–06; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant, Request for Applications (RFA) CD07–001

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): CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant, Request for Applications (RFA) CD07–001.

*Time and Date:* 12 p.m.–4 p.m., September 14, 2006 (Closed).

*Place:* Teleconference.

*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 the review, discussion, and evaluation of applications received in response to RFA CD07–001, ''CDC Public Health Research: Health Protection Research Initiative Graduate Training Program Grant.''

*Contact Person For More Information:* Christine Morrison, PhD., Scientific Review Administrator, Office of Extramural Research, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone 404.639.3098.

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 20, 2006.

**Alvin Hall,**

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

[FR Doc. E6–12015 Filed 7–26–06; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006D–0275]**

### Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.'' This guidance document describes a means by which fecal calprotectin immunological test systems may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify fecal calprotectin immunological test systems into class II (special controls). This guidance document is immediately in effect as the special control for fecal calprotectin immunological test systems, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Fecal Calprotectin, Immunological Test Systems'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Deborah Moore, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0493.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying fecal calprotectin immunological test systems into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This notice announces the guidance document that will serve as the special control for fecal calprotectin immunological test systems.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register**

announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the agency's current thinking on fecal calprotectin immunological test systems. 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 statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1599 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, and the collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 19, 2006.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. E6–11974 Filed 7–26–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 429 [285c–3] of the Public Health Service Act (Pub. L. 95–158), notice is hereby given of a meeting of the statutory Diabetes Mellitus Interagency Coordinating Committee.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Diabetes Mellitus Interagency Coordinating Committee.

*Date:* September 18, 2006.

*Open:* September 18, 2006, 9 a.m. to 3 p.m.

*Agenda:* Psychoactive Drugs and Type 2 Diabetes.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 45, Conference Rooms E1/E2.

*Contact Person:* Sanford A. Garfield, PhD, Senior Advisor, Biometrics and Behavioral Science, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, PHS, DHHS, 6707 Democracy Blvd, Room 685, Bethesda, MD 20892, 301–594–8803, *Garfields@extra.niddk.nih.gov.*

Information is also available on the Institute's/Center's Web site: *http://www.niddk.nih.gov/federal/dmicc.htm*, where an agenda and any additional information for the meeting will be posted when available. For logistics and updated information not available on the Web site, contact Maria Smith, The Scientific Consulting Group, Inc., contractor for the DMICC, at *msmith@scgcorp.com.*

*Please note:* In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign in at the security desk upon entering the building. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the new security measures at NIH, please visit the Web site at *http://www.nih.gov/about/visitorsecurity.htm.*

Dated: July 20, 2006.

**Sanford A. Garfield,**

*Senior Advisor, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.*

[FR Doc. E6–12046 Filed 7–26–06; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

**Proposed Project: Screening, Brief Intervention, Brief Treatment and Referral to Treatment (SBIRT) Cross-Site Evaluation—New**

SAMHSA's Center for Substance Abuse Treatment is conducting a cross-