

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]

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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**