

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](mailto: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.*

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**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](mailto:Garfields@extra.niddk.nih.gov).

Information is also available on the Institute's/Center's Web site: <http://www.niddk.nih.gov/federal/dmcc.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](mailto: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.*

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**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-