

environment; (9) provides application software support; (10) serves as network System Administrator for production and development systems; and (11) installs, configures, and maintains the Internet software environment for enterprise applications.

c. *Quality Assurance and Support Branch (PIH3)*. The Quality Assurance and Support Branch (QASB) has the following functions: (1) Provides functional expertise and troubleshooting support for PSC systems; (2) develops system change requirements; (3) provides interagency IT communications support; (4) performs functional testing of PSC systems; (5) develops training materials for the HHS human resources management system and the HHS time and attendance system; (6) develops and maintains the HHS Time and Attendance Policy Manual; (7) provides advice on enhancement requests; (8) administers the help desk function and tracks all calls and e-mails for support for the human resources and time & attendance systems; (9) provides functional expertise to the technical staff; (10) provides system training including regulations and procedures related to IT; (11) assists in reviews of functional and system requirements and performs documentation testing to ensure the accuracy and completeness of all system enhancements; and (12) develops test plans, test cases, and scenarios.

d. *Application Development Branch (PIH4)*. The Application Development Branch (ADB) provides the following functions: (1) Provides overall technical support for PSC systems; (2) provides software application management, systems administration, and configuration management; (3) provides software development services; (4) provides liaison services to other Agency offices providing automated interfaces; (5) evaluates and recommends various software and hardware products in support of the PSC's systems; (6) provides Tier 2 and Tier 3 "break/fix" support contact for users and help desk personnel for problems with FAD applications; (7) provides support for enterprise reporting; (8) develops and delivers current and/or historical personnel and payroll reports; (9) maintains existing reports, including periodic reports generated for the Office of Personnel Management and HHS internal and external customers; and (10) performs daily loading of HHS personnel data and bi-weekly loading of payroll data into the historical database.

5. *Telecommunications Management Division (PID)*. The Telecommunications Management Division (TMD) provides

the following services: (1) Plans, engineers, and schedules program implementation and management of telecommunications networks and services (such as ordering, installation, and operational control of telephone station equipment); (2) monitors telecommunications billing for dial-tone, voice mail, adds/moves/changes, and telecommunications equipment; (3) plans and administers telecommunications budgets; (4) maintains inventory files and cost data of all installed telecommunications equipment; (5) manages on-site support for users of voice messaging; (6) provides training for end users; and (7) administers the Federal Telecommunications Service contract, and manages carriers, contractors and vendors for PSC and its customers.

6. *Freedom of Information Act and Records Management Division (PIF)*. The Freedom of Information Act (FOIA) and Records Management Division (FRMD): (1) Responds to all FOIA requests for records generated by, and in the custody and control of, all components of the Office of Public Health and Science (OPHS), and the Program Support Center (PSC); (2) responds to all requests for records that involve more than one of the Public Health Service components and the PSC; (3) responds to all administrative appeals; (4) coordinates with the Office of the General Counsel to resolve the administrative appeals which result in litigation; and (5) provides FOIA training and consultation.

III. Under AJ, "Office of Business Transformation (AJJ)" make the following change: Retitle the "Division of Competitive Sourcing (AJJ2)" as the "Division of Commercial Services Management (AJJ2)."

IV. *Delegations of Authority*: All delegations and re-delegations of authority to officers and employees of the Program Support Center, which were in effect immediately prior to this reorganization will be continued in effect with them or their successors, pending further redelegation, provided they are consistent with this reorganization.

Dated: December 20, 2008.

**Segundo Pereira,**

*Acting, Assistant Secretary for Administration and Management.*

[FR Doc. E8-31257 Filed 1-2-09; 8:45 am]

**BILLING CODE 4160-17-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Board of Scientific Counselors, National Center for Health Statistics, (BSC, NCHS)

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 of the aforementioned committee:

*Times and Dates:*

11 a.m.–5:30 p.m., January 22, 2009.

8:30 a.m.–2 p.m., January 23, 2009.

*Place:* NCHS Headquarters, 3311 Toledo Road, Hyattsville, Maryland 20782.

*Status:* This meeting is open to the public; however, visitors must be processed in accordance with established federal policies and procedures. For foreign nationals or non-US citizens, pre-approval is required (please contact Althelia Harris, 301-458-4261, [adw1@cdc.gov](mailto:adw1@cdc.gov) or Virginia Cain, [vcain@cdc.gov](mailto:vcain@cdc.gov) at least 10 days in advance for requirements). All visitors are required to present a valid form of picture identification issued by a state, federal or international government. As required by the Federal Property Management Regulations, Title 41, Code of Federal Regulation, Subpart 101-20.301, all persons entering in or on Federal controlled property and their packages, briefcases, and other containers in their immediate possession are subject to being x-rayed and inspected. Federal law prohibits the knowing possession or the causing to be present of firearms, explosives and other dangerous weapons and illegal substances. The meeting room accommodates approximately 100 people.

*Purpose:* This committee is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, CDC; and the Director, NCHS, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

*Matters To Be Discussed:* The agenda will include welcome remarks by the Director, NCHS; review of the NHANES program; presentation of the ambulatory and hospital care surveys program; and an open session for comments from the public.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests

must contain the name, address, telephone number, and organizational affiliation of the presenter.

Written comments should not exceed five single-spaced typed pages in length and must be received by January 8, 2009.

The agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Virginia S. Cain, PhD, Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7211, Hyattsville, Maryland 20782, telephone (301) 458-4500, fax (301) 458-4020.

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: December 24, 2008.

**Elaine L. Baker,**

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

[FR Doc. E8-31340 Filed 1-2-09; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0642]

#### **Draft Guidance for Industry and Food and Drug Administration Staff; Assay Migration Studies for In Vitro Diagnostic Devices; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Assay Migration Studies for In Vitro Diagnostic Devices." This draft guidance presents a least burdensome regulatory approach to gaining FDA approval of Class III or certain licensed in vitro diagnostic devices in cases when a previously approved assay is migrating (i.e., transitioning) to a New System for which the assay has not been previously approved or licensed.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 6, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Assay Migration Studies for In Vitro Diagnostic Devices" 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 or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 240-276-3151. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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 either <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

#### **FOR FURTHER INFORMATION CONTACT:**

Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0711.

*For further information concerning the guidance including statistical content as it relates to devices regulated by CBER:* Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852, 301-827-6210

*For further information concerning the statistical content in the guidance:* Marina V. Kondratovich, Center for Devices and Radiological Health (HFZ-550), Food and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850, 240-276-3126.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This draft guidance presents a least burdensome regulatory approach to gain FDA's approval of Class III or certain licensed in vitro diagnostic devices, when a previously approved assay is migrating (i.e., transitioning) to a New System, for which the assay has not

been previously approved or licensed. The regulatory approach in this guidance is also applicable to some 510(k) cleared devices, when the device transitioning to a new system presents specific concerns, either because of the nature of the analyte and indications, or because of the specific technology used (e.g., nucleic acid amplification tests). The focus of this guidance is on the study designs and performance criteria that should be fulfilled, so that sponsors can utilize the migration study approach in support of the change. The FDA believes that the assay migration study paradigm proposed in this draft guidance, provides a least burdensome scientific and regulatory pathway for manufacturers to transfer a previously approved or licensed assay, with full clinical data from an Old System to a New System (previously not approved or licensed). The paradigm is suitable in cases when sufficient knowledge can be derived from the documentation of design controls, risk analyses, and prior performance studies on an Old System.

##### **II. Significance of Guidance**

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 assay migration studies for in vitro diagnostic devices. 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 draft guidance may do so by using the Internet. To receive "Assay Migration Studies for In Vitro Diagnostic Devices," 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 1660 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