DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator; American Health Information Community Chronic Care Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the ninth meeting of the American Health Information Community Chronic Care Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. No. 92–463, 5 U.S.C., App.).

DATES: September 20, 2006 from 1 p.m. to 4 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090. [Please bring photo ID for entry to a Federal building.]

FOR FURTHER INFORMATION CONTACT: *http://www.hhs.gov/healthit/ahic/cc_main.html.*

SUPPLEMENTARY INFORMATION: The meeting will be available via Web cast at *http://www.eventcenterlive.com/cfmx/ec/login/login1.cfm?BID=67.*

Dated: August 29, 2006.

Judith Sparrow,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator.

[FR Doc. 06–7455 Filed 9–5–06; 8:45 am]

BILLING CODE 4150–24–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0185]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Identifiable

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: Fax written comments on the collection of information by October 6, 2006.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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:

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that Are Not Individually Identifiable—(OMB Control Number 0910–0582)—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and Institutional Review Committee (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (parts 50 and 56 (21 CFR parts 50 and 56)) apply to all clinical investigations that are regulated by FDA (see §§ 50.1 and 56.101, 21 U.S.C. 360j(g)(3)(A) and (g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document issued under the good guidance practices (GGP) regulations (21 CFR 10.115), FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

In the **Federal Register** of May 19, 2006 (71 FR 29158), FDA published a 60-day notice requesting comments on the information collection provisions. In response to this notice, no comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

No. of Recordkepers	Annual Frequency per Recordkeeper	Total annual Records	Hours per Record	Total Hours	Total Capital Cost	Total Operating and Maintenance Cost
700	1	700	4	2,800	$210,000	$210,000

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours. (700 x 4 = 2,800). FDA estimates that the cost of developing standard operating procedures (SOPs) for each recordkeeper is $300 (6 hours of work x $50 /hour. This results in a total operational and maintenance cost to industry of $210,000 ($300 x 700 recordkeepers). The total cost of this recordkeeping (i.e., capital cost plus operational and maintenance cost) is estimated to be $420,000.

Dated: August 28, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14671 Filed 9–5–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL).

Dates and Times: September 28, 2006, 1 to 5 p.m.; September 29, 2006, 1 to 5 p.m.

Place: Teleconference meeting.

Status: The meeting will be open to the public.

Purpose: The Committee will be focusing on interdisciplinary training and education, specifically examining evidence-based models/research as regards interdisciplinary training and community-based training programs. In addition, the Committee will be looking at the potential impact of interdisciplinary training programs on health service delivery networks including how such training programs address the needs of various underserved populations. The meeting will allow Committee members to discuss and finalize appropriate findings and recommendations to be included in an annual report to the Secretary and Congress regarding interdisciplinary and/or community-based training.

Agenda: The agenda includes an overview of the Committee's general business activities and minutes of the prior meeting. The Committee will review recommendations that are being developed following the testimony provided by experts on interdisciplinary training and/or community-based training during the Advisory Committee meeting held on July 24–25, 2006.

The recommendations discussed, when finalized, will be prepared as a report to the Secretary and the Congress.

Agenda items are subject to change as priorities indicate.

For Further Information Contact: Anyone requesting information regarding the Committee meeting should contact Lou Coccodrilli, Federal Official for the ACICBL, and Acting Director of the Division of State, Community & Public Health, Bureau of Health Professions, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; Telephone (301) 443–6590. Vanessa Saldanha, ASPH Fellow, can also be contacted at *vsaldanha@hrsa.gov* or via telephone at (301) 443–6529.

Dated: August 29, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–14747 Filed 9–5–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps.

Dates and Times: September 14, 2006, 12 p.m.–5 p.m.; September 15, 2006, 9 a.m.–5 p.m.; September 16, 2006, 9 a.m.–5 p.m.; and September 17, 2006, 9 a.m.–12 p.m.

Place: Hyatt Regency Reston, 1800 Presidents Street, Reston, VA 20190.

Status: The meeting will be open to the public.

Agenda: This Council meeting is being held in conjunction with the annual NHSC Loan Repayors Conference. The Council will have the chance to meet with clinicians in the field as well as work on their report outlining some recommendations for the National Health Service Corps Program. Discussions will be focused on the impact of these recommendations on the program participants, communities served by these clinicians and in the administration of the program.

For Further Information Contact: Tira Robinson-Patterson, Division of National Health Service Corps, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A–55, 5600 Fishers Lane, Rockville, MD 20857; telephone: (301) 594–4140.

Dated: August 29, 2006.

Cheryl Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–14752 Filed 9–5–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority; Correction

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** on August 11, 2006, concerning changes to the organization and functions of the Office of the Administrator (RA) and the HIV/AIDS Bureau (RV). The document omitted information regarding movement of the Center for Quality and also erroneously included the Telehealth function within the HIV/AIDS Bureau, which was moved to the Office of Health Information Technology (RT) on 12/27/05 (70 FR 76463–76465).

FOR FURTHER INFORMATION CONTACT: Wendy Ponton, Director, Division of Management Services, Office of Administration and Financial Management, Health Resources and Services Administration, 5600 Fishers Lane, Room 14A–08, Rockville, Maryland 20857; telephone: 301–443–0201.

Correction

In the **Federal Register** issue of August 11, 2006, in FR Doc. E6–13216, on page 46237, in the second column, correct the second paragraph in the Statement of Organization, Functions and Delegations of Authority section to read: This notice reflects changes to the organization and functions of the Office of the Administrator (RA) and the HIV/AIDS Bureau (RV). Specifically, it moves the Center for Quality function from the HIV/AIDS Bureau to the Office of the Administrator.

On page 46237, in the third column, under Section RV–20, Functions, delete item (10), and renumber list accordingly.

Dated: August 30, 2006.

Elizabeth M. Duke,

Administrator.

[FR Doc. E6–14748 Filed 9–5–06; 8:45 am]

BILLING CODE 4165–15–P