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]

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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