proposed information collections projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the OS Reports Clearance Officer on (202) 690–6207.

Comments are invited on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(c) Ways to enhance the quality, utility and clarity of the information to be collected; and

(d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project 1. Follow-up Survey for the Multi-site Evaluation of the Welfare-to-Work Grant Program—New—This data collection will support the Office of the Assistant Secretary for Planning and Evaluation in its efforts to further document the status of Welfare-to-Work formula and competitive grantees and provide information on implementation issues as part of the Congressionally mandated evaluation of the Welfare-to-work grants program.

Respondents: Individuals;

Number of Responses: 4,250;

Burden per Response: .75 hours;

Total Annual Burden: 3,188 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: December 21, 1999.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 99–33942 Filed 12–29–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

Health Care Financing Administration

CLIA Program; Transfer of Clinical Laboratory Complexity Categorization Responsibility

AGENCY: Centers for Disease Control and Prevention, Food and Drug Administration, and Health Care Financing Administration, HHS.

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Health Care Financing Administration (HFCA) are announcing that CDC is transferring the responsibility for the categorization of commercially marketed in vitro diagnostic (IVD) tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to FDA. Categorization is the process of assigning commercial clinical laboratory tests to one of three CLIA regulatory categories (waived, moderate complexity, high complexity). An interagency agreement on the scope and nature of the transfer of this CLIA function was signed on February 27, 1999.

DATES: The transfer from CDC to FDA of responsibility under CLIA for complexity categorization of commercially marketed IVD's is expected to be completed by January 31, 2000.

FOR FURTHER INFORMATION CONTACT: Joseph L. Hackett or Clara A. Sliva, Center for Devices and Radiological Health (CDRH) (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496.

SUPPLEMENTARY INFORMATION: Under section 353 of the Public Health Service Act (42 U.S.C. 263a), as amended by CLIA, and regulations implementing CLIA published on February 28, 1992 (57 FR 7002), existing and new commercial clinical laboratory tests are categorized into one of three regulatory categories. The three test categories are: Waived, moderate complexity, and high complexity tests.

HCFA was originally charged with administering the CLIA program and the Public Health Service was enlisted later to provide technical and scientific support. Under the regulations issued in 1992, FDA was assigned the responsibility of categorizing the complexity of commercially marketed laboratory tests. In 1994, this responsibility was delegated to CDC because of budgetary considerations.

CDC, FDA, and HCFA signed an interagency agreement on February 27, 1999, to transfer the CLIA complexity categorization responsibility for commercially marketed tests from CDC to FDA. The transfer was contingent upon FDA's receipt of funding for this function. The transfer will permit manufacturers of commercially marketed IVD's to submit premarket applications for products and requests for complexity categorizations of those products to one agency. When the transfer is complete, FDA staff in CDRH will evaluate the appropriate complexity category as they review premarket submissions for clinical laboratory devices. Products seeking a waiver categorization, devices exempt from premarket notification, and devices under premarket review by other FDA centers also will be processed by these FDA staff. The criteria for categorization under CLIA will not change. All other CLIA responsibilities currently assigned to CDC, including review of test systems, assays, or examinations not commercially marketed as IVD products, will remain with CDC.

FDA and CDC expect the transfer of responsibility to be completed by January 31, 2000. Until that time, requests for categorization should continue to be submitted to CDC. Both agencies are currently participating in training necessary to accomplish the transfer. FDA intends to provide guidance on how categorizations will be administratively processed before manufacturers begin to send their requests to CDRH.

Dated: December 21, 1999.

Jeffrey P. Koplan,

Director, Centers for Disease Control and Prevention.

Jane E. Henney,

Commissioner of Food and Drugs.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administraion.

[FR Doc. 99–33941 Filed 12–29–99; 8:45 am]

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