referenced requirements of subpart E of Part 493. As a result, CMS concluded that the submitted documents supported exempting permit holding laboratories under the CLEP from the CLIA program requirements. Furthermore, a review of CMS' validation inspections conducted by the CMS Regional Office in New York, New York supported that conclusion.

The Federal validation inspections of CLEP permit holding laboratories, as specified in § 493.563, were conducted on a representative sample basis as well as in response to any substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections has been and will continue to be CMS' principal tool for verifying that the laboratories located within the State that hold valid permits are in compliance with CLIA requirements.

The CMS Regional Office in New York has conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the New York State Office of Laboratory Quality Assurance (LQA). For some of these validation inspections, CMS surveyors simply accompanied New York State's inspectors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The validation surveys verified that the CLEP inspection process covers all CLIA conditions applicable to each laboratory being inspected, and also verified that the CLEP licensure (permit) requirements meet or exceed CLIA condition-level requirements. The CMS validation surveys found the State inspectors highly skilled and qualified. The CLEP inspected laboratories in timely fashion, that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by CMS' New York Regional Office to date indicate that the State of New York is meeting all requirements for approval of CLIA exemption.

This Federal monitoring will continue as an on-going process.

V. Conclusion

Based on review of the documents submitted by the New York State laboratory licensure program, CLEP, pursuant to the requirements of subpart E of part 493, as well as the outcome of the validation inspections conducted by the CMS Regional Office in New York, we find that the State of New York laboratory licensure program meets the requirements of 42 CFR 493.551(a), and that as a result, we may exempt from CLIA program requirements all State licensed (permitted) or approved laboratories.

Approval of the CLIA exemption for laboratories located within and permitted by the State of New York is subject to removal if we determine that the outcome of a comparability review or a validation review inspection is not acceptable, as described under § 493.573 and § 493.575, or if the State of New York fails to pay the required fee every 2 years as required under § 493.646.

VI. Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the State of New York will continue to agree to provide us with changes to a laboratory's specialties or subspecialties based on the State's survey. The State of New York also will provide us with changes in a laboratory's certification status.

VII. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we do not charge a fee to laboratories in the State. The State's share of the costs associated with CLIA must be collected from the State, as specified in § 493.645.

Accordingly, the State of New York must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that New York State's CLEP requirements are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We will bill the State of New York on a semiannual basis.
- The State of New York's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, a portion of those services from which the State of New York received direct benefit or contributed to the CLIA program in the State. Thus, the State of New York is being charged for a portion of CMS' direct and indirect costs as well as a portion of the costs incurred by the CDC and the Food and Drug Administration (FDA) in carrying out their responsibilities under CLIA.

In order to estimate the State of New York's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of New York. We determined that a corresponding percentage of the applicable CDC, FDA, and CMS costs should be borne by the State of New York.

The State of New York has agreed to pay us the State's pro rata share of the overhead costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

VIII. Approval

In light of the foregoing, CMS grants approval of the State of New York's laboratory licensure program (CLEP) under Subpart E. All laboratories located within the State of New York and hold valid CLEP permits are CLIA-exempt for all specialties and subspecialties.

Authority: Section 353(p) of the Public Health Service Act (42 U.S.C. 263a).

Dated: November 7, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–30452 Filed 12–19–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Proposed Projects

Title: Hispanic Healthy Marriage Initiative Grantee Implementation Evaluation.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), in partnership with the Office of the Assistant Secretary for Planning, Research and Evaluation (ASPE), U.S. Department of Health and Human Services, is proposing an information collection activity as part of the Hispanic Healthy Marriage Initiative (HHMI) Grantee Implementation Evaluation study. The proposed information collection consists of two components: (1) Semistructured interviews with key respondents involved with selected marriage education programs serving Hispanic couples and individuals; and (2) focus

groups with Hispanic individuals and couples participating in selected marriage education programs or declining to participate in such programs. Through this information collection and other study activities, ACF and ASPE seek to identify the unique cultural needs of Hispanic couples and families that have implications for the design and delivery of healthy marriage education services to Hispanics, recognizing their diversity with respect to country of origin, language, and level of acculturation, among other factors.

Respondents: Marriage education program directors and managers; staff responsible for outreach, recruitment and intake activities in marriage education programs; marriage education instructors; and key persons in partner organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Program Staff Discussion Guide	81	1	2	162
Partners/Community Leaders Discussion Guide	54	1	2	108
Participant Focus Group Discussion Guide	180	1	1	180
Estimated Total Annual Burden Hours				450

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: December 11, 2008.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

[FR Doc. E8–30172 Filed 12–19–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0298] (formerly Docket No. 2004D–0499)

Compliance Policy Guide; Radiofrequency Identification Feasibility Studies and Pilot Programs for Drugs; Notice to Extend Expiration Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of expiration date.

SUMMARY: The Food and Drug Administration (FDA) is extending the expiration date of compliance policy guide (CPG) Sec. 400.210 entitled ''Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs'' to December 31, 2010.

FOR FURTHER INFORMATION CONTACT: Ilisa Bernstein, Office of the Commissioner, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4341, Silver Spring, MD 20993–0002, 301–796–4830.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 17, 2004 (69 FR 67360), FDA announced the availability of CPG Sec. 400.210 entitled ''Radiofrequency Identification (RFID) Feasibility Studies and Pilot Programs for Drugs.'' FDA has identified RFID as a promising technology to be used in the various efforts to combat counterfeit drugs. The CPG describes how the agency intends to exercise its enforcement discretion regarding certain regulatory requirements that might otherwise be applicable to studies involving RFID technology for drugs. The goal of the CPG is to facilitate performance of RFID studies and to allow industry to gain experience with the use of RFID technology and its effect on the long-term safety and integrity of the U.S. drug supply.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 (FDAAA) was signed into law. Section 913 of FDAAA addresses pharmaceutical safety and creates section 505D of the Federal Food, Drug, and Cosmetic Act (the act). Section 505D(b) of the act requires the development of standards for the identification, validation, authentication, and tracking and tracing of prescription drugs. Section 505D(b)(3) of the act states that these new standards shall address promising technologies, which may include RFID technology.

In implementing section 505D of the act, FDA is currently addressing issues, such as promising technologies, that are relevant also for the CPG. In addition, FDA is considering further the experience of stakeholders and the agency under the CPG. As we consider all of these issues, the CPG will remain in effect until December 31, 2010.

Dated: December 16, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30297 Filed 12–19–08; 8:45 am]

BILLING CODE 4160–01–S