

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](mailto: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.*

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## 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.*

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