

Appendix C

60-Day Federal Register Notice

issued photo identification (i.e., driver's license) and should arrive 45 minutes prior to the start of the meeting to clear through security. Security will provide registered attendees badges that must be worn at all times and returned to security prior to exiting the Hubert Humphrey Building.

Registration questions may be directed to Experient at PAguidelines@experient-inc.com (e-mail), (703) 525-8333 x3346 (phone) or (703) 525-8557 (fax).

Dated: February 5, 2008.

Penelope Slade Royall,

RADM, USPHS, Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Innovative Strategies for Increasing Self-Sufficiency (ISIS)—Intervention Strategy Assessment Guide. *OMB No.:* New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the Innovative Strategies for Increasing Self-Sufficiency (ISIS) demonstration and evaluation. The ISIS project will test a range of promising strategies to promote employment, self-sufficiency, and reduce dependence on cash welfare. The ISIS project will evaluate multiple employment-focused strategies that build on previous approaches and are adapted to the current Federal, State, and local policy environment. The

major goals of the project include increasing the empirical knowledge about the effectiveness of a variety of programs for low-income families to sustain employment and advance to positions that enable self-sufficiency, as well as producing useful findings for both policymakers and program administrators.

This proposed information collection activity focuses on identifying promising strategies to be tested as part of the study. Through semi-structured discussions, respondents will be asked to comment on the most important strategies and interventions for potential evaluation.

Respondents: Semi-structured discussions will be held with administrators or staff of State agencies, local agencies, and programs with responsibility for employment-related services or activities for welfare and other low-income families; researchers in the field of welfare policy, poverty, economic self-sufficiency, and low-wage labor markets; and policymakers at various levels of government.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Intervention Strategy Assessment Guide	400	1	.5	200

Estimated Total Annual Burden Hours: 200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the paper 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)

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 6, 2008.

Brendan C. Kelly,

Reports Clearance Officer.

[FR Doc. 08-599 Filed 2-8-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0055]

Draft Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Validation of Growth-Based Rapid Microbiological Methods for Sterility Testing of Cellular and Gene Therapy Products," dated February 2008. The draft guidance document provides manufacturers of cellular and gene therapy products with recommendations on the validation of growth-based Rapid Microbiological Methods (RMMs) for sterility testing of their products. This draft guidance addresses considerations for method validation and determining equivalence of an RMM to sterility assays. This draft guidance applies to somatic cellular therapy and gene therapy products.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 12, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the