

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](mailto: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.*

[FR Doc. E8-2453 Filed 2-8-08; 8:45 am]

**BILLING CODE 4150-32-P**

**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](mailto: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]

**BILLING CODE 4184-01-M**

**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

Office of Communication, Training, and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr. Center for Biologics Evaluation and Research (HFMA-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

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. This draft guidance applies to somatic cellular therapy and gene therapy products. This draft guidance does not apply directly to human cells, tissues, and cellular and tissue products (HCT/Ps) which are regulated solely under section 361 of the Public Health Service Act as described under 21 CFR 1271.10, or HCT/Ps which are regulated as medical devices under 21 CFR part 820. Such products are not subject to the sterility testing provision in § 610.12 (21 CFR 610.12), or to the requirement in 21 CFR 610.9 to demonstrate that an alternative RMM is equivalent to the sterility method specified in the regulations. However, HCT/P and device establishments seeking to validate an RMM may find these recommendations useful.

The principles of RMM validation described in this draft guidance apply only to growth-based RMMs. Growth-based RMMs, like traditional methods of detecting viable microorganisms as described in § 610.12, rely on the ability to recover and detect organisms from the product and demonstrate their viability by multiplication in liquid media. The specific recommendations in this document may not be applicable for non-growth-based RMMs which

detect microbiological surrogates. This draft guidance focuses on RMMs with qualitative results (i.e., detection of microorganisms). If the RMM does not have the capability to speciate microorganisms, an additional method for speciation will be needed for investigation of detected contaminants. Early discussions with product review staff at CBER are encouraged for individuals intending to use or develop an RMM at any time in the product lifecycle using growth-based, viability-based, surrogate-based, or RMMs that provide quantitative results.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA Regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information to which this draft guidance refers are covered by 21 CFR parts 601 (on BLAs) and 312 (on INDs), and were approved under OMB Control No. 0910-0338 and 0910-0014, respectively.

##### **III. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system.

Electronic submissions will be accepted by FDA through FDMS only.

#### **IV. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: January 29, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-2398 Filed 2-8-08; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **Hemoglobin Based Oxygen Carriers: Current Status and Future Directions; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: Hemoglobin Based Oxygen Carriers: Current Status and Future Directions. The purpose of the public workshop is to discuss the safety of hemoglobin-based oxygen carriers (HBOCs) as related to a variety of potential uses of these investigational products. We are having this discussion because clinical and nonclinical studies of HBOCs, as either blood substitutes or as resuscitation fluids, have raised questions about the safety of these products as a group. The public workshop will feature presentations and roundtable discussions led by experts from academic institutions, government, and industry.

**Date and Time:** The public workshop will be held on April 29, 2008, from 8:30 a.m. to 5 p.m. and April 30, 2008, from 8:30 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Lister Hill Center Auditorium, Building 38A, National Institutes of Health, 8800 Rockville Pike, Bethesda, MD 20894.

**Contact Person:** Rhonda Dawson, Center for Biologics Evaluation and Research (HFMA-302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6129, FAX: 301-827-2843, e-mail: [rhonda.dawson@fda.hhs.gov](mailto:rhonda.dawson@fda.hhs.gov).

**Registration:** Mail or fax your registration information (including name, title, firm name, address, and telephone and fax numbers) to the contact person by April 11, 2008. There