

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* Innovative Strategies for Increasing Self-Sufficiency: Baseline Data Collection.

*OMB No.:* 0970-0343.

*Billing Accounting Code (BAC):* 418409 (CAN G996121).

*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 collecting baseline data elements. Two data collection instruments will be completed by all participants prior to random assignment, and a third will be an interview guide to collect information from program staff. The first is a short baseline information form (BIF) that will collect basic identification, demographic, and contact information.

The form will include relatively standard items from prior evaluations and national surveys. The second instrument will be a self-administered questionnaire (SAQ), covering information related to the project goals. The third instrument, baseline implementation data collection interviews, will be used to collect information from knowledgeable informants about the service context for each evaluation site using a baseline implementation guide. The purpose of such interviews is to document and assess the service environment in which the evaluation is implemented and the opportunities for control group members to access the same or similar services as the treatment group members.

*Respondents:* Individuals enrolled in ISIS demonstration interventions, control group members, ISIS program operators (BIF and SAQ) and State and local informants (interviews).

**ANNUAL BURDEN ESTIMATES**

| Instrument   | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|--|------------------------------|------------------------------------|-----------------------------------|---------------------------|
| Baseline Information Form .....                          | 4,800                        | 1                                  | 0.75                              | 3,600                     |
| Self-Administered Questionnaire .....                    | 4800                         | 1                                  | 0.75                              | 3,600                     |
| Baseline Implementation Data Collection Interviews ..... | 30                           | 1                                  | 1                                 | 30                        |

*Estimated Total Annual Burden Hours: 7,230*

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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 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) 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: September 21, 2010.  
**Steven M. Hanmer**,  
*Reports Clearance Officer.*  
 [FR Doc. 2010-24122 Filed 9-27-10; 8:45 am]  
**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-D-0428]

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays." This draft guidance document describes a means by which the herpes simplex virus (HSV) serological assay device type may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to designate this guidance as the class II special control. This draft guidance is not final nor is it in effect at this time.

**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 of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 27, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays" to the Division of

Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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

**FOR FURTHER INFORMATION CONTACT:** Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993-0002, 301-796-6193.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft guidance document provides recommendations on the types of information and data that FDA believes needs to be included in a premarket notification 510(k) submission for HSV types 1 and 2 serological assays. HSV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the assays consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome. We have revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions defined and differentiated the required studies and the study populations for the

assessment of the safety and effectiveness of the different types of HSV 1 and HSV 2 serological assays. Additionally, we made several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading. Elsewhere in this issue of the **Federal Register**, FDA is proposing to designate this guidance as the class II special control for HSV types 1 and 2 serological assays. If this classification rule is finalized, FDA intends that this guidance document will serve as the special control for this device.

Following the effective date of any final classification rule based on this proposal, any firm submitting a premarket notification (510(k)) for HSV types 1 and 2 serological assays will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.

**II. Significance of Guidance**

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on HSV types 1 and 2 serological assays. 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 requirements of the applicable statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays," you may either send an email request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1713 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

**IV. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations

and guidance documents. 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 in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910-0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 16, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR); Notice of National Conversation on Public Health and Chemical Exposures Leadership Council Meeting**

*Time and Date:* 9 a.m.—5 p.m. EDT, Tuesday, October 5, 2010.

*Location:* Omni Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008.

*Status:* Open to the public, on a first come, first served basis, limited by the space available. An opportunity for the public to listen to the meeting by phone will be available. For information on observing the meeting in person or by phone, see "contact for additional information" below.

*Purpose:* This is the sixth meeting of the National Conversation on Public