ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Preparation and Submission of Data Verification Procedures §§ 261.60—261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202 §§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process §§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report Part 265	54	4	2,201	475,416
SSP–MOE Data Report Part 265	29	4	714	82,824

Estimated Total Annual Burden Hours: 625,200.

In compliance with the requirements of Section 506(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: ACF Reports Clearance Officer. Email 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 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 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–26383 Filed 11–4–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1213]

Draft Guidance for Industry: Use of Donor Screening Tests To Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection With Treponema pallidum (Syphilis); 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: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with *Treponema pallidum* (Syphilis),'' dated October 2013. The draft guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps (HCT/P Establishments), with updated recommendations concerning donor testing for evidence of *Treponema pallidum (T. pallidum*) infection, the etiologic agent of syphilis. HCT/P Establishments must, as required under Federal regulations, test a donor specimen for evidence of *T. pallidum* infection using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies. The draft guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for *T. pallidum* infection under the criteria specified in Federal regulations. The recommendations in this guidance, when finalized, will supersede those recommendations for testing HCT/P donors for evidence of *T. pallidum* infection contained in the document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated August 2007.

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 either electronic or written comments on the draft guidance by February 3, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–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 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.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–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: Use of Donor Screening Tests to Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) for Infection with *Treponema pallidum* (Syphilis),'' dated October 2013. The draft guidance document provides HCT/P Establishments with

updated recommendations concerning donor testing for evidence of *T. pallidum* infection. HCT/P Establishments must, as required under § 1271.80(a) and (c) (21 CFR 1271.80(a) and (c)), test a donor specimen for evidence of infection due to *T. pallidum* using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, unless an exception to this requirement applies under 21 CFR 1271.90. The draft guidance clarifies that FDA does not consider diagnostic tests or pre-amendment devices (which have not been licensed, approved, or cleared) to be adequate for use in donor testing for *T. pallidum* infection under the criteria specified in § 1271.80(c). FDA will no longer exercise enforcement discretion that permits the use of diagnostic syphilis tests or pre-amendments devices for use as an HCT/P donor screening test because the wide availability of FDA-licensed, approved, or cleared test systems with an indication for use in donor screening no longer supports such enforcement discretion.

In the **Federal Register** of February 28, 2007 (72 FR 9007), FDA announced the availability of the guidance entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated February 2007. FDA issued a revised version of this guidance under the same title, dated August 2007 (hereafter referred to as the 2007 Donor Eligibility guidance). The draft guidance announced in this notice, when finalized, will supersede the recommendations for testing HCT/P donors for *T. pallidum* that were contained in the 2007 Donor Eligibility guidance.

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. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: October 30, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26397 Filed 11–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—A.

Date: November 21, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: John J. Laffan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.18J, Bethesda, MD 20892–4874, 301–594–2773, *laffanjo@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—B.

Date: November 22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Arthur L. Zachary, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12, Bethesda, MD 20892–4874, 301–594–2886, *zacharya@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 30, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26435 Filed 11–4–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Office of Research Infrastructure Programs Special Emphasis Panel, October 15, 2013, 08:00 a.m. to October 15, 2013, 05:30 p.m., National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD, 20892, which was published in the **Federal Register** on September 16, 2013, 78 FR 56903.

The meeting date is changed from October 15, 2013 to November 14, 2013. The meeting is closed to the public.

Dated: October 30, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–26414 Filed 11–4–13; 8:45 am]

BILLING CODE 4140–01–P