

to residents of Illinois with funding from the Retirement Research Foundation. Additional funds are needed to leverage the foundation's funding, in order to ensure that the current provision of services to Illinois residents will be continued. This supplementary funding would be provided for the approved period.

Authority: This program is authorized under Title II of the Older Americans Act (OAA) (42 U.S.C. 3032), as amended by the Older Americans Act Amendments of 2006, Public Law 109–365.

(Catalog of Federal Domestic Assistance 93.048).

Dated: August 14, 2015.

Kathy Greenlee,

Assistant Secretary for Aging and Administrator, Administration for Community Living.

[FR Doc. 2015–22630 Filed 9–8–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Announcement of the Intent To Award Single-Source Grants to the National Association of Area Agencies on Aging and the National Association of States United for Aging and Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award, subject to the availability of funds, single-source grant awards in the amount of \$335,000 to the National Association of Area Agencies on Aging (n4a) and \$153,500 to the National Association of State United for Aging and Disabilities (NASUAD). The awards will continue supporting and stimulating the ongoing work by these organizations to further develop and assist states and community-based organizations with building their business capacity for managed long-term services and supports and delivery system reform. CFDA Numbers: 93.048

DATES: The awards will be issued for a project period of September 30, 2015 through September 29, 2016.

FOR FURTHER INFORMATION CONTACT: Marisa Scala-Foley, Office of Integrated Care Innovations, Administration for Community Living, 1 Massachusetts Avenue NW., Washington, DC 20001. Telephone: 202–357–3516; Email: Marisa.Scala-Foley@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: In 2012, n4a and NASUAD were awarded grants from ACL to build the business capacity of state and community-based aging and disability organizations for managed long-term services and supports (MLTSS). This one-year of grant funding, through continuation grant, will continue to support n4a and NASUAD in their efforts to:

- Identify and track emerging trends, best practices, barriers, lessons learned and progress in the aging and disability networks' integration into MLTSS and delivery system reform;
- increase state and community-based aging and disability organizations' capacity, readiness and involvement in the provision of MLTSS through the provision of broad-based and targeted technical assistance, education and training; and
- develop products that complement and enhance the first two areas of focus.

This program is authorized under the Older Americans Act of 1965, as amended in 2006, Public Law 109–365.

Dated: August 28, 2015.

Sharon Lewis,

Principal Deputy Administrator, Administration for Community Living.

[FR Doc. 2015–22631 Filed 9–8–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1213]

Use of Donor Screening Tests To Test Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products for Infection With *Treponema pallidum* (Syphilis); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled “Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum* (Syphilis); Guidance for Industry.” The guidance document provides establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (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 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 guidance announced in this notice finalizes the draft guidance of the same title, dated October 2013. The recommendations in the guidance announced in this notice supersedes 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: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the 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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled “Use of Donor Screening Tests to Test Donors of

Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum* (Syphilis); Guidance for Industry.” The 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 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. FDA recommends that HCT/P Establishments implement the recommendations in the guidance as soon as feasible, but not later than 6 months after issuance of this guidance.

In the **Federal Register** of November 5, 2013 (78 FR 66366), FDA announced the availability of the draft guidance of the same title, dated October 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. FDA did not make changes to the recommendations in the draft guidance. FDA made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2013.

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 guidance announced in this notice supersedes the recommendations on compliance with the requirements for testing HCT/P donors for *T. pallidum* that are

contained in the 2007 Donor Eligibility guidance.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Use of Donor Screening Tests to Test Donors of Human Cells, Tissues and Cellular and Tissue-Based Products for Infection with *Treponema pallidum* (Syphilis); Guidance for Industry.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Comments

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 guidance at either <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22677 Filed 9–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Sixth Annual Coalition Against Major Diseases/Food and Drug Administration Scientific Workshop; Public Workshop; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of August 3, 2015 (80 FR 45998). That notice, announcing the

sixth annual scientific workshop co-sponsored by FDA and the Coalition Against Major Diseases Consortium of the Critical Path Institute, contained incorrect Web links for online registration and for the FDA Meeting Information Page (where the workshop agenda will be made available) and an incorrect registration deadline. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT:

Jacqueline Brooks-Leighton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 4521, Silver Spring, MD 20993, 240–402–5292, FAX: 301–796–9907, email: jacqueline.brooks-leighton@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. 2015–18969, appearing on page 45998, in the **Federal Register** of Monday August 3, 2015, the following corrections are made:

On page 45998, in the second full paragraph of the third column, the registration link, <https://www.SignUp4.net/public/ap.aspx?EID=SIXT10E>, is corrected to read <http://www.cvent.com/events/6th-annual-coalition-against-major-diseases-food-and-drug-administration-scientific-workshop-public/invitation-ed6c207cbf09447185a891e4bf62ad7a.aspx?i=70715ca1-f255-46b2-a370-3fe3881bbab2>.

On page 45998, in the third full paragraph of the third column, the registration deadline, October 14, 2015, is corrected to read October 13, 2015.

On page 45998, in the third full paragraph of the third column, the link for the FDA Meeting information page, <http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm>, is corrected to read <http://www.fda.gov/Drugs/NewsEvents/ucm457486.htm>.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22674 Filed 9–8–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3015]

Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.