entirety and renumber the current paragraph F as paragraph E.

FOR FURTHER INFORMATION CONTACT: Katherine Chon, Director, Office on Trafficking in Persons, Administration for Children and Families, 901 D Street SW., Washington, DC 20447; (202) 401–9372.

This reorganization will be effective on June 10, 2015.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2015–14313 Filed 6–10–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services; Notice of Meeting

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of Tribal Consultation.

SUMMARY: The Department of Health and Human Services, Administration for Children and Families, Office of Community Services (OCS) will host a virtual Tribal Consultation to consult on the Assets for Independence (AFI) program proposed Performance Progress Report (PPR).

DATES: July 6, 2015.

ADDRESSES: Consultation will be via webinar/teleconference.

FOR FURTHER INFORMATION CONTACT: Gretchen Lehman, Program Manager, Assets for Independence, Office of Community Services, email *Gretchen.Lehman@acf.hhs.gov* or phone (202) 401–6614. To register for the consultation, go to *https://www.surveymonkey.com/s/GLXK9W6.* If you do not have access to the internet, you can register to participate in the consultation by phone by calling (866) 778–6037. If you are not able to participate in this consultation, but want to submit testimony on this issue, please mail it to the following address no later than July 10, 2015: Jeannie L. Chaffin, Office of Community Services, 370 L'Enfant Promenade SW., Washington, DC 20447.

SUPPLEMENTARY INFORMATION: AFI is a competitive, discretionary grant program that enables eligible organizations to implement and demonstrate an assets-based approach for supporting low-income individuals and their families. Tribal governments that apply jointly with 501(c)(3) non-profit organizations are eligible for AFI grants. For more information on the AFI program, go to *http://www.acf.hhs.gov/programs/ocs/resource/assets-for-independence-program-summary.*

OCS is proposing to create an AFI program specific PPR to replace two current AFI reports: The Semiannual Standard Form Performance Progress Report (SF–PPR) and the annual data report. The AFI PPR would collect data on project activities and attributes similar to the reports that it is replacing. OCS plans to use the data collected in the AFI PPR to prepare the annual AFI Report to Congress, to evaluate and monitor the performance of the AFI program overall and of individual projects, and to inform and support technical assistance efforts. The AFI Act (Title IV of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998, Public Law 105–285, [42 U.S.C. 604 note]) requires that organizations operating AFI projects submit annual progress reports, and the AFI PPR would fulfill this requirement.

OCS has proposed that the AFI PPR would be submitted quarterly: Three times per year using an abbreviated short form and one time using a long form. Both draft data collection instruments are available for review at *http://idaresources.acf.hhs.gov/AFIPPR,* along with additional details about this proposal.

Dated: June 8, 2015.

Jeannie L. Chaffin,

Director, Office of Community Services.

[FR Doc. 2015–14312 Filed 6–10–15; 8:45 am]

BILLING CODE 4184–26–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1219]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Survey of Health Care Practitioners for Device Labeling Format and Content

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Survey of Health Care Practitioners for Device Labeling Format and Content'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On April 14, 2015, the Agency submitted a proposed collection of information entitled ''Survey of Health Care Practitioners for Device Labeling Format and Content'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0790. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14290 Filed 6–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1414]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On January 30, 2015, the Agency submitted a proposed collection of information

entitled ''Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0633. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: June 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14285 Filed 6–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0576]

Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; 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 ''Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Guidance for Industry.'' The guidance document is to assist sponsors and investigators in designing early-phase clinical trials for cellular therapy (CT) and gene therapy (GT) products (referred to collectively as CGT products). The guidance document provides recommendations regarding clinical trials in which the primary objectives are the initial assessments of safety, tolerability, or feasibility of administration of investigational products. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2013.

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 240–402–7800. 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: Valerie Butler, 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 ''Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products; Guidance for Industry.'' The guidance document is to assist sponsors and investigators in designing early-phase clinical trials for CGT products. The document provides recommendations regarding clinical trials in which the primary objectives are the initial assessments of safety, tolerability, or feasibility of administration of investigational products. The scope of the guidance is limited to products for which the Office of Cellular, Tissue, and Gene Therapies/Center for Biologics Evaluation and Research/FDA has regulatory authority. CGT products within the scope of the guidance meet the definition of ''biological product'' in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)) and include CT and GT products that are used as therapeutic vaccines. The guidance does not apply to those human cells, tissues, and cellular- and tissue-based products (HCT/Ps) regulated solely under section 361 of the PHS Act (42 U.S.C. 264), or to products regulated as medical devices under the Federal Food, Drug, and Cosmetic Act, or to the therapeutic biological products for which the Center for Drug Evaluation and Research has regulatory responsibility.

The design of early-phase clinical trials of CGT products often differs from the design of clinical trials for other types of pharmaceutical products. Differences in trial design are necessitated by the distinctive features of these products, and also may reflect previous clinical experience. The guidance document describes features of CGT products that influence clinical trial design, including product characteristics, manufacturing considerations, and preclinical considerations, and suggests other documents for additional information. Consequently, the guidance document provides recommendations with respect to these products as to clinical trial design, including early phase trial objectives, choosing a study population, using a control group and blinding, dose selection, treatment plans, monitoring, and follow-up. Finally, the guidance encourages prospective sponsors to meet with FDA review staff regarding their investigational new drug application (IND) submission and offers references for additional guidance on submitting an IND.

In the **Federal Register** of July 2, 2013 (78 FR 39736), FDA announced the availability of the draft guidance of the same title dated July 2013. FDA requested that comments on the guidance be submitted by November 22, 2013. In the **Federal Register** of November 20, 2013 (78 FR 69690), FDA extended the comment period for the draft guidance to May 9, 2014, to provide interested persons additional time to submit comments and to allow for public discussion of the draft guidance document at the Cellular, Tissue, and Gene Therapies Advisory Committee meeting, which was ultimately held on February 25–26, 2014 (78 FR 79699, December 31, 2013).

FDA received a number of comments on the draft guidance and these comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on considerations for the design of early-phase clinical trials of cellular and gene therapy products. 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 statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information