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 The guidance announced in this notice finalizes the draft guidance of the same title dated July 2013.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

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 in 21 CFR part 312 have been approved under OMB control number 0910–0014.

III. 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.*

IV. 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: June 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14261 Filed 6–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Health Center Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of class deviation from competition requirements for the Health Center Program.

SUMMARY: In accordance with the Awarding Agency Grants Administration Manual (AAGAM) Chapter 2.04.103, the Bureau of Primary Health Care (BPHC) has been granted a class deviation from the exceptions to maximum competition requirements contained in the AAGAM Chapter 2.04.104A–5 to provide additional funding without competition to the 115 Health Center Program awardees whose budget period ends October 31, 2015, for up to 4 months. The extension allows BPHC to eliminate the November 1 budget period start date by redistributing these grants to established starting dates later in the fiscal year, thereby allowing awardees comparable opportunity to prepare and submit applications while allowing BPHC to remain compliant with internal process timelines.

SUPPLEMENTARY INFORMATION:

Intended Recipient of the Award: Health Center Program awardees with a project period end date of October 31, 2015.

Amount of Non-Competitive Awards: $44,481,501.

Period of Supplemental Funding: November 1, 2015, to a maximum of February 28, 2016.

CFDA Number: 93.224.

Authority: Section 330 of the Public Health Service Act, as amended (42 U.S.C. 254b, as amended).

Justification: Targeting the nation's neediest populations and geographic areas, the Health Center Program currently funds nearly 1,300 health centers that operate approximately 9,000 service delivery sites in every state, the District of Columbia, Puerto Rico, the Virgin Islands, and the Pacific Basin. In 2013, more than 21 million patients, including medically underserved and uninsured patients, received comprehensive, culturally competent, quality primary health care services through the Health Center Program awardees. Due to the vast size of the Health Center Program, the active grants are distributed across eight budget periods that begin on the first of the month, November through June.

BPHC uses the information awardees report annually via the Uniform Data System (UDS) to objectively determine the patient and service area requirements that new and continuing applications must address. The requirements are available for applicant use in June. The deviation allows BPHC to redistribute the awardees with November 1 start dates to budget period start dates later in the fiscal year, thus allowing these awardees comparable opportunity to prepare and submit applications while allowing BPHC to remain compliant with internal process timelines. By September 15, 2015, $44,481,501 will be awarded to these 115 awardees to continue approved activities for up to 4 months. Awardees will report progress and financial obligations made during their budget period extension through routine reports.

TABLE 1—RECIPIENT AWARDEES

Grant No.	Name	State	New budget period start	Award amount
H80CS00001	CITY OF SPRINGFIELD	MA	February	$333,353
H80CS00002	CITY OF MANCHESTER	NH	March	224,147
H80CS00003	COMMUNITY HEALTHLINK, INC	MA	March	316,608
H80CS00006	BOSTON HEALTH CARE FOR THE HOMELESS PROGRAM, INC., THE.	MA	January	505,654
H80CS00007	CARE FOR THE HOMELESS	NY	January	734,361
H80CS00008	MUNICIPALITY OF SAN JUAN	PR	March	226,508
H80CS00009	CITY OF NEWARK, NEW JERSEY, INC	NJ	January	411,022
H80CS00011	MONTEFIORE MEDICAL CENTER	NY	January	401,335
H80CS00013	UNDER 21, INC	NY	March	209,692
H80CS00016	PUBLIC HEALTH MANAGEMENT CORPORATION	PA	January	710,886
H80CS00017	HEALTH CARE FOR THE HOMELESS, INC	MD	January	606,970
H80CS00018	DAILY PLANET, INC	VA	February	490,501
H80CS00019	NORTH BROWARD HOSPITAL DISTRICT	FL	February	437,971
H80CS00020	BIRMINGHAM HEALTH CARE, INC	AL	January	713,355
H80CS00022	SAINT JOSEPHS MERCY CARE SVCS	GA	January	614,459
H80CS00023	COUNTY OF HAMILTON	TN	March	364,024
H80CS00024	COUNTY OF PINELLAS	FL	March	193,752
H80CS00026	CAMILLUS HEALTH CONCERN, INC	FL	January	515,685