SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Considerations for the Design of Early-Phase Clinical Trials of Cellular and Gene Therapy Products,'' dated July 2013. The draft guidance document provides sponsors of INDs for CGT products with recommendations to assist in designing early-phase clinical trials of CGT products. The scope of this guidance is limited to products for which the Office of Cellular, Tissue and Gene Therapies/FDA has regulatory authority. CGT products within the scope of this guidance meet the definition of ''biological product'' in section 351(i) of the Public Health Service (PHS) Act (42 U.S.C. 262(i)). 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), to products regulated as medical devices under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), or to the therapeutic biological products for which the Center for Drug Evaluation and Research (CDER) 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 The draft guidance document describes features of CGT products that influence clinical trial design, including product characteristics, manufacturing considerations and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 Consequently, the draft guidance document provides recommendations with respect to these products as to clinical trial design, including early-phase trial objectives, choosing a study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 Finally, the draft guidance encourages prospective sponsors to meet with FDA review staff regarding their IND submission and offers references for additional guidance on submitting an IND.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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. Paperwork Reduction Act of 1995

This draft 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

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.*

IV. 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: June 25, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15797 Filed 7–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0744]

Draft Guidance for Industry on Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases.'' The purpose of the draft guidance is to assist sponsors in the development of new antibacterial drugs to treat serious bacterial diseases, particularly in areas of unmet need, and new antibacterial drugs that are pathogen-focused (i.e., drugs that have a narrow spectrum of activity or are only active against a single genus or species of bacteria).

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 September 30, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Joseph G. Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases.'' The purpose of this draft guidance is to assist sponsors in the development of new antibacterial drugs for the treatment of serious bacterial diseases in patients with unmet medical needs and new antibacterial drugs that are pathogen-focused (i.e., drugs that

have a narrow spectrum of activity or are only active against a single genus or species of bacteria).

Efforts to develop new antibacterial drugs have diminished in the past few decades. Because bacteria continue to develop resistance to available antibacterial drugs, an increasing number of patients are suffering from bacterial diseases that do not respond to currently available antibacterial drugs and therefore have unmet medical needs for antibacterial therapy. To foster new antibacterial drug development that will have the potential to keep pace with continued pressures leading to antibacterial resistance, FDA is exploring approaches to help streamline development programs for new antibacterial drugs. This effort is intended not only to spur development of new drugs for populations with infections caused by resistant organisms, but also to facilitate development of drugs for broad indications that are associated with other unmet medical needs. In addition, the draft guidance outlines development approaches for pathogen-focused antibacterial drugs (i.e., drugs that have a narrow spectrum of activity or are only active against a single genus and species of bacteria).

This draft guidance describes some examples of approaches that may be used by sponsors as part of streamlined development programs. Some of these approaches are not novel, but are included to provide examples of various ways of collecting the evidence needed to demonstrate safety and efficacy to address unmet medical needs. FDA is inviting proposals for other innovative approaches that should be considered, particularly for infections caused by resistant organisms. FDA is interested in approaches such as using information from other sites of infection; pooling data from various sites; additional endpoints; an increased emphasis on the use of animal data to complement clinical data; or any other approaches that may be used to generate reliable evidence of efficacy.

As part of FDA's efforts to facilitate the development of antibacterial drugs for serious or life-threatening bacterial infections, particularly in areas of unmet need, this draft guidance specifies how nonclinical and clinical data can be used to inform an efficient and streamlined pathogen-focused antibacterial drug development program and provides advice on approaches for the development of antibacterial drugs that target a more limited spectrum of pathogens. As such, it is intended to fulfill the requirement in section 806(a), Title VIII (entitled ''Generating Antibiotic Incentives Now''), of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) (Pub. L. 112–144), to publish a draft guidance on pathogen-focused antibacterial drug development. After consideration of comments submitted in response to this draft guidance, FDA intends to begin work on finalizing the guidance, as required by section 806(b) of FDASIA.

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 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 requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that 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 and 21 part CFR 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

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 document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov*.

Dated: June 26, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15783 Filed 7–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on the National Health Service Corps; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on the National Health Service Corps (NHSC)

Date and Time: July 18, 2013—2:00pm–3:30pm ET

Place: The meeting will be via audio conference call.

Status: The meeting will be open to the public.

Agenda: The Council is holding a meeting via conference call to discuss the Affordable Care Act, NHSC retention resources, and partnerships. The public can join the meeting via audio conference call on the date and time specified above using the following information: Dial-in number: 1–800–857–5081; Passcode: 1060359. There will be an opportunity for the public to comment towards the end of the call.

FOR FURTHER INFORMATION CONTACT: Njeri Jones, Bureau of Clinician Recruitment and Service, Health Resources and Services Administration, Parklawn Building, Room 13–64, 5600 Fishers Lane, Rockville, MD 20857; email: *NJones@hrsa.gov;* telephone: 301–443–2541.

Dated: June 25, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–15713 Filed 7–1–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice for Request for Nominations

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill seven vacancies on the National Advisory Council on Nurse Education and Practice (NACNEP).

Authority: The National Advisory Council on Nurse Education and Practice is in accordance with the provisions of 42 United