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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*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: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12923 Filed 5–30–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0556]

New Approaches to Antibacterial Drug Development; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is seeking input from the public on the following topics related to antibacterial drug development: Potential new study designs, proposed priorities for CDER guidances, and strategies intended to slow the rate of emerging resistance to antibacterial drugs. The purpose of this notice is to request information and comments from the public on these areas of focus.

DATES: Submit either electronic or written comments by *July 30, 2013* at 5 p.m. EST.

ADDRESSES: Submit electronic comments 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: Jonas Santiago, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5346, FAX: 301–847–3529, email: *jonas.santiago@fda.hhs.gov.*

I. Background

Antibacterial drug development is critical to the public health and is an FDA priority. We recognize the mounting concern that antibacterial drug development has not kept pace with the increasing threat of drug-resistant and untreatable infections.

To address this concern, we are seeking to explore new clinical development paradigms for antibacterial drugs. Areas of ongoing need are numerous and include new drugs for treatment of hospital-acquired bacterial pneumonia, ventilator-associated bacterial pneumonia, complicated urinary tract infection, complicated intra-abdominal infection, and infections caused by drug-resistant organisms.

On September 24, 2012,[1] FDA announced the formation of the CDER Antibacterial Drug Development Task Force, which supports new antibacterial drug development. The task force is a multidisciplinary group of CDER scientists and clinicians seeking to identify priority areas and to develop and implement possible solutions to the challenges of antibacterial drug development. This includes the use of existing partnerships and collaborations to work with other experts in the field, including academia, industry, professional societies, patient advocacy groups, and Government Agencies. Specifically, the task force seeks to:

- Explore novel scientific approaches to facilitate antibacterial drug development (e.g., broader use of clinical pharmacology data, new statistical methods, innovative clinical trial designs, use of additional available data sources, and advancement of alternative measures to evaluate clinical effectiveness of potential new therapies);
- Identify issues related to unmet medical need for antibacterial drugs, including the reasons for the lack of a robust pipeline for antibacterial drug development;
- Identify new approaches for weighing risks, benefits, and uncertainties of potential new antibacterial drugs addressing unmet need; and
- Evaluate existing FDA guidances related to antibacterial drug development to determine if revision or elaboration is needed and identify areas where future guidance would be helpful.

[1] FDA's press release is available at *http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm320643.htm.*

II. Potential New Study Design Approaches

The task force explores novel scientific approaches to facilitate antibacterial drug development and is seeking input from the public on study design approaches with potential utility for future antibacterial drug development. Possible elements being considered include:

- Bayesian approaches;
- Adaptive approaches;
- Use of novel point of care diagnostics to avoid use of confounding therapies;
- Evaluating safety and efficacy by enrolling patients in trials with infections at any one of a number of different body sites;
- Large simple trials; and
- Accelerated approval using either a surrogate endpoint reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit.

To advance the development of antibacterial drugs, we seek input on the listed examples as well as additional ideas regarding the design, conduct, and analysis of clinical trials.

III. Guidance Development

The task force focuses on developing guidance to address issues related to development of new antibacterial drugs. Initial guidance efforts focused on community-acquired bacterial pneumonia, acute bacterial skin and skin structure infections, and antibacterial drugs for patients with limited or no alternative therapies (including development of drugs that have a limited spectrum of activity). As the task force works to prioritize areas of future draft and final guidance development, we seek input from the public on the following areas of priority as well as on additional areas for potential future guidance development:

- Complicated Urinary Tract Infection (draft issued February 23, 2012); [2]
- Uncomplicated Gonorrhea;
- Complicated Intra-Abdominal Infection (draft issued September 28, 2012); [3]
- Diabetic Foot Infection; and
- Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia (draft issued November 26, 2010).[4]

IV. Emerging Resistance to Antibacterial Drugs

In addition to facilitating antibacterial drug development, the task force recognizes the need to address the issue of emerging drug resistance. The public health need caused by the lack of a robust pipeline is further compounded by the diminishing effectiveness of currently available antibacterial drugs due to emerging drug resistance. Therefore, we are seeking comment on strategies to preserve the utility of antibacterial drugs.

V. Categories for Public Comment

We request the following information from the public:

- Novel study designs to expedite the development of new antibacterial drugs;
- Comments on our prioritized list of proposed draft or final guidance development; and
- Potential strategies intended to slow the rate of emerging drug resistance.

When responding to this notice, please include the category or categories that your response addresses.

VI. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document 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. When responding, include the category or categories that your response addresses as listed in section V 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*.

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12925 Filed 5–30–13; 8:45 am]

BILLING CODE 4160–01–P

[2] Complicated Urinary Tract Infection Draft Guidance available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070981.pdf*.

[3] Complicated Intra-Abdominal Infection Draft Guidance available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM321390.pdf*.

[4] Hospital Acquired and Ventilator Associated Pneumonia Draft Guidance available at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM234907.pdf*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Cancellation of Meeting

Notice is hereby given of the cancellation of the National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, June 13, 2013, 8:00 a.m. to June 13, 2013, 4:00 p.m., St. Gregory Hotel, 2033 M Street NW., Washington, DC, 20036 which was published in the **Federal Register** on April 10, 2013, 78 FR 21381.

This meeting is being cancelled due to a scheduling conflict.

Dated: May 24, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–12883 Filed 5–30–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cognition and Perception.

Date: June 19, 2013.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jane A Doussard-Roosevelt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 435–4445, *doussarj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Societal and Ethical Issues in Research.

Date: June 20, 2013.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Agenda: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *steeleln@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 12–251: Review of B/START Applications.

Date: June 21, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–12–018: NIH Director's Early Independence Awards Review.

Date: June 24–25, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz Carlton Hotel, 1150 22nd Street, NW., Washington, DC 20037.

Contact Person: Weijia Ni, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, MSC 7848, Bethesda, MD 20892, (301) 237–9918, *niw@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Therapeutic Approaches to Genetic Diseases Study Section.

Date: June 26, 2013.

Time: 8:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301–435–1779, *riverase@csr.nih.gov.*