

that would be used to make product-specific BE recommendations available to the public on FDA's Web site at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for paliperidone palmitate extended-release injectable suspension. FDA initially approved new drug application 022264 for INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension. There are no approved ANDAs for this product. In August 2011, we issued a draft guidance for industry on BE recommendations for paliperidone palmitate extended-release injectable suspension, which we subsequently revised in December 2013. We are now issuing a further revised draft guidance for industry on BE recommendations for generic paliperidone palmitate extended-release injectable suspension ("Draft Guidance on Paliperidone Palmitate").

In May 2013, Janssen Research and Development, LLC, manufacturer of the reference listed drug, INVEGA SUSTENNA, submitted a citizen petition requesting that FDA require that any ANDA referencing INVEGA SUSTENNA extended-release injectable suspension meet certain conditions related to demonstrating BE (Docket No. FDA-2013-P-0608). FDA is reviewing the issues raised in the petition. FDA will consider any comments on the Draft Guidance on Paliperidone Palmitate in responding to the petition.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for paliperidone palmitate extended-release injectable suspension. It does not create or confer any rights for or on any person and do not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/>

[www.regulations.gov/Guidances/default.htm](http://www.regulations.gov/Guidances/default.htm) or <http://www.regulations.gov>.

Dated: December 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-4170]

#### Establishment of a Public Docket; Clinical Trial Designs in Emerging Infectious Diseases

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is establishing a public docket to receive input on clinical trial designs in emerging infectious diseases. Interested parties are invited to submit comments, supported by research and data, regarding clinical trial designs.

**DATES:** Submit either electronic or written comments on the collection of information by January 28, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2015-N-4170 for "Clinical Trial Designs in Emerging Infectious Diseases." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments

received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**SUPPLEMENTARY INFORMATION:** FDA held a workshop on "Clinical Trial Designs in Emerging Infectious Diseases" in partnership with the National Institute of Allergy and Infectious Diseases, the HHS Office of the Assistant Secretary for Preparedness and Response, and the Centers for Disease Control and Prevention as a step in collecting information. The objectives of the workshop were to: (1) Discuss the deployment of investigational products in the context of emerging infectious diseases, drawing on the lessons learned in the Ebola virus epidemic; (2) explore the strengths and weaknesses of different clinical trial designs for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases (EID) in resource-limited settings from scientific, ethical, and operational perspectives; (3) identify areas of consensus and areas needing further discussion, with the goal of formulating acceptable options for the deployment of investigational products in clinical trials for future EIDs; and (4) discuss planning and other factors that can impact on the ability to establish clinical trials in a timely fashion to evaluate investigational therapies. The meeting agenda, transcripts, and web cast recordings are available on the FDA Web site at <http://www.fda.gov/emergencypreparedness/courterterrorism/medicalcountermeasures/aboutmcmi/ucm466153.htm>. The meeting agenda and transcripts will also be available in the docket.

FDA is opening this docket to provide an avenue for the public to submit additional information that may be relevant to the design and conduct of clinical trials for establishing the safety and efficacy of investigational products for the treatment and/or prevention of life-threatening emerging infectious diseases. Individuals submitting comments are specifically invited to address the scientific, ethical, and practical considerations that should be taken into account when designing and implementing clinical trials for future emerging infectious diseases in resource-limited settings.

Dated: December 23, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 80 FR 66545-66546 dated October 29, 2015).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA), Bureau of Health Workforce (RQ). Specifically, this notice: (1) Abolishes the Office of Workforce Development and Analysis (RQA); (2) abolishes the Office of Health Careers (RQB); and (3) updates the functional statement for the Bureau of Health Workforce (RQ).

#### Chapter RQ—Bureau of Health Workforce

##### Section RQ-10, Organization

Delete the organizational structure for the Bureau of Health Workforce (RQ) and replace in its entirety.

The Bureau of Health Workforce is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration.

1. Office of the Associate Administrator (RQ);
2. Division of Policy and Shortage Designation (RQ1);
3. Division of Business Operations (RQ2);
4. Division of External Affairs (RQ3);
5. National Center for Health Workforce Analysis (RQ4);
6. Division of Medicine and Dentistry (RQ5);
7. Division of Nursing and Public Health (RQ6);
8. Division of Practitioner Data Bank (RQ7);
9. Division of Participant Support and Compliance (RQ8);
10. Division of Health Careers and Financial Support (RQ9);
11. Division of National Health Service Corps (RQC); and
12. Division of Regional Operations (RQD).

#### Section RQ-20, Functions

Delete the functional statement for the Bureau of Health Workforce (RQ) and replace in its entirety.

This notice reflects organizational changes in Bureau of Health Workforce (RQ). Specifically, this notice: (1) Abolish the Office of Workforce Development and Analysis; (RQA); (2) abolishes the Office of Health Careers (RQB); and (3) updates the functional statement for the Bureau of Health Workforce (RQ).

#### Bureau of Health Workforce (RQ)

The Bureau of Health Workforce (BHW) improves the health of the nation's underserved communities and vulnerable populations by developing, implementing, evaluating, and refining programs that strengthen the nation's health care workforce. BHW programs support a diverse, culturally competent workforce by addressing components including: Education and training; recruitment and retention; financial support for students, faculty, and practitioners; supporting institutions; data analysis; and evaluation and coordination of health workforce activities. These efforts support development of a skilled health workforce serving in areas of the nation with the greatest need.

#### Office of the Associate Administrator (RQ)

The Office of the Associate Administrator provides overall leadership, direction, coordination, and planning in support of the BHW's programs designed to help meet the health professions workforce needs of the nation and improve the health of the nation's underserved communities and vulnerable populations. The office guides and directs the bureau's workforce analysis efforts and provides guidance and support for advisory councils. Additionally, the office provides direction by coordinating the recruitment, education, training, and retention of diverse health professionals in the healthcare system and supporting communities' efforts to build more integrated and sustainable systems of care. Specifically: (1) Directs and provides policy guidance for workforce recruitment, student and faculty assistance, training, and placement of health professionals to serve in underserved areas; (2) directs the bureau's health professions workforce data collection and analysis efforts in support of BHW's programs, and provides oversight for the evaluation of grantee performance and program outcomes; (3) guides and supports work