This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic.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 an approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively, and the collections of information referred to in the guidance for clinical trial sponsors ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24036 Filed 9–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0419]

Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' This guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB–COPD), and finalizes the revised draft guidance issued on August 22, 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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 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: 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 guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the overall clinical development program of drugs to support an indication for the treatment of ABECB–COPD. This guidance finalizes the revised draft guidance published on August 22, 2008 (73 FR 49684), which in turn revised the draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis—Developing Antimicrobial Drugs for Treatment'' published in 1998. Changes from the revised draft guidance are incorporated into the appropriate sections of the guidance and were based on comments submitted to the docket for the draft guidance. In addition, developments in scientific and medical information and technology in the treatment of ABECB–COPD are reflected in this guidance. This guidance fulfills the requirement set forth in the Food and Drug Administration Amendments Act of 2007 that directed FDA to update the ABECB–COPD guidance within 5 years.[1] This guidance also responds to the requirement set forth in the Food and Drug Administration Safety and Innovation Act of 2012 that FDA review guidances for the conduct of clinical trials with respect to antibacterial and antifungal drugs and revise such guidances as appropriate.[2]

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on developing drugs for the treatment of ABECB–COPD. 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 guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget 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 0910–0014; the collections of information in 21 CFR

[1] See Title IX, section 911, of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85).

[2] See Title VIII, section 804(a)(1), of the Food and Drug Administration Safety and Innovation Act of 2012 (Pub. L. 112–144).

part 314 have been approved under 0910–0001; and the collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24035 Filed 9–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0972]

Clinical Development Programs for Disease-Modifying Agents for Peripheral Neuropathy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing a scientific public workshop to solicit information on a variety of issues related to the clinical development of disease-modifying agents for the treatment of peripheral neuropathy. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design. FDA intends to take this information into account in developing FDA guidance on clinical development programs for disease-modifying products for the management of peripheral neuropathy.

Date and Time: The public workshop will be held on February 11, 2013, from 8:30 a.m. to 5 p.m. and February 12, 2013, from 8:30 a.m. to 2 p.m.

Location: The public workshop will be held at FDA White Oak Campus, Building 31, The Great Room (Rm. 1503),White Oak Conference Center, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Entrance for the consultation meeting's participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*

Contacts:

Randi Clark, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4287, *Randi.Clark@fda.hhs.gov,*

or

Allison Meyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1258, *Allison.Meyer@fda.hhs.gov.*

Registration to Attend the Workshop and Requests to Participate in Open Public Hearing: As part of the public workshop, an open public hearing will be held between 11 a.m. and 12 p.m. on February 11, 2013. If you wish to attend the public workshop or provide oral comments during the open public hearing, please email your registration to *CDER_Neuropathy_Workshop@fda.hhs.gov* by February 1, 2013. Those without email access may register by contacting one of the persons listed in the *Contacts* section of this document. Please provide complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number.

For those interested in providing oral comments for the open public hearing, please also provide a short abstract of your remarks by February 1, 2013. We will try to accommodate all persons who wish to speak; however, the duration of each speaker's comments during this open public hearing may be limited by time constraints.

Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants based on space limitations. Registrants will receive confirmation once they have been accepted for the workshop. Onsite registration on the day of the meeting will be based on space availability. If registration reaches maximum capacity, FDA will post a notice closing meeting registration for the workshop at *http://www.fda.gov/Drugs/NewsEvents/ucm310416.htm.*

If you need special accommodations because of a disability, please contact Randi Clark or Allison Meyer (see *Contacts*) at least 7 days in advance of the public workshop.

Comments: Submit either electronic or written comments by March 11, 2013. 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. 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.*

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing this public workshop to further the understanding of the development of disease-modifying agents for the treatment of painful peripheral neuropathies. Discussion will focus on possible therapeutic targets for these agents, the types of painful peripheral neuropathies amenable to treatment with disease-modifying agents, and clinical trial design.

FDA will explore the following topics during this public workshop:

1. Pharmacodynamic mechanisms and pharmacogenetic/pharmacogenomic targets of therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of disease for peripheral neuropathies.

2. Periperal neuropathy patient populations and study entry criteria for clinical trials designed to evaluate disease-modifying effects of therapeutic agents.

3. Clinically relevant endpoints for trials evaluating therapeutic agents intended to prevent, slow, modify, arrest, or reverse the course of these diseases.