considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 10, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Elektra J. Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6429, Silver Spring, MD 20993–0002, 301–796–0900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Qualification of Exacerbations of Chronic Pulmonary Disease Tool for Measurement of Symptoms of Acute Bacterial Exacerbation of Chronic Bronchitis in Patients with Chronic Obstructive Pulmonary Disease.''

In March 2006, FDA issued the ''Critical Path Opportunities Report and List'', in which FDA described six key areas along the critical path to improved therapies and listed specific opportunities for advancement within these topic areas. The report noted that a new product development toolkit containing new scientific and technical methods was needed to improve the efficiency of drug development.

Innovative and improved DDTs can help streamline the drug development process, improve the chances for clinical trial success, and yield more information about a treatment and/or disease. DDTs include, but are not limited to, biomarkers and clinical outcome assessments (COAs). CDER has developed a formal process, the DDT qualification process, to work with developers of these tools to guide them as they refine the tools and rigorously evaluate them for use in the regulatory context. Once qualified, DDTs will be publicly available for use in any drug development program for the qualified COU. COA DDTs are developed and reviewed using this process when they are intended ultimately for use as primary or secondary endpoints in clinical trials designed to provide substantial evidence of treatment benefit. Upon qualification by CDER, a qualification statement is provided describing the concept of interest and COU for which the tool is qualified. This draft guidance describes the qualification statement for the EXACT, a COA DDT.

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 qualification of the EXACT COA DDT. 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. 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*.

III. 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: January 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00259 Filed 1–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0136]

Draft Guidance for Industry on Community-Acquired Bacterial Pneumonia: Developing 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 draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of community-acquired bacterial pneumonia (CABP). The science of clinical trial design and our understanding of this disease have advanced in recent years, and this draft guidance informs sponsors of our current recommendations for clinical development. FDA is specifically requesting comment on critical areas of scientific interest including the appropriate primary efficacy endpoints, the use of an intent-to-treat (ITT) population for the primary analysis population, and the use of antibacterial therapy by patients before participating in clinical trials. This draft guidance revises the draft guidance of the same name that published March 20, 2009.

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 April 10, 2014.

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: Sumati Nambiar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6232, Silver Spring, MD 20993–0002, 301–796–1300; or 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 ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antibacterial drugs for the treatment of CABP. Issues in CABP clinical trials were discussed at a 2008 workshop cosponsored by FDA and professional societies. Recently, there have been additional discussions about clinical trial design and endpoints for CABP at several meetings of the Anti-Infective Drugs Advisory Committee. As a result of these public discussions, the science of clinical trial design and our understanding of endpoints and approaches to clinical development have advanced.

This revised draft guidance supersedes the draft guidance published in March 2009 and informs sponsors of the changes in our recommendations. Although we acknowledge the challenges in conducting clinical trials of investigational antibacterial drugs in CABP, this revised draft guidance incorporates changes intended to attain a greater degree of balance between the practicability of conducting CABP clinical trials and the trial procedures needed for a scientifically sound and interpretable trial. We are specifically requesting input from the public on these changes for consideration before finalizing the guidance. Specifically, the changes from the 2009 draft guidance include:

- A description of two potential primary efficacy endpoints for CABP clinical trials: (1) Improvement in patient symptoms early in the course of therapy for CABP (at day 3 to day 5) and (2) all-cause mortality.
- A justification for a noninferiority margin based on clinical responses observed early in the course of therapy, as well as a justification for all-cause mortality as a primary efficacy endpoint.
- Suggestions for efficacy analyses based on: (1) An overall ITT population and (2) a microbiological intent-to-treat population consisting of those patients who have a documented bacterial pathogen known to cause CABP.
- An approach for accommodating enrollment of patients who have received prior antibacterial therapy, provided certain constraints are met.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Publ. L. 112–144), which requires FDA to ''review and, as appropriate, revise not fewer than 3 guidance documents per year . . . for the conduct of clinical trials with respect to antibacterial and antifungal drugs. . . .''

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 have been approved under OMB control number 0910–0014 and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

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: January 6, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00255 Filed 1–9–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–1975–N–0355 (Formerly 75N–0185), FDA–1976–N–0272 (Formerly 76N–0056), FDA–1976–N–0344 (Formerly 76N–0057), FDA–1978–N–0701 (Formerly 78N–0070), FDA–1979–N–0224 (Formerly 79N–0169), and FDA–1983–N–0297 (Formerly 83N–0030); DESI 1626, 3265, 12283, and 50213]

Drugs for Human Use; Drug Efficacy Study Implementation; Certain Prescription Drugs Offered for Various Indications; Final Resolution of Hearing Requests Under Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that all outstanding hearing requests pertaining to Docket Nos. FDA–1975–N–0355 (formerly 75N–0185) (DESI 3265); FDA–1976–N–0272 (formerly 76N–0056), FDA–1976–N–0344 (formerly 76N–0057), and FDA–1978–N–0701 (formerly 78N–0070) (DESI 1626); FDA–1979–N–0224 (formerly 79N–0169) (DESI 12283); and FDA–1983–N–0297 (formerly 83N–0030) (DESI 50213) have been withdrawn. Shipment in interstate commerce of any of the products identified in these dockets, or any identical, related, or similar (IRS) product to the products in these dockets, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) (other than an over-the-counter (OTC) product that complies with an applicable OTC monograph) is unlawful as of the effective date of this notice.

DATES: *Effective Date:* This notice is effective January 10, 2014.

ADDRESSES: All communications in response to this notice should be identified with the appropriate docket number and directed to Sakineh Walther, Division of Prescription Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5242, Silver Spring,