recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–102 and 105 Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations

CMS–10209 Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations; *Use:* We will use the collected information to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS–102 is a multi-purpose form designed to capture and record all budget and expenditure data. Form CMS–105 captures the annual projected CLIA workload that the State survey agency will accomplish. Our regional offices also use the information to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the state. *Form Numbers:* CMS–102 and CMS–105 (OCN: 0938–0599); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,500. (For policy questions regarding this collection contact Angela Stancel at 410–786–4876.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Chronic Care Improvement Program (CCIP) and Quality Improvement (QI) Project Reporting Tools; *Use:* Medicare Advantage Organizations (MAOs) are required to have an ongoing quality improvement (QI) program that meets our requirements and includes at least one chronic care improvement program (CCIP) and one QI Project. Every MAO must have a QI program that monitors and identifies areas where implementing appropriate interventions would improve patient outcomes and patient safety. Information collected using the CCIP and QIP reporting tools is an integral resource for oversight, monitoring, compliance, and auditing activities necessary to ensure high quality value-based health care for Medicare beneficiaries. *Form Number:* CMS–10209 (OCN: 0938–1023); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 1,904; *Total Annual Responses:* 1,904; *Total Annual Hours:* 28,560. (For policy questions regarding this collection contact Ellen Dieujuste at 410–786–2191).

Dated: January 6, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–00195 Filed 1–9–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1630]

Draft Guidance for Industry on 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; 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 ''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.'' This draft guidance provides a statement of qualification for the Exacerbations of Chronic Pulmonary Disease Tool (EXACT) patient-reported outcome instrument and summarizes the concept of interest and context of use (COU) for which the tool is qualified through the Center for Drug Evaluation and Research's (CDER's) drug development tool (DDT) qualification program. Qualification of the EXACT represents a conclusion that, within the stated COU, the instrument can be relied on to have a specific interpretation and application in drug development and regulatory review. This draft guidance is an attachment to the guidance for industry entitled ''Qualification Process for Drug Development Tools.''

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: 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.