TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	9	1.33	12	33	396
FDA Review of a Pre-EUA Package or an Amendment Thereto	11	1.45	16	35	560
Manufacturers of an Unapproved EUA Product	5	1.6	8	2	16
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Total					1,152

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	5	1.6	8	25	200
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					470

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 25, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–24043 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–D–0973]

Draft Guidance for Industry on Complicated Intra-Abdominal Infections: Developing Drugs for Treatment; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Complicated Intra-Abdominal Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the clinical development of drugs for the treatment of complicated intra-abdominal infections (cIAIs). Specifically, this guidance addresses FDA's current thinking regarding the overall drug development program for the treatment of cIAIs, including clinical trial designs to support approval of drugs.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 31, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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: 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 ''Complicated Intra-Abdominal Infections: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors and investigators in the development of drugs for the treatment of cIAIs.

Intra-abdominal infections are common in clinical practice and comprise a wide variety of clinical presentations and differing sources of infection. The infections can be diffuse across the entire peritoneal cavity or retroperitoneal spaces, or can be localized with one or more abscesses surrounding diseased or perforated viscera. A wide variety of bacterial pathogens are responsible for cIAIs, including Gram-negative aerobic bacteria, Gram-positive bacteria, and anaerobic bacteria, and there are also mixed infections.

This draft guidance includes recommendations for an efficacy endpoint and a non-inferiority trial design. The efficacy endpoint of clinical success represents the desired outcome of an antibacterial treatment of a cIAI and has been used in previously conducted trials of treatment for cIAI. Clinical success is defined as the complete resolution of the baseline signs and symptoms attributable to cIAI at a fixed time point approximately 28 days following randomization. The draft guidance provides scientific support for a noninferiority margin based on the results of previously conducted clinical trials with various effective antibiotics. The draft guidance also provides a discussion about patients with unmet need who have an infection caused by bacterial pathogens that show resistance to most antibacterial drugs on in vitro susceptibility testing.

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]

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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).