Description: The Early Head Start Research and Evaluation Project (EHSREP) is a longitudinal study originally designed to meet the 1994 requirement for a national evaluation of the Early Head Start program. Child and family assessments were conducted when children were 14 months old, 24 months old, 36 months old, in the spring prior to kindergarten entry, and again in the spring of the sixth year of formal schooling (5th grade for most children). Today, children of the EHSREP are approximately 14–17 years of age (depending on their age at the time of enrollment in the study).

The Administration for Children and Families (ACF) within the Department of Health and Human Services (HHS) is proposing to track the children/families who participated in the EHSREP until the children reach 18 years of age. The purpose of tracking these participants is to maintain up-to-date contact information for the children/families in the event that ACF determines that a future follow-up to the EHSREP will take place.

Respondents: Participants in the Early Head Start Research and Evaluation Project.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Tracking Interview	2,533	1	.25	633

Estimated Total Annual Burden Hours: 633.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–24032 Filed 9–28–12; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance: Emergency Use Authorization of Medical Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed extension of the collection of information related to emergency use authorizations by the Agency.

DATES: Submit either electronic or written comments on the collection of information by November 30, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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. ''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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Reporting and Recordkeeping for Emergency Use Authorization of Medical Products (OMB Control Number 0910–0595)—Extension

The guidance describes the Agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108–276). The FD&C Act permits the Commissioner of Food and Drugs to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the Commissioner may establish conditions on the authorization. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the FD&C Act also gives the Commissioner authority to establish other conditions on an authorization that she finds to be necessary or appropriate to protect the public health.

For purposes of estimating the annual burden of reporting (see table 1 of this document), FDA has established four categories of respondents as follows: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (i.e., a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (e.g., administering product, disseminating information) who must report to FDA regarding such activity; and (4) public health authorities (e.g., State, local) who carry out an activity (e.g, administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (e.g., Center for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases such as with antimicrobial products for which there are multiple generic manufacturers, the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for ''original'' EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (i.e., estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (see table 2 of this document).

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, since those products are already subject to approved collections of information (i.e., Adverse Experience Reporting for biological products is approved under 0910–0308 through November 30, 2014; Adverse Drug Experience Reporting is approved under 0910–0230 through August 31, 2015; adverse device experience reporting is approved under OMB control number 0910–0471 through May 31, 2014; investigational new drug (IND) application regulations are approved under 0910–0014 through April 30, 2015, and investigational device exemption (IDE) reporting is approved under OMB control number 0910–0078 through February 28, 2013. Any additional burden imposed by this proposed collection would be minimal. FDA estimates the burden of this collection of information as follows:

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.