SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" dated September 2010. The draft guidance provides investigational new drug application (IND) sponsors with recommendations on the submission of INDs for early clinical trials with live biotherapeutic products (LBPs).

DATES: Although you can comment on any guidance at any time (21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 13, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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: Benjamin A. Chacko, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information" dated September 2010. The draft guidance provides IND sponsors with recommendations on the submission of INDs for early clinical trials with LBPs.

Regulations in part 312 (21 CFR part 312) require sponsors who wish to study LBPs in humans to submit an IND to FDA, unless the sponsor falls into one of the exemptions for clinical investigations found under § 312.2(b). The general principles underlying the IND submission and the general requirements for an IND's content and format are contained in §§ 312.22 and 312.23, respectively. This draft guidance focuses on the chemistry, manufacturing, and control information that should be provided in an IND in order to meet the requirements under § 312.23 for early clinical trials evaluating LBPs. This draft guidance is applicable to all INDs of LBPs, whether clinical trials are conducted commercially, in an academic setting, or otherwise (§ 312.2).

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA'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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 have been approved under the Office of Management and Budget (OMB) control number 0910–0014.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: October 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25850 Filed 10–13–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0503]

Draft Guidance for Industry on Investigational New Drug Applications—Determining Whether Human Research Studies Can Be Conducted Without an Investigational New Drug Application; 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 "Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND." This draft guidance is intended to assist clinical investigators, sponsors, and sponsor-investigators in determining whether planned human research studies must be conducted under an investigational new drug application (IND). The guidance describes the basic criteria for when an IND is required, describes specific situations in which an IND is not required, and discusses a range of issues that, in FDA's experience, have been the source of confusion or misperceptions about the application of the IND requirements.

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 comments 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 January 12, 2011. Submit either electronic or written comments concerning proposed collection of information by December 13, 2010.

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, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation Research (CBER), Food and Drug Administration, 1401

Rockville Pike, Suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the 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:

Sandy Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993–0002, 301–796–1077, or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND." FDA receives frequent inquiries from external constituents, in particular the academic research community (*e.g.,* clinical investigators, Institutional Review Boards (IRBs)) and the pharmaceutical industry, concerning whether various types of human research studies can be conducted without an IND. Because of the volume and nature of the inquiries, this guidance is intended to be a resource to assist potential sponsors and clinical investigators in determining whether an IND should be submitted for their planned research. Generally, clinical investigations in which a drug is administered to study subjects must be conducted under an IND as required by part 312 (21 CFR part 312). This guidance explains the general requirements for when an IND is needed, describes the types of clinical studies that are exempt by regulation from the IND requirements, and addresses a range of issues that commonly arise in inquiries to FDA concerning the application of the IND requirements.

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 determining whether human research studies can be conducted without an IND. 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

Under the Paperwork Reduction Act (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 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 comment 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 on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Draft Guidance for Industry on Investigational New Drug Applications (INDs)—Determining Whether Human Research Studies Can Be Conducted Without an IND.

Description: The draft guidance would assist clinical investigators, sponsors, and sponsor-investigators in determining whether human research studies must be conducted under an IND as described in part 312, *Investigational New Drug Application.* The draft guidance describes the basic criteria for when an IND is required, specific situations in which an IND is not required, and a range of issues that have been the source of confusion or misperceptions about the application of the IND regulations. Section VIII of the draft guidance, "Process for Addressing Inquiries Concerning the Application of the IND Requirements," provides a process for seeking advice from FDA concerning the application of the IND regulations to a planned clinical investigation. Under § 312.2(e), FDA, on request, will advise on the applicability of part 312 to a planned clinical investigation.

Part 312 contains an information collection that has been approved by OMB under OMB control number 0910–0014, and this approval would extend to the recommendations in the draft guidance. However, requests for FDA advice, under § 312.2(e), on the application of the IND regulations to a planned clinical investigation has not been part of this approval by OMB. Therefore, we are requesting OMB approval of the information collection in Section VIII of the draft guidance. As indicated in table 1 of this document, based on FDA's experience with the requests it has received for advice on the application of the IND regulations to planned clinical investigations, we estimate that we will receive annually approximately 45 formal inquiries as described in Section VIII of the draft guidance from approximately 20 sponsors and/or investigators, and approximately 110 informal inquiries as described in Section VIII from approximately 40 sponsors and/or investigators. We also estimate that it will take approximately 8 hours to prepare and submit each formal inquiry and approximately 30 minutes to prepare and submit each informal inquiry.

FDA requests comments on this analysis of information collection burdens:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Formal Inquiry	20	2.25	45	8 hours	360
Informal Inquiry	40	2.75	110	30 minutes	55
Total					415

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

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the draft guidance, including comments regarding proposed collection of information. It is only necessary to send one set of comments. It is no longer necessary to send two copies of any mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: October 6, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–25851 Filed 10–13–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2009–0018]

Intent To Request Renewal From OMB of One Current Public Collection of Information: Certified Cargo Screening Program

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), OMB control number 1652–0053, abstracted below that we will submit to the Office of Management and Budget (OMB) for renewal in compliance with the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. The collections include: (1) Applications from entities that wish to become Certified Cargo Screening Facilities (CCSF) or operate as a TSA-approved validation firm; (2) personal information to allow TSA to conduct security threat assessments on key individuals employed by the CCSFs and validation firms; (3) implementation of a standard security program or submission of a proposed modified security program; (4) information on the amount of cargo screened; (5) recordkeeping requirements for CCSFs and validation firms; and (6) submission of validation reports to TSA. TSA is seeking the renewal of the ICR for the continuation of the program in order to secure passenger aircraft carrying cargo by the deadlines set out in the Implementing Recommendations of the 9/11 Commission Act of 2007.

DATES: Send your comments by December 13, 2010.

ADDRESSES: Comments may be e-mailed to *TSAPRA@dhs.gov* or delivered to the TSA Paperwork Reduction Act (PRA) Officer, Office of Information Technology (OIT), TSA–40, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6040.

FOR FURTHER INFORMATION CONTACT: Please email *TSA.PRA@dhs.gov* with questions or comments.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov.* Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

OMB Control Number 1652–0053, Certified Cargo Screening Program, 49 CFR Parts 1515, 1520, 1522, 1540, 1544, 1546, 1548, and 1549

TSA is seeking renewal of an expiring collection of information. Section 1602 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110–53, 121 Stat. 266, 278, August 3, 2007) requires the development of a system to screen 50 percent of the cargo transported on a passenger aircraft by February 2009, and to screen 100 percent of such cargo by August 2010. In September 2009, TSA issued an interim final rule (IFR) amending 49 CFR to implement this statutory requirement. See 74 FR 47672 (September 16, 2009). TSA received approval from OMB for the collections of information contained in the IFR. TSA now seeks to extend this approval from OMB. Accordingly, TSA must proceed with this ICR for this program in order to continue to meet the Congressional mandate. The ICR will allow TSA to collect several categories of information as explained below.

Data Collection

TSA certifies qualified facilities as CCSFs. Companies seeking to become CCSFs are required to submit an application to TSA at least 90 days before the intended date of operation. All CCSF applicants submit applications and related information either electronically through email or through the online Air Cargo Document