TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of survey	Number of respondents	Annual frequency per response	Average burden per response	Total hours
Mail, telephone, Web-based	50,000	1	[2] 0.25	12,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Fifteen (15) minutes.

Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17590 Filed 7–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0220]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry—Pharmacogenomic Data Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry—Pharmacogenomic Data Submissions'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 9, 2014, the Agency submitted a proposed collection of information entitled ''Guidance for Industry—Pharmacogenomic Data Submissions'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0557. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17481 Filed 7–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1006]

Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.'' The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that certain submissions under the FD&C Act and Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of the final version of the guidance on that topic. The draft guidance outlines Electronic Common Technical Document (eCTD) specification requirements for certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) and is being issued for public comment. This draft guidance revises and replaces a previous draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' that was issued in January 2013 (2013 draft guidance on eCTD Specifications). When finalized, this revised draft guidance will supersede the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' that was issued in June 2008.

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 September 23, 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, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, 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.

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: Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1161, Silver Spring, MD 20993, email: *virginia.hussong@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.'' FDASIA (Public Law 112–144), signed by the President on July 9, 2012, amended the FD&C Act to add section 745A (21 U.S.C.379k–1) entitled ''Electronic Format for Submissions.'' Section 745A(a)(1) of the FD&C Act requires that submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C 355(b), (i), or (j)), and submissions under section 351(a) or (k) of the PHS Act (42 U.S.C. 262(a) or (k)), be submitted to FDA in electronic format no earlier than 24 months after FDA issues final guidance on that topic.

In accordance with section 745A(a)(1) of the FD&C Act, FDA is issuing this draft guidance, announcing its determination that submission types identified in this draft guidance must be submitted electronically (except for submissions that are exempted), in the format specified in this guidance.

This guidance (and the technical specification documents it incorporates by reference) describes how submissions under section 745A(a) of the FD&C Act [1] must be organized and submitted in electronic format using eCTD specifications version 3.2.2. The eCTD is an International Conference on Harmonization (ICH) format based on specifications developed by ICH and its member parties. FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) have been receiving submissions in the eCTD format since 2003, and eCTD has been the recommended format for electronic submissions to CDER and CBER since January 1, 2008. The majority of new electronic submissions are now received in eCTD format.

This guidance revises and replaces the previous 2013 draft guidance on eCTD specifications. This revised version of the draft guidance, when finalized, will supersede the guidance for industry titled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' that was issued in June 2008. This revised draft guidance, when finalized, will be applicable to all submissions within the scope of section 745A(a) of the FD&C Act, i.e., certain NDAs, ANDAs, BLAs, and INDs and all subsequent submissions, including amendments, supplements, and reports, to these submission types.[2]

In general, this revised draft guidance contains the following changes from the previous 2013 draft guidance on eCTD specifications:

- It is now explicit that certain master files are within the scope of section 745A(a) of the FD&C Act.
- Similarly, it is now explicit that advertising and promotional labeling materials are also within the scope of section 745A(a) of the FD&C Act.
- Use of the FDA Electronic Submissions Gateway (ESG) will be required.
- Use of FDA fillable forms will be required with all eCTD submissions.
- Specified file formats and software versions will be required for submissions filed with the FDA.

After publication of the **Federal Register** notice of availability of the final version of the guidance, all submissions with a filing date 24 months after the **Federal Register** notice must use the appropriate FDA-supported eCTD specifications for certain NDA, ANDA, and BLA submissions. IND submissions must use the FDA-supported eCTD specifications for electronic submissions filed 36 months after the **Federal Register** notice of availability is published.

In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying in a guidance document the format for the submissions. Accordingly, to the extent that this draft guidance provides the requirements under section 745A(a) of the FD&C Act, indicated by the use of the words *must* or *required,* it is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d)).

II. Paperwork Reduction Act of 1995

The 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 draft guidance pertains to sponsors and applicants making regulatory submissions to FDA in electronic format for NDAs, ANDAs, BLAs, INDs, master files, and advertising and promotional labeling. The information collection discussed in the draft guidance is contained in our IND regulations (21 CFR part 312) and approved under OMB control number 0910–0014, our NDA regulations (including ANDAs) (21 CFR part 314) and approved under OMB control number 0910–0001, and our BLA regulations (21 CFR part 601) and approved under OMB control number 0910–0338.

Sponsors and applicants have been submitting NDAs, ANDAs, BLAs, INDs, and master files electronically since 2003, and the majority of these submissions are already received in electronic format. Under section 745A(a) of the FD&C Act, sponsors and applicants are required to file most of these submissions electronically. These requirements will be phased in over 2- and 3-year periods after the issuance of the final version of the guidance.

For some sponsors and applicants, there may be new costs, including capital costs or operating and maintenance costs, which would result from the requirements under FDASIA and the final version of the guidance, because some sponsors and applicants may have to upgrade eCTD specifications and/or change their method of submitting information to the FDA. FDA estimates that for some sponsors and applicants the costs may be as follows:

- eCTD Publishing Software: $25,000 to $150,000;
- Publishing Operations Support: $50,000 to $1,000,000; and
- Training: $5,000 to $50,000.

III. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments regarding this document 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 *http://*

[1] For more information concerning how the FDA interprets section 745(a), see the draft guidance for industry ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act'' (available at *http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/guidances/default.htm).*

[2] See id.

www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory Information/Guidances/default.htm, or *http://www.regulations.gov.*

Dated: July 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17588 Filed 7–24–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration's (FDA's) Center for Drug Evaluation and Research/Office of Medical Policy and the Duke University Office of Continuing Medical Education are cosponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide clinical investigators with expertise in the design, conduct, and analysis of clinical trials; improve the quality of clinical trials; and enhance the safety of trial participants. Senior FDA staff will communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

Date and Time: The training course will be held on November 4 and 5, 2014, from 8 a.m. to 5 p.m., and on November 6, 2014, from 8 a.m. to 3:30 p.m.

Location: The course will be held at the Holiday Inn College Park, 10000 Baltimore Ave., College Park, MD 20740.

Contact Person: Tomeka Arnett, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6355, Silver Spring, MD 20993, 301–796–8486.

Registration: Register by October 17, 2014. The registration fee is $150 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration.

Register online for the training course at the registration Web site *http://continuingeducation.dcri.duke.edu/citc* or download a full-size copy of the registration form from the registration site and mail a check and completed form to Duke Clinical Research Institute (DCRI), Attention—Duke CME/CEE, 300 West Morgan St., Suite 800, Durham, NC 27701. You will receive an email that confirms your registration. (FDA has verified the Web site address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Attendees are responsible for their own accommodations. A block of rooms has been reserved under ''FDA Clinical Investigator Course'' at the Holiday Inn College Park at a reduced conference rate. Reservations for these accommodations can be made online using the course registration Web site mentioned previously. Click on ''registration form.'' You will see a direct link to the hotel.

Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site mentioned previously.

If you need special accommodations due to a disability, please contact Tomeka Arnett (see *Contact Person*) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trial investigators play a critical role in the development of medical products. They bear the responsibility for ensuring the safe and ethical treatment of study subjects and for acquiring adequate and reliable data to support regulatory decisions. This course is intended to assist clinical investigators in understanding what preclinical and clinical information is needed to support the investigational use of medical products, as well as the scientific, regulatory, and ethical considerations involved in the conduct of clinical trials. The course will cover a wide variety of key topics, including material on novel safety concerns, adverse event monitoring, compliance with the legal and ethical obligations of clinical research, and acceptable scientific and analytic standards in the design and conduct of clinical studies. The faculty will include a diverse representation of senior FDA staff, enabling FDA to communicate directly with clinical investigators on issues of greatest importance for successful clinical research.

II. Description of the Training Course

A. Purpose

The training course is designed to provide clinical investigators with an overview of the following information:

- The essential toxicological, pharmacological, and manufacturing data to support investigational use in humans;
- fundamental issues in the design and conduct of clinical trials;
- statistical and analytic considerations in the interpretation of trial data;
- appropriate safety evaluation during studies; and
- the ethical considerations and regulatory requirements for clinical trials.

In addition, the course should accomplish the following:

- Foster a cadre of clinical investigators with knowledge, experience, and commitment to investigational medicine;
- promote communication between clinical investigators and FDA;
- enhance investigators' understanding of FDA's role in experimental medicine; and
- improve the quality of data while enhancing subject protection in the performance of clinical trials.

B. Proposed Agenda

The course will be conducted over 3 days and comprises approximately 26 lectures, each lasting between 30 and 45 minutes. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

The course will address FDA's role in clinical studies and regulatory considerations for clinical trials and will include a review of the material generally appearing in an ''investigator's brochure,'' i.e., the preclinical information (toxicology, animal studies, and chemistry/manufacturing information) that supports initial clinical trials in humans. Presenters will discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. The course will also include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. On November 6, 2014, participants will choose among three breakout sessions that will explain how to put together an application to FDA for drugs, biologics, or devices.