clinical considerations for these products.

In the **Federal Register** of October 14, 2015 (80 FR 61822), FDA announced the availability of the draft guidance of the same title dated October 2015. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. Minor editorial changes were made in response to the comment to improve clarity. The guidance announced in this notice finalizes the draft guidance dated October 2015 and supplements the guidance entitled ''Guidance for FDA Reviewers and Sponsors: Content and Review of Chemistry, Manufacturing, and Control (CMC) Information for Human Gene Therapy Investigational New Drug Applications (INDs),'' dated April 2008.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for MVGTs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 211 and 610 have been approved under OMB control number 0910–0139 and in 21 CFR part 312 under OMB control number 0910–0014.

III. Electronic Access

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

Dated: September 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22353 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1214]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation (M–CERSI), is announcing a 3-day training course for clinical investigators on the scientific, ethical, and regulatory aspects of clinical trials for medical products. This training course is intended to provide clinical investigators, such as clinicians, nurses, pharmacists, and other health care providers involved in conducting clinical trials, with expertise in the design, conduct, and analysis of clinical trials; to improve the quality of clinical trials; and to enhance the safety of trial participants. Senior FDA staff, along with other experts, will present on issues critical for successful conduct of clinical research.

DATES: The training course will be held on November 7, 2016, from 8:20 a.m. to 5:30 p.m. (registration begins at 7:30 a.m.); on November 8, 2016, from 8:30 a.m. to 4:45 p.m.; and on November 9, 2016, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The course will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Place, Silver Spring, MD 20910. GPS device address: 8525 Fenton St., Silver Spring, MD 20910. For additional information, please refer to *http://www.silverspringdowntown.com/go/silver-spring-civic-building-and-veterans-plaza.* (FDA has verified the Web address, but FDA is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Nicole Silva, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6323, Silver Spring, MD 20993, 301–796–3419, *Nicole.Silva@fda.hhs.gov.*

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 train clinical investigators in all elements of clinical trials, including the preclinical and clinical information needed to support the investigational use of medical products; the statistical design of trials; and scientific, regulatory, and ethical considerations related to conduct of clinical trials. The course lecturers will include a diverse representation of senior FDA staff and other experts, enabling communication on issues critical for successful conduct of 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 aims to:

- 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;
- Improve the quality of clinical trial data; and
- Enhance protection of subjects in clinical trials.

B. Agenda

The course will be conducted over 3 days and will be presented mainly by senior FDA staff with other lecturers presenting on selected topics. The agenda is available at *http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/default.htm.*

C. Target Audience

The course is targeted toward clinicians, nurses, pharmacists and other health care professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Registration: There is no registration fee to attend this in-person training

course; however, seats are limited and registration will be on a first-come, first-served basis. To register, you need to complete the registration online by October 28, 2016, at *http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/default.htm.* Upon completion of registration, you will receive an email that confirms your registration. There will be no onsite registration or remote access for this training.

Accommodations: Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Nicole Silva (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance. Persons attending the course are advised that FDA is not responsible for providing access to electrical outlets.

Dated: September 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–22348 Filed 9–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1853]

Agency Information Collection Activities; Proposed Collection; Comment Request; Unique Device Identification System

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 information collection associated with the Unique Device Identification System.

DATES: Submit either electronic or written comments on the collection of information by November 15, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–1853 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Unique Device Identification System.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@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