comments and recommendations must be submitted in one of the following ways by *October 20, 2009:*

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attention:* Document Identifier/OMB Control Number (CMS–10198), Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: August 14, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–20128 Filed 8–20–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0391]

Clinical Investigator Training Course

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Critical Path Programs and the Clinical Trials Transformation Initiative (CTTI) are co-sponsoring a 3-day training course for clinical investigators on scientific, ethical, and regulatory aspects of clinical trials. This training course is intended to provide 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.

DATES: The training course will be held on November 16 and 17, 2009, from 8 a.m. to 5 p.m. and on November 18, 2009, from 8 a.m. to 3:30 p.m.

ADDRESSES: The course will be held at the National Labor College, 10000 New Hampshire Ave., Silver Spring, MD 20903.

FOR FURTHER INFORMATION CONTACT: Devota DeMarco, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3605, *Devota.DeMarco@fda.hhs.gov*; or

Nancy Stanisic, Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660, *Nancy.Stanisic@fda.hhs.gov*.

Registration: Register by November 2, 2009, at the registration/information Web site at *https://www.trials transformation.org/fda-clinical-investigator-training-course/* or by fax at 919–660–1769. Registration materials, payment procedures, accommodation information, and a detailed description of the course can be found at the registration/information Web site. The registration fee is $300 per person. The fee includes course materials and onsite lunch. Early registration is recommended because seating is limited. There will be no onsite registration. If you need special accommodations due to a disability, please contact one of the persons listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

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 topics:

- 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:

- 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 will comprise approximately 26 lectures, each lasting between 30 and 45 minutes. Two sessions of case studies will be included for which participants will be expected to do preparatory reading and answer questions. The course will be presented mainly by senior FDA staff, with guest lecturers presenting selected topics.

On day one, the course will address the role of FDA in clinical studies, regulatory considerations for clinical trials, and 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. Presentations will also discuss the role of clinical pharmacology in early clinical studies and how this information is used in the design of subsequent studies. Day two will include discussions of scientific, statistical, ethical, and regulatory aspects of clinical studies. Day three will include discussions of safety assessment in clinical trials, including hepatic and cardiovascular safety, approaches to special populations (e.g., pregnant women and pediatrics), and the role of personalized medicine and new scientific techniques in medical product development.

C. Target Audience

The course is targeted at healthcare professionals responsible for, or involved in, the conduct and/or design of clinical trials.

Dated: August 14, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–20084 Filed 8–20–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0395]

Draft Guidance for Industry, User Facilities, and Food and Drug Administration Staff; eMDR—Electronic Medical Device Reporting; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''eMDR—Electronic Medical Device Reporting.'' The draft guidance document addresses general issues related to the submission of postmarket medical device reports (MDRs) in electronic format. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to require that manufacturers, importers, and user facilities submit most MDRs to the agency in electronic format.

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 written or electronic comments on the draft guidance by November 19, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''eMDR—Electronic Medical Device Reporting'' to the Division of Small Manufacturers, International, and Consumer Assistance , Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Howard Press, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Building 66, rm. 3320, Silver Spring, MD 20993–0002, 301–796–6087.

SUPPLEMENTARY INFORMATION:

I. Background

The draft guidance document provides information related to the submission of postmarket MDRs in electronic format, including technical information. The information provided in the draft guidance document is intended to help reporters prepare the MDR for electronic submission in a way that would satisfy the requirements of FDA's proposed electronic Medical device reporting regulation that is published elsewhere in this issue of the **Federal Register**.

II. Significance of Guidance

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 electronic medical device reporting (eMDR). 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive an electronic copy of ''eMDR—Electronic Medical Device Reporting'' you may either send an e-mail request to *dsmica@fda.hhs.gov* or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1679 to identify the guidance you are requesting.

The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's proposed rule on medical device reporting, electronic submission requirements, published elsewhere in this issue of the **Federal Register**. The proposed collections of information in the proposed rule are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). In accordance with the proposed medical device regulation, medical device manufacturers, importers, and user facilities would be required to submit MDRs to FDA, to maintain records, and may also seek exemption or variance from these requirements. Manufacturers, importer, and user facilities are currently submitting paper MDR reports on FDA Form 3500 A, for which the existing information collection requirements under 21 CFR part 803 are approved under OMB control number 0910–0437. The changes to the burden associated with this proposed rule have been sent to OMB as a revision to OMB control number 0910–0437 for review under section 307(d) of the PRA.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: August 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–19681 Filed 8–20–09; 8:45 am]

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