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]

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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Draft Guidance for Industry, User Facilities, and Food and Drug Administration Staff; eMDR—Electronic Medical Device Reporting; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''eMDR—Electronic Medical Device Reporting.'' The draft guidance document addresses general issues related to the submission of postmarket medical device reports (MDRs) in electronic format.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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 19, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''eMDR—Electronic Medical Device Reporting'' to the Division of Small Manufacturers, International, and Consumer Assistance , Center for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 Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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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