4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-1056]

Guidance for Industry and Food and Drug Administration Staff; eCopy Program for Medical Device Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "eCopy Program for Medical Device Submissions." The purpose of the guidance is to explain the new electronic copy (eCopy) Program for medical device submissions, which is intended to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version. The guidance describes how FDA has implemented the eCopy Program under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This guidance also provides the standards for a valid eCopy under the FD&C Act and identifies the submission types that must include an eCopy in accordance with these standards for the submission to be processed and accepted for review by FDA. This final guidance will be considered in effect on January 1, 2013, or at the time of publication, whichever is later.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "eCopy Program for Medical Device Submissions" to the Division of Small Manufacturers,

International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 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 electronic comments on the 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Samie Allen,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 1533,

Silver Spring, MD 20993-0002,

301-796-6055; or

Stephen Ripley,

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 final guidance for industry and FDA staff entitled "eCopy Program for Medical Device Submissions." This guidance explains the new eCopy Program for medical device submissions. This final guidance will be considered in effect on January 1, 2013, or at the time of publication, whichever is later. After this date, submission of an eCopy for a medical device submission is no longer voluntary. Section 745A(b) of the FD&C Act, added by section 1136 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), requires the submission of an eCopy of certain device submissions after issuance of final guidance. This guidance describes how FDA has implemented the eCopy Program under section 745A(b) of the FD&C Act. The inclusion of an eCopy is expected to improve the efficiency of the review process by allowing for the immediate availability of an electronic version for review rather than relying solely on the paper version.

The eCopy Program is not intended to impact (reduce or increase) the type or amount of data the applicant includes in a submission to support clearance or approval. An eCopy is defined as an exact duplicate of the paper submission, created and submitted on a compact disc, digital video disc, or flash drive, accompanied by a copy of the signed cover letter and the complete paper submission.

In the Federal Register of October 17, 2012 (77 FR 63837), FDA announced the availability of the draft guidance document. Interested persons were invited to comment by November 16, 2012. Eight comments were received and in general were supportive of the eCopy Program. However, the comments contained multiple recommendations pertaining to the organization of the guidance and requests for clarification on details such as how many copies

are needed for each submission type, for what types of submissions an eCopy is required, the necessity for a signed cover letter, how eCopy processing is conducted, when a submission begins the review process, and how to interpret some of the standards in the Attachment. In response to these comments, FDA revised the guidance document to clarify the primary points of confusion identified, and restructured the information for better readability.

II. Significance of Guidance

In section 745A(b), Congress granted explicit statutory authorization to FDA to implement the statutory eCopy requirement by providing standards, criteria for waivers, and exemptions in guidance. To the extent that this document provides requirements under section 745A(b)(2)(A) of the FD&C Act (i.e., standards, criteria for waivers, and exemptions), indicated by the use of the words must or required, this document 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).)

However, this document also contains guidance on implementing the eCopy Program. To the extent that this guidance describes recommendations that are not standards, criteria for waivers, or exemptions under section 745A(b)(2), it is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). Such parts of this guidance represent the Agency's current thinking on this topic, and do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used for these recommendations if such an approach satisfies the requirements of the applicable statutes and regulations. The use of the word should in this guidance means that something is suggested or recommended, but not required. This final guidance contains both binding and nonbinding provisions.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. To receive "eCopy Program for Medical Device Submissions," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1797 to identify the guidance you are requesting.

IV. 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 part 807, subpart E, have been approved under OMB control number 0910-0120 (510(k)); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078 (Investigational Device Exemptions); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231 (Premarket Approval); the collections of information in section 513(g) of the FD&C Act (21 U.S.C. 360c(g)) have been approved under OMB control number 0910-0705 (513(g)); the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control numbers 0910-0332 and 0910-0661 (Humanitarian Use Devices); and the collections of information in section 564 of the FD&C Act (21 U.S.C. 360bbb-3) have been approved under OMB control number 0910-0595 (Emergency Use Authorization).

V. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see ADDRESSES) or electronic comments to http://www.regulations.gov. 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.

Dated: December 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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