4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Draft Guidance for Industry and Food and Drug Administration Staff; eCopy Program for Medical Device Submissions; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "eCopy Program for Medical Device Submissions." The purpose of the draft guidance is to explain the new electronic copy (eCopy) program for medical device submissions. The draft guidance describes how FDA plans to implement the eCopy Program under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).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. This draft guidance is not final nor is it in effect at this time.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "eCopy Program for Medical Device Submissions" to the Division of Small Manufacturers,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 (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to CDRH at 301-847-8149. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Phil Desjardins,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 5452,

Silver Spring, MD 20993-0002,

301-796-5678; or

Steve 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 draft guidance for industry and FDA staff entitled "eCopy Program for Medical Device Submissions." This guidance explains the new eCopy Program for medical device submissions. At this time, submission of an eCopy of a medical device submission is voluntary. However, 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 draft guidance describes how FDA plans to implement 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 in another electronic media format that FDA has agreed to accept, accompanied by a copy of the signed cover letter and the complete original paper submission.

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, when finalized, will 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. The final guidance will contain both binding and nonbinding provisions.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 or from the CBER

Internet site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. 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 draft 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). Prior to implementation of this requirement or issuance of a final guidance on this topic FDA will update the existing OMB approved information collections to properly document the submission of information through both paper and electronic means.

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: October 11, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-25494 Filed 10/16/2012 at 8:45 am; Publication Date: 10/17/2012]