4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1601]

Custom Device Exemption; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Custom Device Exemption." FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the Food, Drug, and Cosmetic Act (the FD&C Act). The intent of this guidance is to define terms used in the custom device exemption, explain how to interpret the "five units per year of a particular device type" language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

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: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Custom Device Exemption" to the Office of the Center Director, Guidance

and Policy Development, 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.

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: Division of Premarket and Labeling Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993-0002, 301-796-5770, CustomDevices@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The custom device exemption is set forth at section 520(b) of the FD&C Act (21 U.S.C. 360j(b)). A custom device is in a narrow category of devices for which, because of the rarity of a patient's medical condition or a physician's special need, compliance with premarket review regulations and performance standards under sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) would be impractical.

Effective on July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures applicable to custom devices, addressing, among other things:

- Devices created or modified in order to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type not to exceed five units per year qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, devices that qualify for the custom device exemption were clarified to include no more than "five units per year of a particular device type" that otherwise meet all the requirements necessary to qualify for the custom device exemption. In this guidance, FDA interprets the five units in terms of five new custom devices per year (i.e., five new patients for the patient-focused custom device or five new physicians for the physician-focused custom device, assuming all other required elements for the custom device exemption are satisfied). The five-unit limitation includes all devices provided by a manufacturer to, and remaining in the possession of, the ordering physician and/or patient.

The guidance defines terms used in the custom device exemption, explains how FDA plans to interpret the term "five units per year of a particular device type" set forth in section 520(b)(2)(B) of the FD&C Act, describes what information manufacturers should submit in a custom device annual report to FDA, and provides guidance on how to submit an annual report for devices distributed under the custom device exemption.

On January 14, 2014, FDA issued the draft guidance entitled "Custom Device Exemption" (Ref. 1). The Agency has reviewed the comments submitted for the draft guidance and has incorporated many of the recommendations in this final guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on custom devices. 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. A search capability for all Center for Devices and Radiological Health 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 "Custom Device Exemption," you may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1820 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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. This draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA (44 U.S.C. 3501-3520). The collections of information in 21 CFR 814, subparts B and E have been approved under OMB control number 0910-0231; the collections of information in 21 part 812 have been approved under OMB control

number 0910-0078; the collections of information in 21 part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of custom device annual reporting have been approved under OMB control number 0910-0767.

V. Comments

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

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the Federal Register.)

1. The FDA draft guidance entitled "Custom Device Exemption," available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380497.pdf.

Dated: September 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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