Federal Register: Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Humanitarian...

U.S. Food & Drug Administration

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[Notices]
[Page 39263-39264]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0434]

Guidance for Humanitarian Device Exemption Holders, Institutional Review Boards, Clinical Investigators, and Food and Drug Administration Staff; Humanitarian Device Exemption Regulation; Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ``Humanitarian Device Exemption (HDE) Regulation: Questions and Answers.'' This guidance answers commonly asked questions about Humanitarian Use Devices (HUDs) and applications for HDEs.

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 ``Humanitarian Device Exemption (HDE) Regulation:

Questions and Answers'' to the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), 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, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. The 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 information on electronic access to the guidance.
Submit electronic comments on the guidance to http://www.regulations.gov [1]. 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: Sheila Brown, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1651, Silver Spring, MD 20993-0002, 301-796-6563, or Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance answers commonly asked questions about HUDs and applications for HDE authorized by section 510(m)(2) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360(m)(2)). This update of the version issued in 2006 reflects additional requirements set forth in the Pediatric Medical Device Safety and Improvement Act of 2007 (Public Law 110-85). The Pediatric Medical Device Safety and Improvement Act of 2007 includes a provision requiring that all original HDE applications include both a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients (new section 515A(a)(2) of the act). It also amends section 520(m) of the act to exempt some HUDs from the prohibition on profit (new section 520(m)(6) of the act). Specifically, HDE applications indicated for use in pediatric patients that are approved on or after September 27, 2007, may be assigned an annual distribution number (ADN) and be sold for profit, subject to certain restrictions. Finally, the Pediatric Medical Device Safety and Improvement Act of 2007 includes a provision requiring that the agency provide guidance to Institutional Review Boards (IRBs) on the review of HUDs. This update of the HDE guidance

Page 39264 [2]

includes 29 specific questions and answers for IRBs as well as guidance to HDE holders on whether and how they may become eligible to receive profit from the sale of their device. In the Federal Register of August 5, 2008 (73 FR 45460), FDA published a 60-day notice requesting public comment. The comment period closed on November 3, 2008. FDA published a 30-day notice on September 30, 2009 (74 FR 50214), but republished a 30-day notice on February 18, 2010 (75 FR 7270), to provide a more descriptive response to the comments received in response to the August 5, 2008, notice. This document supersedes: Humanitarian Device Exemption (HDE) Regulation: Questions and Answers, issued July 18, 2006.

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 the ``HDE Regulation: Questions and Answers.'' 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 guidance may do so by using the Internet. To receive ``HDE Regulation: Questions and Answers,'' you may either send an e-mail request to dsmica@fda.hhs.gov [3] 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 1668 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm [4]. Guidance documents are also available at http://www.regulations.gov [1] or the CBER Internet site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm [5].

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910-0661, May 31, 2013, expiration date.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

Dated: July 1, 2010.
Nancy Stade,
Acting Associate Director for Regulations and Policy, Center for Devices and Radiological Health.
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SOURCE [6]

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