

Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Jill Hartzler Warner, Office of Policy, Planning, and Preparedness (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3370.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers," dated August 2008. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA. FDA implements a rigorous process for soliciting and vetting candidates for advisory committee meetings to minimize any potential for financial conflicts of interest. The agency is authorized by statute to grant waivers to allow individuals with potentially conflicting financial interests to participate in meetings where we conclude, after close scrutiny, that certain criteria are met. See 18 U.S.C. 208(b)(1), (b)(3) and section 712(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (added by the Food and Drug Administration Amendments Act of 2007, Public Law No. 110-85, section 701 (effective October 1, 2007)).

In January 2002, FDA issued "Draft Guidance on Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," and requested comments on the draft guidance (Docket No. 2002D-0049). The draft guidance was limited in application to Special Government Employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed.

FDA has recently undertaken an internal assessment of its advisory committee process. As a result of this review, and based on the comments submitted to the docket for the January 2002 draft guidance, FDA has revised the 2002 draft guidance to broaden its applicability, to bring as much transparency as possible to FDA's waiver process, and to increase the consistency and clarity of the process.

The guidance revises procedures, consistent with section 712(c)(3) of the act, to make publicly available relevant information regarding financial interests and waivers granted by the agency for SGEs and regular Government employees invited to participate in FDA advisory committee meetings.

The guidance also includes a template for disclosing to the public the disqualifying financial interests for which waivers are sought and a template for all waivers that FDA grants. The guidance further describes FDA's process for making these documents available on its Web site in advance of each advisory committee meeting.

In the **Federal Register** of October 31, 2007 (72 FR 61657), FDA announced the availability of the draft guidance of the same title dated October 2007. FDA received one comment on the draft guidance generally supporting the guidance. Editorial changes were made to improve clarity.

This guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on public availability of information regarding advisory committee members' financial interests and waivers granted by FDA to permit participation in advisory committee meetings. 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 statutes and regulations.

**II. Comments**

Interested persons may, at any time, 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at <http://www.fda.gov/opacom/morechoices/industry/guidedc.htm> or <http://www.regulations.gov>.

Dated: July 31, 2008.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**Draft 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 draft guidance entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers." This draft guidance answers commonly asked questions about Humanitarian Use Devices (HUDs) and applications for HDE. This draft guidance is neither 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 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 3, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. 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:**

Stephen P. Rhodes, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4036.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft 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 the 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 515A(a)(2) of the act). It also amends section 520(m) of the act (21 U.S.C. 360j(m)) 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 includes 30 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.

**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 the aspects of HDE regulation discussed in the guidance. 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 "Humanitarian Device Exemption (HDE) Regulation: Questions and Answers," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1666 to identify the guidance you are requesting.

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 at <http://www.regulations.gov>.

**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. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information

is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title:* Pediatric Use Information to Accompany Humanitarian Device Exemption Applications.

*Description:* Title III of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) amended chapter V of the act (21 U.S.C. 351 *et seq.*) by inserting section 515A Pediatric Uses of Devices (21 U.S.C. 360e-1).

This new provision requires that new applications under section 520(m) of the act 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.

Title III of FDAAA also amended section 520(m) of the act as follows:

- Section 520(m)(6)(A)(ii) provides that the Secretary of Health and Human Services will assign an annual distribution number for devices indicated for use in pediatric patients or in a pediatric subpopulation. The ADN shall be based on the following information in an HDE application: (1) the number of individuals affected by the disease or condition that such device is intended to treat, diagnose, or cure, and of that number; (2) the number of individuals likely to use the device; and (3) the number of devices reasonably necessary to treat such individuals.

- Section 520(m)(6)(A)(iii) provides that an HDE holder immediately notify the agency if the number of devices distributed during any calendar year exceeds the annual distribution number.

- Section 520(m)(6)(C) provides that an HDE holder may petition to modify the annual distribution number if additional information on the number of individuals affected by the disease or condition arises.

The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements.

Respondents to this collection of information are holders of HDEs

indicated for use in pediatric patients or in a pediatric subpopulation that were approved on or after September, 27,

2007, the enactment date of the Pediatric Medical Device Safety and Improvement Act of 2007.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Section of the Federal Food, Drug, and Cosmetic Act	No. of Applicants	Annual Frequency per Response	Total Annual HDE Applications	Hours per Response	Total Hours
515A(a)(2)	5	1	5	100	500
520(m)(6)(A)(ii)	3	1	3	50	150
520(m)(6)(A)(iii)	1	1	1	100	100
520(m)(6)(C)	5	1	5	100	500
Total					1,250

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of original HDE applications that the Center for Devices and Radiological Health (CDRH) received in the period between October 1, 2004, and September 30, 2007. During that time, CDRH received 16 original HDE applications or about 5 per year.

FDA estimates that for each year CDRH will receive five HDE applications and that three of these applications will be indicated for pediatric use. One HDE holder will notify the agency that the number of devices distributed in the year has exceeded the annual distribution number and five HDE holders will petition to have the annual distribution number modified due to additional information on the number of individuals affected by the disease or condition.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 814, subparts A, B, and C have been approved under OMB control number 0910-0231; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332; and the collections of information in 21 CFR

10.30 have been approved under OMB control number 0910-0183.

**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.

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Dated: July 30, 2008.

**Jeffrey Shuren,**  
*Associate Commissioner for Policy and Planning.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0386]

**International Conference on Harmonisation; Draft Guidance on E2F Development Safety Update Report; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “E2F Development Safety Update Report.” The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance describes the format, content, and timing of a development safety update report (DSUR) for an investigational drug. The DSUR would serve as a harmonized, annual clinical trial safety report that would be standard among the three ICH regions. The DSUR could be submitted in the United States in place of an annual report for an investigational new drug application (IND). The harmonized DSUR is intended to promote a consistent approach to annual clinical safety reporting among the ICH regions and enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

**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 3, 2008.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002; or the Office of Communication, Training and Manufacturers Assistance (HFMA-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike,