

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 ¹

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

¹There 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This draft guidance also refers to previously approved collections of information found in FDA regulations.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.

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>.

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,

suite 200N, Rockville, MD 20852-1448. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the draft guidance: Ellis F. Unger, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4170, Silver Spring, MD 20993, 301-796-2240; or

Peter F. Bross, Center for Biologics Evaluation and Research (HFM-755), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5102.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of

Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In June 2008, the ICH Steering Committee agreed that a draft guidance entitled "E2F Development Safety Update Report" should be made available for public comment. The draft guidance is the product of the E2F Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Efficacy Expert Working Group.

The draft guidance describes the format, content, and timing of a DSUR for an investigational drug. The DSUR would serve as a harmonized, annual clinical trial safety report that would be standard among the ICH regions. The DSUR is patterned after the periodic safety update report (PSUR) (used for safety reporting in the postmarketing environment) and could be submitted in the United States in place of an annual report for an 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.

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 this topic. 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 submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. 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.regulations.gov>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/guidelines.htm>.

Dated: July 28, 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-0396]

International Conference on Harmonisation; Draft Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex on Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter; 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 "Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 4A: Microbiological Examination of Non-Sterile Products: Microbial Enumeration Tests General Chapter." 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 provides the results