

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM
Display Date 6-11-08

Publication Date 6-12-08

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[Docket No. FDA-2001-D-0067] (formerly Docket No. 2001D-0185)

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports.” This draft guidance consolidates and revises information in two existing draft guidances pertaining to electronic submission of postmarketing individual case safety reports (ICSRs) and attachments to ICSR (ICSR attachments). The submission of ICSR and ICSR attachments in an electronic format significantly improves the agency’s efficiency in processing, archiving, and reviewing the reports.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201,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 to the Office of Communication, Training, and Manufacturers Assistance (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 that office in processing your requests. The guidance may also be obtained by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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:

Roger Goetsch, Center for Drug Evaluation and Research (HFD–410), Food and Drug Administration, 12300 Twinbrook Pkwy., suite 240, Rockville, MD 20851, 301–770–9299; or

Steven 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

FDA is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports” (the electronic ICSR draft guidance). The

electronic ICSR draft guidance will apply to drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs); prescription drug products marketed for human use without an approved NDA or ANDA; nonprescription drug products marketed without an approved application; biological products, including therapeutic vaccines, marketed for human use with approved biologic license applications (BLAs) and submission tracking numbers (STNs); and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264). The electronic ICSR draft guidance will not apply to prophylactic vaccines, whole blood, or components of whole blood.

A. Consolidation of Earlier Guidance

This electronic ICSR draft guidance consolidates and revises information pertaining to electronic submission of postmarketing ICSRs and ICSR attachments in the following guidances:

- Draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports” issued in May 2001 (Expedited Reports draft guidance) (66 FR 22585, May 4, 2001), and
- Draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports” issued in June 2003 (Periodic Reports draft guidance) (68 FR 37504, June 24, 2003).

The electronic ICSR draft guidance replaces the Expedited Reports draft guidance in its entirety, and we have removed the Expedited Reports draft guidance from the Center for Drug Evaluation and Research (CDER) and CBER’s guidance pages. The electronic ICSR draft guidance also replaces the ICSR and

ICSR attachment portion of the Periodic Reports draft guidance, but does not address the descriptive information portion. We have removed the Periodic Reports draft guidance from CDER and CBER's guidance pages. For information on electronic submission of the descriptive information portion of periodic adverse drug experience reports, see the section on periodic safety update reports in the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications" (see Revision 2, June 2008).

B. International Standards for Electronic Transmission

FDA has cooperated with industry associations, standards development organizations, and the regulatory authorities of certain other nations to promote international harmonization of regulatory requirements. Much of this effort has been coordinated through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Under the auspices of the ICH, standards for electronic submission of safety information for human drug and biological products have been developed. This draft guidance is intended to provide guidance to industry regarding submission of postmarketing ICSRs and ICSR attachments to FDA in electronic form using the standards established by the ICH.

C. Updated Recommendations

As a result of comments received on the Expedited Reports and Periodic Reports draft guidances, as well as evolving technology, a number of substantive changes have been made to the agency's recommendations for the electronic transmission of ICSRs and ICSR attachments. In addition to consolidating all the information pertaining to electronic submission of ICSRs

and ICSR attachments into a single guidance, the electronic ICSR draft guidance also provides references to technical specifications for these submissions.

Since the Expedited Reports and Periodic Reports draft guidances were issued, the agency has received ICSRs for HCT/Ps regulated under section 361 of the PHS Act. On December 22, 2006, the President signed the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462), which amended the Federal Food, Drug, and Cosmetic Act to add safety reporting requirements for nonprescription drug products marketed without an approved application (21 U.S.C. 379aa). The recommendations in this electronic ICSR draft guidance will apply to these products as well as to products with approved NDAs, ANDAs, BLAs and STNs, and prescription drug products marketed without an approved NDA or ANDA.

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 providing postmarketing ICSRs and ICSR attachments in electronic format. 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 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. Paperwork Reduction Act of 1995

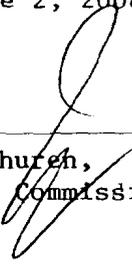
This electronic ICSR draft guidance refers to proposed collections of information required by Public Law 109–462 and subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA is now requesting public comment (see **DATES**) on these proposed collections of information. The agency’s analysis and estimates of the proposed collections of information in the electronic ICSR draft guidance that are required by Public Law 109–462 have been described previously in FDA’s notice of availability for a draft guidance entitled “Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application” (72 FR 58316, October 15, 2007) (the October 2007 PRA analysis). For burden estimates for the proposed collections of information in the electronic ICSR draft guidance, see the October 2007 PRA analysis.

This electronic ICSR draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 310.305, 314.80, 600.80, and 1271.350 have been approved under OMB control numbers 0910–0291, 0910–0230, 0910–0308, and 0910–0543 respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.regulations.gov>.

Dated: 6/2/08
June 2, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

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Dawn P. Hawkins