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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier J. Cooke

Food and Drug Administration

[Docket No. 2003D–0231]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports." This is one in a series of guidance documents on providing regulatory submissions to FDA in electronic format. This specific guidance discusses issues related to the electronic submission of postmarketing periodic adverse drug experience reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), and therapeutic and blood products marketed for human use with biologics license applications (BLAs). This guidance does not apply to vaccines, whole blood or components of whole blood. The submission of these reports in electronic format will significantly improve the agency's efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5411, Levinr@cder.fda.gov; or Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM–588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5132, *Fauntleroy@cber.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Postmarketing Periodic Adverse Drug Experience Reports." A postmarketing periodic adverse drug experience report includes individual case safety reports (ICSRs), attachments to ICSRs (ICSR attachments), if applicable, and descriptive information. The descriptive information includes the narrative summary and

analysis of the information in the report, an analysis of the 15-day alert reports submitted during the reporting interval, and the history of actions taken since the last report because of adverse drug experiences (e.g., labeling changes, studies initiated).

This draft guidance discusses general issues related to the electronic submission of postmarketing periodic adverse drug experience reports. It provides guidance on the submission of periodic ICSRs, ICSR attachments, and descriptive information in electronic format. Applicants are referred to the draft guidance for industry "Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports" (May 2001) for details on submitting periodic ICSRs and ICSR attachments to FDA.[1] Applicants are also referred to the guidance for industry "Providing Regulatory Submissions in Electronic Format—General Considerations" (January 1999) for details on submitting the descriptive information to FDA on physical media.

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 periodic adverse drug experience reports 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 on the draft guidance. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*

[1]FDA is considering comments from the public on this draft guidance for industry and plans to issue a final guidance on this topic in the future.

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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This notice contains no new collections of information. The information requested for marketed human drug and biological products is already covered by the collection of information on postmarketing safety reporting regulations (21 CFR 314.80 and 600.80) submitted to the Office of Management and Budget (OMB) for review and clearance. This notice merely provides applicants with an alternative mechanism for submitting postmarketing periodic adverse drug experience reports to the agency.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB approved the information collection for MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) and assigned it OMB control number 0910–0291. The approval for 0910–0291 expires on June 30, 2003; an extension of the approval is pending at OMB. OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on September 30, 2005, and the approval for 0910–0308 expires on May 31, 2005.

IV. Electronic Access

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

Dated: 6/17/03
June 17, 2003

Jeffrey Shuren,
Assistant Commissioner for Policy.

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