

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier	Komone Oliver

[Docket No. 01D-0185]

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Postmarketing Expedited Safety Reports.”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 expedited safety reports for drug products marketed for human use with new drug applications (NDAs) and abbreviated new drug applications (ANDAs), prescription drug products marketed for human use without an approved NDA or ANDA, and therapeutic biological products marketed for human use with biologic license applications (BLAs). This guidance does not apply to vaccines. The submission of these reports in an electronic format will significantly improve the agency’s efficiency in processing, archiving, and reviewing the reports.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Deborah Yaplee, Center for Drug Evaluation and Research (HFD-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3237, aersesub@cder.fda.gov; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM-588), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-5101, 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 Expedited Safety Reports." FDA has cooperated with industry associations 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, including a standard medical terminology for regulatory purposes, ICH M1; electronic standards for the transfer of regulatory information, ICH M2; and standardized data elements for transmission of individual case safety reports, ICH E2B and E2BM formats.

This draft guidance is intended to provide guidance to industry regarding submission of postmarketing expedited safety reports to FDA electronically using the standards established by the ICH. FDA believes the changes recommended by the ICH will result in more effective and efficient safety reporting to regulatory authorities worldwide.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on providing postmarketing expedited safety reports in an 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

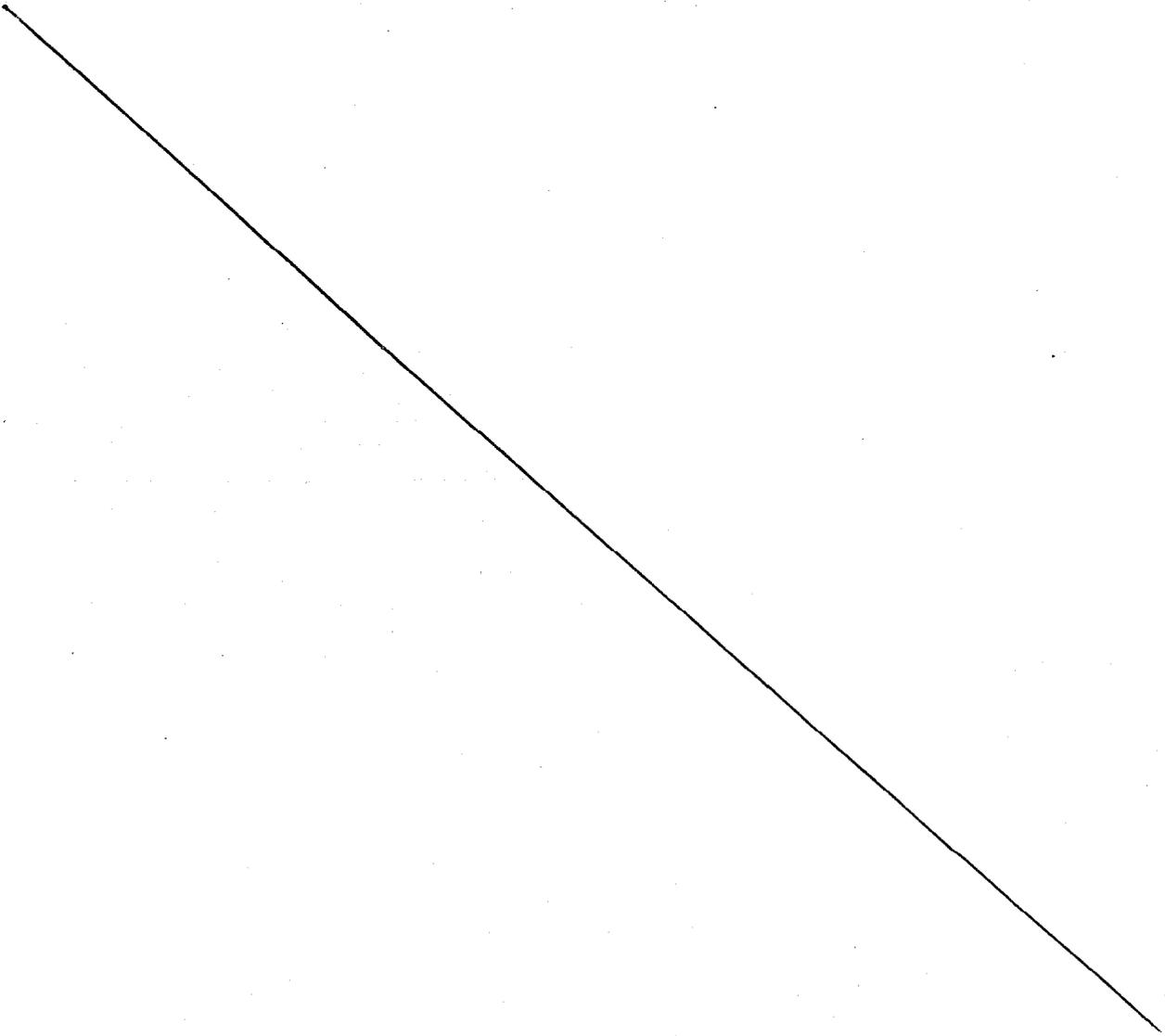
Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch 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 310.305, 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 expedited safety 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 April 30, 2003.

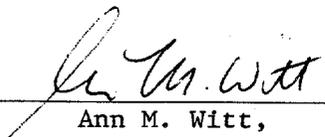
OMB also approved the information collection for adverse experience reporting for marketed drugs and licensed biological products and assigned them OMB control numbers 0910–0230 and 0910–0308, respectively. The approval for 0910–0230 expires on May 31, 2002, and the approval for 0910–0308 expires on April 30, 2003.



IV. Electronic Access

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

Dated: April 27, 2001
April 27, 2001.



Ann M. Witt,
Acting Associate Commissioner for Policy.

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