

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0056]

DMB

Display Date	3-9-01
Publication Date	3-12-01
Certifier	Skese

Draft Guidance for Industry on Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines." This draft guidance is intended to assist applicants and other responsible parties in fulfilling FDA's postmarketing safety reporting requirements for marketed human drugs and biological products.

DATES: Submit written comments on the draft guidance by [*insert date 60 days after date of publication in the Federal Register*].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ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the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 request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

cd00157

NADI

For information concerning human drug products: Min C. Chen, Center for Drug Evaluation and Research (HFD-430), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3169.

For information concerning human biological products: Miles M. Braun, Center for Biologics Evaluation and Research (HFM-220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3974.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled "Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines." This draft guidance discusses postmarketing safety reporting requirements for prescription drugs marketed for human use without an approved application § 310.305 (21 CFR 310.305), human drugs with approved new drug applications (NDA) § 314.80 (21 CFR 314.80), human drugs with approved abbreviated new drug applications (21 CFR 314.98), and human biological products with approved biologics license applications (BLA) §§ 600.80 and 600.81 (21 CFR 600.80 and 600.81).

This draft guidance does not apply to in vitro diagnostic products, whole blood or its components, or product manufacturing defects (unless the defect is associated with an adverse experience in humans). Moreover, it does not discuss the following: Investigational new drug application safety reports (21 CFR 312.32), safety update reports for drugs (21 CFR 314.50(d)(5)(vi)), approved NDA annual reports (21 CFR 314.81(b)(2)), or approved BLA annual reports (21 CFR 601.28).

Currently, FDA has three guidances for industry on postmarketing safety reporting: "Guideline for Postmarketing Reporting of Adverse Drug Experiences" (March 1992), "Guideline for Adverse Experience Reporting for Licensed Biological Products" (October 1993), and "Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report" (August 27, 1997). This draft guidance for industry consolidates the three

existing guidances into a single document and revises the information contained within them to be consistent with the final rulemaking described below.

FDA has undertaken a major effort to clarify and revise its regulations regarding pre- and postmarketing safety reporting requirements for human drug and biological products. With regard to the postmarketing expedited safety reporting regulations for human drug and biological products, the agency published a final rule in the **Federal Register** of October 7, 1997 (62 FR 52237), amending these requirements, as well as others, to implement certain definitions, reporting periods, and formats recommended by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In addition, FDA published a final rule in the **Federal Register** of June 25, 1997 (62 FR 34166), that revokes the postmarketing safety reporting requirement to submit increased frequency reports for human drug and biological products in an expedited manner. This draft guidance for industry revises the agency's existing guidances on postmarketing safety reporting to be consistent with the final rules of June 25, 1997, and October 7, 1997.

At this time, the agency is considering additional recommendations developed by ICH and plans to propose other amendments to its postmarketing safety reporting regulations. As additional amendments are made to these regulations, the agency intends to develop guidances for industry to provide recommendations on how industry can fulfill these requirements.

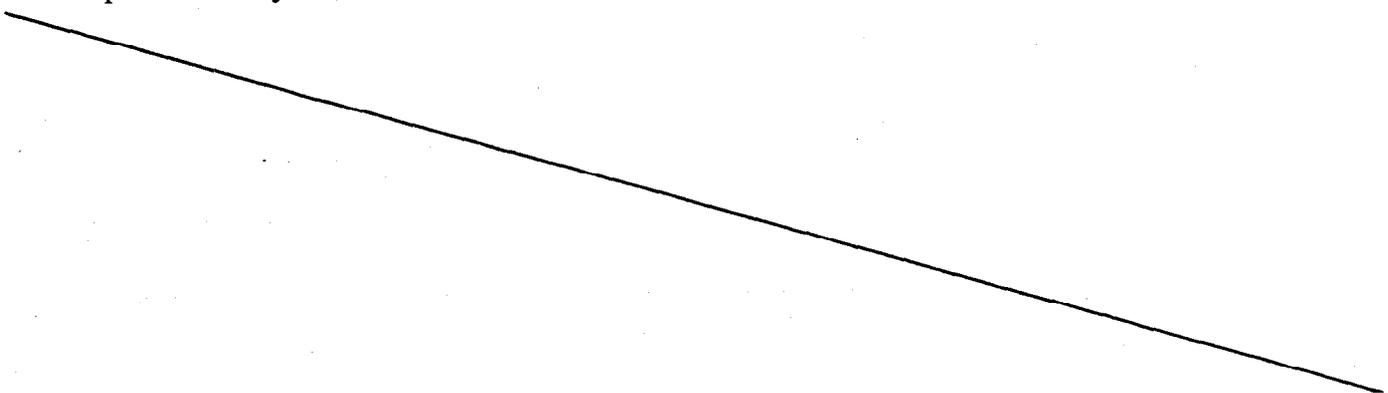
This draft guidance is being issued consistent with FDA's good guidance practices regulation^{*} (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on postmarketing safety reporting for human drug and biological products including vaccines. It 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 requirement 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 (§§ 310.305, 314.80, 600.80, and 600.81) submitted to the Office of Management and Budget (OMB) for review and clearance. 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 March 31, 2001; an extension has been requested and 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 May 31, 2002, and the approval for 0910–0308 expires on May 31, 2001.



IV. Electronic Access

Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> and at <http://www.fda.gov/cber/guidelines.htm>.

Dated: March 2, 2001
March 2, 2001

Ann M. Witt

Ann M. Witt
Acting Associate Commissioner for Policy

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Suzette N. Reese