

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1999N-1852] (formerly 99N-1852)

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Guidance for Industry on Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." This guidance provides recommendations on procedures, content, and format for submitting a postmarketing study status report for an approved human drug or licensed biological product; timeframes for FDA's review of postmarketing study commitments; and information about postmarketing study commitments that will be available to the public. The guidance is intended to assist applicants in meeting the requirements of section 130 of the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville,

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MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 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. The document may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800.

Submit written comments on the 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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Beth Duvall-Miller (CDER), Center for Drug Evaluation and Research (6411), Food and Drug Administration, 10903 New Hampshire Ave., bldg. 22, rm. 6466, Silver Spring, MD 20993, 301-796-0700; or Robert Yetter (CBER), Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Reports on the Status of Postmarketing Study Commitments—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." Section 506B ("Reports of Postmarketing Studies") of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 356b) provides FDA with additional authority for monitoring the progress of postmarketing studies that

drug and biological applicants have made a commitment to conduct.

Postmarketing studies are those studies conducted after approval to gather additional information about the safety, efficacy, or optimal use of the approved drug or biological product.

Under section 506B(a) of the act, an applicant who has entered into an agreement with FDA to conduct a postmarketing study is required to provide the agency with an annual report on the status of the study until FDA notifies the applicant, in writing, that all postmarketing study commitments established under the application(s) have either been fulfilled or have been released. The annual report must address the progress of the study or the reasons for the failure of the applicant to conduct the study. Section 506B(c) of the act directs FDA to develop and publish annually in the **Federal Register** a report on the status of postmarketing studies that applicants have made a commitment to conduct and for which status reports have been submitted. In the **Federal Register** of October 30, 2000 (65 FR 64607), the agency published a final rule to implement section 506B of the act. The final rule makes several changes to the existing regulations for approved human drugs and licensed biological products.

In the **Federal Register** of April 4, 2001 (66 FR 17912), FDA published a notice announcing the availability of a draft guidance for industry entitled "Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997." The notice gave interested persons an opportunity to submit comments by July 3, 2001. A number of comments were received in the docket for the 2001 draft guidance. After careful consideration of the comments, the draft guidance was revised. In addition to edits to improve clarity, the substantive changes made

to the draft guidance included an update of the types of postmarketing studies currently required by FDA and an improved explanation of the procedures for establishing and revising study schedules.

This guidance is intended to provide information on the following: (1) Procedures concerning the submission of postmarketing study commitment status reports; (2) the content and format of a postmarketing study commitment status report; (3) timeframes for FDA's review of postmarketing study commitment final study reports; and (4) information about postmarketing study commitments that will be available to the public. This guidance applies to postmarketing study commitments for approved human drug products and licensed biological products that meet the definition of "drug" under the act. It does not apply to biological products that meet the definition of medical "device" under the act; or to veterinary drug products, which will be addressed separately.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the submission of postmarketing study commitment reports for approved human drug or licensed biological products. 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.

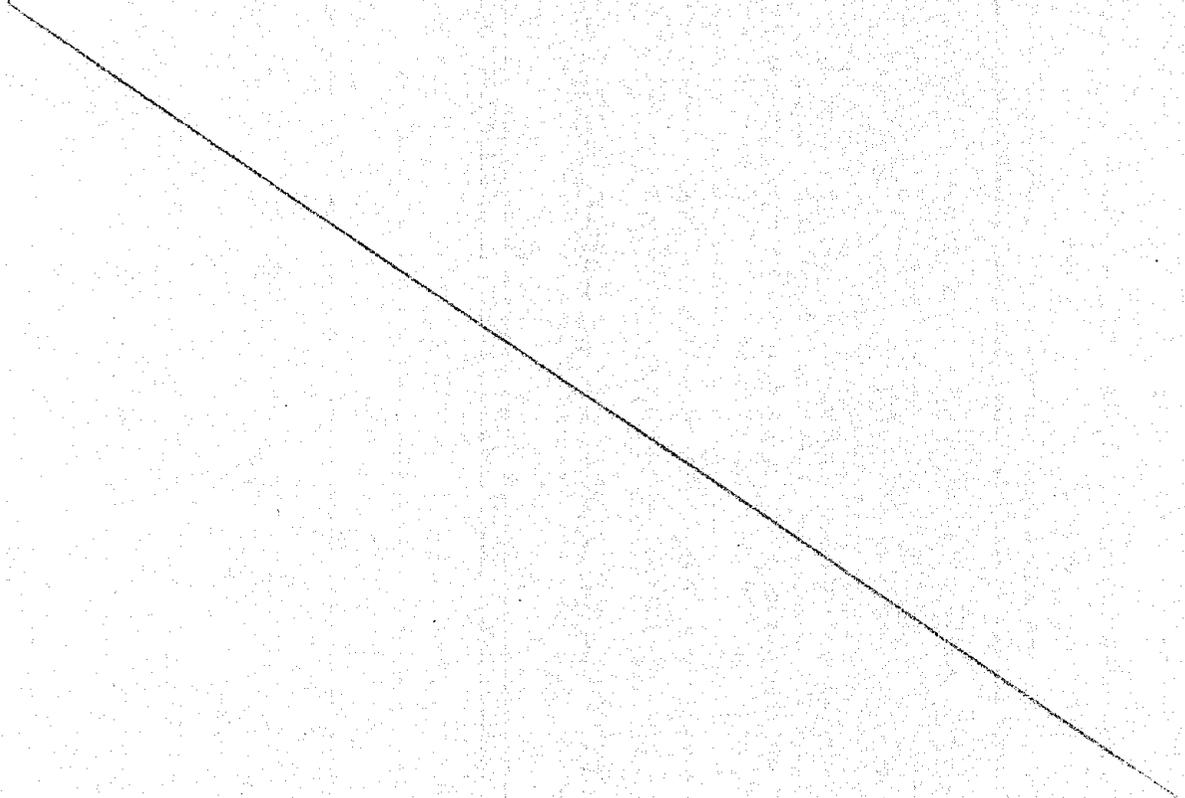
II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information

in 21 CFR 314.81 and 601.70 have been approved under OMB control numbers 0910-0001 and 0910-0433.

III. Comments

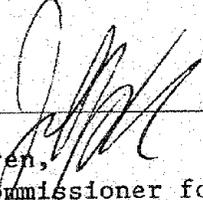
Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



IV. Electronic Access

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

Dated: 2/7/06
February 7, 2006.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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