

the risks and about protective measures allows consumers to more accurately assess how much they would pay for reductions in this risk, but more

importantly, it also informs the consumer as to what the risks are and how they can protect themselves. This information is important since the

consumer is the last line of defense in the campaign against foodborne illnesses. The total burden hours are 1,000.

Instrument	Number of respondents	Number of responses/respondent	Hours per response
Mail survey .....	3,000	1	20/60

Dated: October 28, 2003.

**Gaylon D. Morris,**

*Acting Director, Executive Secretariat,  
Centers for Disease Control and Prevention.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999N-1852]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; "Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997"

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

**DATES:** Submit written comments on the collection of information by December 5, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

#### Draft Guidance for Industry: Reports on the Status of Postmarketing Studies—Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting requirements contained in the 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 draft guidance provides recommendations on these topics:

- 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 studies; and
- Information about postmarketing studies that will be available to the public.

The draft guidance is intended to assist applicants in meeting the requirements 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 biologics applicants have made a commitment to conduct. Postmarketing studies are those studies conducted after approval to gather information about approved drug or biologics products. Such studies are used to gather additional information about product safety, efficacy, or optimal use.

Under 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 the study is completed or terminated. 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 made several changes to the regulations for approved human drugs and licensed biological products.

The draft guidance is intended to provide information on the following topics: (1) Procedures concerning the submission of postmarketing study status reports; (2) the content and format of a postmarketing study status report; (3) timeframes for FDA's review of postmarketing study reports; and (4) information about postmarketing studies that will be available to the public. The draft guidance applies to postmarketing studies 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.

In addition to the information collection provisions covered by the October 30, 2000, final rule, the guidance recommends an additional reporting requirement. The draft guidance proposes that applicants with postmarketing study commitments submit with their annual report a redacted version of each status report that already has been formatted and completed for submission. The draft guidance requests that applicants redact complete reports to the extent necessary to protect trade secrets or to conceal individual patient identifiers. FDA will use this redacted report for release to the public on its Web site and in the report on the status of postmarketing studies required under section 506B(c) of the act. FDA will accept the redacted version of the applicant's status report either in an electronic format compatible with FDA's electronic database or in hard copy.