for different types of violence that are unique or shared; (c) linkages across types of violence varied by gender and developmental stage; and (d) other socio-environmental factors which buffer or exacerbate risk for violence. The questionnaires include information about aggressive and violent behaviors (*e.g.*, verbal, coercive, physical, and sexual) that youth use against dating partners and peers; and suicidal thoughts, plans, and attempts. Additionally, the questionnaires will include information about psycho-social and behavioral factors that may buffer or exacerbate risk for violent behavior. The scales used in the questionnaire are original or modified versions of established scales that were developed for use with adolescents.

A better understanding or the linkages among dating violence, other peer violence, and suicidal behavior, and how these linkages differ by gender and age is needed to guide the selection, timing, and focus of prevention strategies. Ultimately, this information will guide CDC in designing programs that reduce multiple forms of violence among adolescents and young adults. The estimated annualized burden is 4624 hours.

Respondents	Number of respondents	Number or responses/ respondent	Average burden/response (in hrs.)
Students (recruitment, students <18 years)	5,882	1	5/60
Parents (permission, students <18 years)	5,882	1	5/60
Students participants	4,500	1	45/60
School administrators	29	1	1
Classroom teachers	240	1	1

Dated: October 24, 2003.

Gaylon D. Morris,

Acting Director, Executive Secretariat, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–81–03]

Public Comment and Recommendations Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 498–1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503; or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project: Willingness to Pay Project—NEW—Epidemiology Program Office (EPO), Centers for Disease Control and Prevention (CDC). The mission of the Prevention Effectiveness Branch is to provide information and training to build internal and external capacity in economic and decision sciences. We are requesting clearance for a package that was submitted previously and withdrawn from the program. This pilot project will use quantitative research to develop use informational approaches (educational materials or product labeling) to educate consumers about food safety issues, develop and test survey instruments and test experimental protocols to be used in the main quantitative data collection; the main data collection will be used to provide nationally-representative estimates of consumers' willingness to pay for (a) Publicly-provided reductions in the probability of contracting foodborne illnesses; (b) reductions in severity of symptoms associated with foodborne illnesses, and (c) materials that facilitate private, defensive precautions against foodborne illness during home food preparation (*e.g.*, meat thermometers, antibacterial soaps and cutting boards). The main data collection will also be used to estimate the effect of education programs and product labeling on willingness to pay for the reductions; compare the empirical estimates of the above mentioned consumer willingness to pay derived from a conjoint analysis instrument and a simulated marketplace experiment. Public awareness and stated concern regarding foodborne illnesses have increased rapidly over the past decade. The general public while seemingly well informed and concerned about some relevant food safety issues appears unknowledgeable or ill-informed about emerging issues. The Food Safety Survey data suggest that information provided to consumers at the point of purchase may be a fruitful means of educating the public about food safety, and analyses of consumer purchase data indicate that health-related information provided at the point of purchase can make significant long-term changes in purchasing behavior. While providing health-related information about food has been the focus of major policy initiatives in the last few years, little empirical economic research has attempted to understand the market and welfare effects of different health information policies. In addition, previous research does not address the distribution of effects across different consumers. Policy makers and food manufacturers cannot provide labels that satisfy everyone's information desires while simultaneously catering to consumers' cognitive and time constraints. As a result, policy makers need to understand how different sectors of the consumer population will be affected, particularly those members of the population who face relatively high food safety risks. The lack of information hinders policy makers from making informed decisions on the proper allocation of resources in this area since the benefits or reducing the risk of illness are not well known. Not having the information readily available makes cost-effectiveness and cost-benefit analyses difficult to do as well as resource-intensive. This data collection effort then will reduce this burden by making data available to researchers for use in program and policy evaluation. If this data collection effort were not to take place, agencies will either have to continue to piece together data when conducting economic analyses of food safety policies and regulations, or they will fund a large-scale effort like the one being proposed. Another large-scale effort would be a waste of public funds. Providing consumers information about

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.

[FR Doc. 03–27796 Filed 11–4–03; 8:45 am]

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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.