

These estimates are based on conversations with treatment and detoxification programs, on the number of responses received in past years, and on examination of received responses.

Dated: November 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0376]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The purpose of the proposed collection of information, a two-part telephone survey of tobacco retailers, is to assess the effectiveness of an advertising campaign aimed at increasing retailers' awareness of, and motivating retailers to comply with, new regulations that prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age and require retailers to verify, by means of photographic identification containing the bearer's date of birth, the age of every purchaser who is younger than 27 years old. The

first phase of the survey must be completed by December 31, 1997.

DATES: Submit written comments on the collection of information by December 5, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-18, Rockville, MD 20857, 301-827-1482.

SUPPLEMENTARY INFORMATION: With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Tobacco Retailer Tracking Survey

On February 28, 1997, new Federal regulations at 21 CFR part 897 went into effect that prohibit retailers from selling cigarettes and smokeless tobacco to persons younger than 18 years of age, and require retailers to verify, by means of photographic identification, the age

of purchasers younger than 27 years old. FDA is planning to conduct a pilot advertising will campaign, in one State, aimed at raising retailers' awareness of the new regulations, and motivating retailers to comply. The campaign will target persons who sell cigarettes or smokeless tobacco to consumers for their personal use, including clerks and cashiers in grocery and convenience stores, pharmacies and drug stores, gas stations, liquor stores, taverns and bars, and tobacco stores. As part of the pilot, FDA is proposing to conduct a two-part telephone survey of tobacco retailers to measure their awareness of, and self-reported compliance with, the new regulations before and after exposure to the advertising campaign in the test State. FDA also would study levels of awareness and self-reported compliance among tobacco retailers in a control State matched demographically with the test State. Retailers in the control State would not be exposed to the media campaign, and FDA would not be actively conducting compliance checks before awareness and self-reported levels of compliance are measured.

A random sample of 1,350 tobacco retailers in the test State (675 for each phase) and 300 tobacco retailers in the control State would be selected for a telephone interview. All interviewing would be conducted by a single market research firm that would employ computer-aided telephone interviewing technology to expedite the fieldwork and ensure accuracy. FDA plans to use the results of the survey in designing a nationwide advertising campaign that would help to reduce youth access to cigarettes and smokeless tobacco. Under 21 U.S.C. 393(b)(2)(C), FDA is authorized to conduct surveys and other research relating to its responsibilities under the Federal Food, Drug, and Cosmetic Act.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,650 survey	1	1,650	.2	330
Total		1,650		330

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. This information is needed by December 31, 1997, and is essential to the agency's mission. The use of normal PRA

clearance procedures would be likely to result in the prevention or disruption of this collection of information.

Dated: November 19, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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