Dated: September 11, 1998.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–24894 Filed 9–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0747]

Agency Information Collection Activities: Proposed Collection; Comment Request; Customer/Partner Service Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on voluntary customer/partner service surveys to implement Executive Order 12862.

DATES: Submit written comments on the collection of information by November 16, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

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.

Customer/Partner Service Surveys

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research relating to regulated articles and to conduct educational and public information programs relating to responsibilities of the agency. Executive Order 12862, entitled ''Setting Customer Service Standards,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys will be voluntary. This request covers customer service surveys or regulated entities, such as food processors; cosmetic, drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers partner surveys of State and local governments.

FDA will use the information gathered from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will assess timeliness, appropriateness, accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA projects 14 customer/partner service surveys per year, with a sample of between 50 and 6,000 customers each. Some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/partner service and developing long-term data.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Hours per Responses	Total Hours
Mail/telephone surveys	20,000	1	.30	6,000
Total				6,000

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

These estimates are based on the number of customer/partner service surveys FDA has conducted since January 26, 1998.

Dated: September 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24753 Filed 9–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0748]

Agency Emergency Processing Request Under OMB Review; Attitudinal and Behavorial Efffects of Direct-To-Consumer Advertising of Prescription Drugs

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). This notice solicits comments on a survey of the public to examine the impact of direct-to-consumer (DTC) advertising.

DATES: Submit written comments on the collection of information by September 28, 1998.

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–26, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13 by September 28, 1998, because this information is essential to the agency's mission. The agency cannot reasonably comply with the provisions of the PRA because the use of normal clearance procedures would prevent this collection of information from being carried out in a timely manner. FDA needs information about consumers' reactions to and behaviors that stem from DTC prescription drug advertising in order to develop policy on appropriate requirements for disclosure of risk and efficacy information about the drugs. In August 1997, when the agency issued its draft guidance on consumer-directed broadcast advertisements, FDA announced its intention to evaluate the effects of the guidance and of DTC promotion in general within 2 years of finalizing the guidance. FDA is currently in the process of finalizing this guidance. In addition, the amount of prescription drug DTC advertising is growing so quickly that rapid assessment of the public is required in order to assess public response before such advertising increases further. The information to be collected on consumer exposure and response to prescription drug DTC advertising is needed: (1) As a baseline measurement against which the effects of the final guidance will be evaluated and (2) as a timely and immediate assessment of consumers' initial response to the already high and rapidly increasing level of prescription drug DTC advertising.

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.

Attitudinal and Behavioral Effects of Direct-To-Consumer (DTC) Advertising of Prescription Drugs

Under the Food, Drug, and Cosmetic Act (the act), FDA has responsibility to ensure that the labeling and advertising of prescription drugs is truthful and not misleading. Section 502(n) of the act (21 U.S.C. 352(n)) prohibits the advertising of prescription drugs that is false or misleading or that fails to provide a ''brief summary'' of products' risks. Although advertising of prescription drugs was once restricted to health professionals, consumers increasingly have become a primary target audience, and DTC advertising has dramatically increased in the past few years. However, DTC advertising raises many questions and issues. While bringing new information to consumers, it also may confuse consumers, and no rigorous research has been done about the effects of DTC on health professional-patient relationships, compliance, or the health-care system, despite a request by FDA at a public hearing on DTC in October 1995. This data collection by FDA will serve as a baseline prior to increased advertising of prescription drugs expected in the near future.

A national randomized telephone survey will be conducted with 1,000 adults 18 years of age and over who recently visited a physician. Respondents will be asked their views about any prescription drug they may have received and prescription drugs in general, and their attitudes and behavior in relation to DTC advertising, including any visits to a health professional. In a followup mail survey, respondents will be sent a questionnaire with a variety of print DTC ads. They will be asked to rate their familiarity with the advertisements. The information from this data collection is needed to help FDA make policy decisions about disclosure requirements for promoting prescription drugs DTC.

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