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]

BILLING CODE 4160–01–F

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:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11,000 (screener)	1	11,000	.017	183.3
1,000 (survey)	1	1,000	.317	317.0
1,000 (mail followup)	1	1,000	.167	167.0
Total Burden				667.3

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

Dated: September 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24796 Filed 9–15–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0174]

International Conference on Harmonisation; Guidance on Statistical Principles for Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''E9 Statistical Principles for Clinical Trials.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to provide recommendations to sponsors and scientific experts regarding statistical principles and methodology which, when applied to clinical trials for marketing applications, will facilitate the general acceptance of analyses and conclusions drawn from the trials.

DATES: Effective September 16, 1998. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's FAX Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert O'Neill, Center for Drug Evaluation and Research (HFD–700), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3195.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are: The European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In the **Federal Register** of May 9, 1997 (62 FR 25712), FDA published a draft tripartite guideline entitled ''Statistical Principles for Clinical Trials'' (E9). The notice gave interested persons an opportunity to submit comments by June 23, 1997.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 5, 1998.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The guidance addresses principles of statistical methodology applied to clinical trials for marketing applications. The guidance provides recommendations to sponsors for the design, conduct, analysis, and evaluation of clinical trials of an investigational product in the context of its overall clinical development. The document also provides guidance to scientific experts in preparing application summaries or assessing evidence of efficacy and safety, principally from late Phase II and Phase III clinical trials. Application of the principles of statistical methodology is intended to facilitate the general acceptance of analyses and conclusions drawn from clinical trials.

This guidance represents the agency's current thinking on statistical principles for clinical trials of drugs and biologics.