for mail and telephone surveys, and a sample of up to 3,000 respondents for cable or Internet surveys.

In the **Federal Register** of March 12, 2003 (68 FR 11867), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the upper bound 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	Total Annual Responses	Hours per Responses	Total Hours
Mail questionnaire	1,000	1	1,000	3	3,000
Phone Survey	1,000	1	1,000	.5	500
Internet or Cable Survey	3,000	1	3,000	1	3,000
Total					6,500

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

These estimates are based on the expected number of respondents necessary to obtain a statistically significant stratification of the average to large size industries—including small business entities covered by FDA regulations—and consumers of regulated products.

Dated: May 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14105 Filed 6–4–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0202]

Agency Information Collection Activities; Proposed Collection; Comment Request; Assessment of Public Perceptions and Knowledge of Clinical Trials and Informed Consent Human Subject Protection

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a 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, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of U.S. consumers' knowledge and attitudes about clinical research and informed consent in clinical research.

DATES: Submit written or electronic comments on the collection of information by August 4, 2003.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm*. 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: Karen Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collections of information set forth in this document.

With respect to each of the following collections 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.

Assessment of Public Perceptions and Knowledge of Clinical Trials and Informed Consent

FDA regulates clinical research of products subject to section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) and title 21 of the Code of Federal Regulations (21 CFR) to ensure that products approved for marketing are safe and effective for use. FDA is also charged with ensuring protection of the rights and welfare of human subjects participating in clinical research. Matters involving human subject protection during clinical drug trials are evaluated within the Division of Scientific Investigations in FDA's Center for Drug Evaluation and Research.

FDA regulations describe the requirements for informed consent of study subjects in clinical research in part 50 (21 CFR part 50). Part 50 requires that, to protect clinical research subjects, subjects must be adequately informed before they consent to participate in clinical research. The informed consent process, which is an essential part of human subject protection in clinical trials, is a process of information exchange: A person who is considering participating in clinical

research learns about the research, makes an educated decision about participating, and is provided with additional information on a continuing basis, as needed, so as to remain adequately informed throughout participation in the study.

Examination of the available medical literature provides little information on the extent to which persons who may consider participating in FDA regulated clinical research understand clinical research or the informed consent process. We (FDA) propose to perform a survey, the goal of which is to gain information about the general public's perceptions and knowledge about clinical research and informed consent. To accomplish this goal, a sample of the general public will be asked to answer a questionnaire in a mall-intercept survey.

Seven hundred and fifty adult males and females (over the age of 18) who come from varied socioeconomic, ethnic, and educational backgrounds will be recruited for participation. A sample of nine subjects will be interviewed in a 30-minute pretest that will be used to help refine the questionnaire as needed, based on feedback from the pretest participants. Thereafter, the remaining subjects will participate in 15-minute interviews conducted at appropriate facilities in three geographically distributed shopping malls in the United States: Northeast, Midwest, and West.

Individuals who appear to be age appropriate will be approached by recruiters in public areas of the shopping malls. The recruiters will be clearly identified with name badges or other identification showing their affiliation with the study contractor. The recruiter will briefly explain the purpose of the study and ask the individuals if they are interested in participating in the interview. Those who agree to participate will be interviewed.

The survey questionnaire that will be used is available for review upon request.

Results of the proposed research will be used to help design a plan to educate U.S. consumers about clinical research, human subject protection, and the role of the informed consent process in clinical trials. It is expected that future consumer education programs will enhance protection for future research subjects by making subjects better informed about the clinical research process, their rights in clinical research, and the importance of the informed consent process to their protection.

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
9 (pre-test)	1	9	0.5	4.5
741 (consumer survey)	1	741	0.25	185.25
Total				189.75

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

Dated: May 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14216 Filed 6–4–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Notification From Industry Organizations Interested in Participating in Selection Process for Nonvoting Industry Representatives on Public Advisory Committees and Request for Nominations for Nonvoting Industry Representatives on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on its public advisory committees for the Center for Drug Evaluation and Research (CDER) notify FDA in writing. FDA is also requesting nominations for nonvoting industry representatives to serve on CDER's public advisory committees. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by July 7, 2003 for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by July 7, 2003.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Igor Cerny (*see* **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Igor Cerny, Advisors and Consultants Staff (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001.

SUPPLEMENTARY INFORMATION: Section 120 of the FDA Modernization Act of 1997 (FDAMA) (21 U.S.C. 355) requires that newly formed FDA advisory committees include representatives from the drug manufacturing industries. Although not required for existing committees, to keep within the spirit of FDAMA, the agency intends to add nonvoting industry representatives to all CDER advisory committees identified in the following paragraphs.

I. CDER Advisory Committees

1. Advisory Committee for Pharmaceutical Science

Advises on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

2. Advisory Committee for Reproductive Health Drugs

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in obstetrics, gynecology, and contraception.

3. Anesthetic and Life Support Drugs Advisory Committee

Reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in anesthesiology and surgery.