

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 BURDEN¹

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

¹There 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.

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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.