

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 BURDEN¹

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.

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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