Estimated Response Burden for Respondents to the Head Start Quality Research Centers (FACES QRC 2003)—Fall 2003, Spring 2004, Spring 2005.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 1 (2003)				
Head Start Parent Interview	800	1	1.00	800
Head Start Child Assessment	800	1	0.66	528
Teacher Child Rating	80	10	0.25	20
Teacher Interview	80	1	1.00	80
Year 2 (2004)				
Head Start Parent Interview	1,480	1	1.00	1,480
Head Start Child Assessment	1,480	1	0.66	977
Teacher Child Rating	160	8	0.25	320
Year 3 (2005)				
Head Start Parent Interview	680	1	1.00	680
Head Start Child Assessment	680	1	0.66	449
Teacher Child Rating	180	6	0.25	270
Estimated Total Annual Burden Hours				5,604

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *rsargis@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 2, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–14153 Filed 6–4–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0079]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Consumer and Producer Surveys on Economic Issues

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the information collection by July 7, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Consumer and Producer Surveys on Economic Issues (OMB Control Number 0910–0478)—Extension

Under section 903(d)(2) 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 collect information relating to responsibilities of the agency. Executive Order 12866, the Regulatory Flexibility Act (RFA), and the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) direct Federal agencies to conduct regulatory impact analysis, and to consider flexible regulatory approaches. In order to perform the mandatory analysis, it is often necessary to survey regulated producers to determine existing practices and the changes in those practices likely under various policy options, both consumers and manufacturers to explore attitudes towards policy proposals, and industry experts to solicit expert opinion. FDA is seeking OMB clearance to conduct future surveys to implement Executive Order 12866, RFA, and SBREFA. Participation in the surveys will be voluntary. This request covers regulated entities, such as food processors, dietary supplement manufacturers, health professionals, or other experts and consumers.

FDA will use the information gathered from these surveys to identify current business practices, expert opinion, and consumer or manufacturer attitudes towards existing or proposed policy. FDA projects approximately 2 to 6 surveys per year, with a sample of between 10 and 1,000 respondents each

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]

BILLING CODE 4160–01–S

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