DATES: Fax written comments on the collection of information by August 18, 2004.

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 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 Management Programs (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.

Voluntary Registration of Cosmetic Product Establishments—21 CFR Part 710 (OMB Control Number 0910–0027)—Extension

The Federal Food, Drug, and Cosmetic Act (the act) provides FDA with the responsibility for assuring consumers that cosmetic products in the United States are safe and properly labeled. Cosmetic products that are adulterated under section 601 of the act (21 U.S.C. 361) or misbranded under section 602 of the act (21 U.S.C. 362) may not be distributed in interstate commerce. To assist FDA in carrying out its responsibility to regulate cosmetics, FDA has developed the Voluntary Cosmetic Registration Program (VCRP). In 21 CFR part 710, FDA requests that establishments that manufacture or package cosmetic products register with the agency on Form FDA 2511 entitled ''Registration of Cosmetic Product Establishment.'' Form FDA 2511 is available on FDA's VCRP Web site at *http://www.cfsan.fda.gov/acrobat/frm2511.pdf*.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. FDA places the registration information in a computer database and uses the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. FDA also uses the information for estimating the size of the cosmetic industry and for conducting onsite establishment inspections. Registration is permanent, although FDA requests that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

In the **Federal Register** of February 27, 2004 (69 FR 9339), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
710	FDA 2511	15	1	15	0.4	6

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

The VCRP was suspended during fiscal year (FY) 1998 due to a lack of budgetary funding and was reinstated at the beginning of FY 1999. The estimated hour burden for this information collection is 30 percent of the previous level reported in 2000. In general, the larger cosmetic companies have resumed participating in the VCRP, whereas the smaller companies are lagging.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16307 Filed 7–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of National Cancer Institute's Cancer Trials Support Unit To Improve Cancer Clinical Trials System

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Evaluation of National Cancer Institute's Cancer Trials Support Unit To Improve Cancer Clinical Trials System. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This evaluation will examine the success of the Cancer Trials Support Unit (CTSU), a pilot project designed to improve physician and patient accessibility to NCI-sponsored phase 3 treatment trials and to facilitate data management and regulatory administration for these trials. This evaluation includes two surveys that will be available online to minimize respondent burden. The Online Information Survey will elicit information related to CTSU regulatory and data management systems, particularly with respect to the completeness of information, respondents' opinions about usability and their recommendations or modifications, as well as their assessment in relation to other systems in use. The Online Data Submission Survey will assess opinions about the online data submission process, reasons for choosing to continue submitting data on paper, perceived barriers or ease of use, and suggestions for improvement. The findings will provide valuable information concerning whether this program is meeting its intended goals and provide recommendations for change and further study. *Frequency of*

Response: Once. *Affected Public:* Registered members of the CTSU and Clinical Trials Cooperative Group staff. *Type of Respondents:* The Online Information Survey will survey registered CTSU users and Cooperative Group staff. The Online Data Submission Survey will survey registered CTSU users and Cooperative Group staff. The annualized cost to respondents is estimated at $10,400. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 520. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 0.50 Hours. *Estimated Total Annual Burden Hours Requested:* 260.

The total burden estimate per respondent is shown below:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requests
Online Information System Survey—registered CTSU users and Cooperative Group staff ..	290	1	0.50	145
Online Data Submission Survey—registered CTSU users and Cooperative Group staff	230	1	0.50	115
Total	.....	.....	.....	260

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 those who are able to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Bryce B. Reeve, Ph.D., Outcomes Research Branch, ARP, DCCPS, National Cancer Institute, 6130 Executive Blvd. MSC 7344, Bethesda, MD 20892–7344. Phone: (301) 594–6574, e-mail: *reeveb@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: July 12, 2004.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 04–16315 Filed 7–16–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of National Cancer Institute's Central Institutional Review Board To Improve Cancer Clinical Trials System

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Evaluation of National Cancer Institute's Central Institutional Review Board To Improve Cancer Clinical Trials System. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* This study will evaluate the success of the Central Institutional Review Board (CIRB), a pilot project designed to streamline the protocol activation process by conducting human subject protection reviews that can be utilized by local Institutional Review Boards (IRBs) for facilitated approval of multi-institutional, NCI-sponsored phase III clinical trails. This evaluation includes two surveys that will be made available online to minimize respondent burden. The CIRB Survey will assess acceptance level and satisfaction of local IRB chairs, coordinators, and principal investigators with the CIRB. The Cooperative Group Staff survey will assess the opinions and experiences of the operations and regulations staff of the nine Clinical Trials Cooperative Groups about CIRB operations, office processes, and procedures. The findings will provide valuable information concerning whether the CIRB is meeting its intended goals and will provide recommendations for change and further study. *Frequency of Response:* Once. *Affected Public:* Registered members of the CIRB and Clinical Trials Cooperative Group staff. *Type of Respondents:* IRB chairs, IRB coordinators, principal investigators, and the operations and regulations staff of Clinical Trials Cooperative Groups. The annualized cost to respondents is estimated at $5,500. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. *Estimated Number of Respondents:* 279. *Estimated Number of Responses per Respondent:* 1. *Average Burden per Response:* 0.50 Hours. *Estimated Total Annual Burden Hours Requested:* 139.50.

The total burden estimate per respondent is shown below:

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response	Estimated total annual burden hours requested
IRB chairs, IRB coordinators, principal investigators	225	1	0.50	112.50
Clinical Trials Cooperative Group operations and regulations staff	54	1	0.50	27