TABLE 1.—ESTIMATED REPORTING BURDEN[1]—Continued

21 CFR Section/Form No.	No. of Respondents	Number of Responses Per Respondent	Total Annual Responses	Hours per Responses	Total Hours
(2) Form FDA–2656 Annual Update of Drug Establishment 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.26 21 CFR 207.40	8,382	.82	6,859	2.50 hr.	17,147.50
(3) Form FDA–2657 Drug Product Listing 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31 21 CFR 207.40	15,530	3	46,713	2.50 hr.	116,782.50
(4) Form FDA–2658 Registered Establishments' Report of Private Label Distributors 21 CFR 207.21 21 CFR 207.22 21 CFR 207.25 21 CFR 207.30 21 CFR 207.31	7,216	2.14	15,415	2.50 hr.	38,537.50
Total Reporting Burden					189,217.50

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

In the **Federal Register** of April 8, 2004 (69 FR 18588), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16305 Filed 7–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0379]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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 the **Federal Register** of March 9, 2004 (69 FR 11018), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0518. The approval expires on June 30, 2007. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: July 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16306 Filed 7–16–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0063]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Voluntary Registration of Cosmetic Product Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information 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 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*