assessment. The agency recommends that a request for special protocol assessment be submitted as an amendment to an IND for two reasons: (1) To ensure that each request is kept in the administrative file with the entire IND, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the evaluation of the protocol and to ensure that appropriate steps will be taken in a timely manner.

The guidance recommends that the following information should be submitted to the appropriate Center with each request for special protocol assessment so that the Center may quickly and efficiently respond to the request:

- Questions to the agency concerning specific issues regarding the protocol; and
- All data, assumptions, and information needed to permit an adequate evaluation of the protocol, including: (1) The role of the study in the overall development of the drug; (2) information supporting the proposed trial, including power calculations, the choice of study endpoints, and other critical design features; (3) regulatory outcomes that could be supported by the results of the study; (4) final labeling that could be supported by the results of the study; and (5) for a stability protocol, product characterization and relevant manufacturing data.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the Public Health Service Act (42 U.S.C. 262) who requests special protocol assessment.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for special protocol assessment.

Notifications for a Carcinogenicity Protocol

Based on data collected within CDER and CBER, including the number of notifications for carcinogenicity protocols and the number of carcinogenicity protocols submitted in fiscal year (FY) 2007, 2008, and 2009, CDER estimates that it will receive approximately 60 notifications of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately 28 sponsors. CBER estimates that it will receive approximately one notification of an intent to request special protocol assessment of a carcinogenicity protocol per year from approximately one sponsor. The hours per response, which is the estimated number of hours that a sponsor would spend preparing the notification and background information to be submitted in accordance with the guidance, is estimated to be approximately 8 hours.

Requests for Special Protocol Assessment

Based on data collected within CDER and CBER, including the number of requests for special protocol assessment submitted in FY 2007, 2008, and 2009, CDER estimates that it will receive approximately 372 requests for special protocol assessment per year from approximately 216 sponsors. CBER estimates that it will receive approximately 10 requests from approximately 10 sponsors. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for special protocol assessment, including the time it takes to gather and copy questions to be posed to the agency regarding the protocol and data, assumptions, and information needed to permit an adequate evaluation of the protocol. Based on the agency's experience with these submissions, FDA estimates approximately 15 hours on average would be needed per response.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Notification for Carcinogenicity Protocols	29	2.10	61	8	488
Requests for Special Protocol Assessment	226	1.69	382	15	5,730
Total					6,218

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

Dated: July 7, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–16972 Filed 7–12–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Cancer Trials Support Unit (CTSU) Public Use Forms and Customer Satisfaction Surveys (NCI)

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: Cancer Trial Support Unit (CTSU). *Type of Information Collection Request:* Existing Collection in Use Without an OMB Number. *Need and Use of Information Collection:* CTSU collects annual surveys of customer satisfaction for clinical site staff using the CTSU Help Desk and the CTSU web site. An ongoing user satisfaction survey is in place for the Oncology Patient Enrollment Network (OPEN). User satisfaction surveys are compiled as part of the project quality assurance activities and are used to direct improvements to processes and technology. In addition, the CTSU collects standardized forms to process site regulatory information, changes to membership, patient enrollment data, and routing information for case report forms. This questionnaire adheres to The Public Health Service Act, Section 413 (42 U.S.C. 285a–2) authorizes CTEP to establish and support programs to facilitate the participation of qualified investigators on CTEP-supported

studies, and to institute programs that minimize redundancy among grant and contract holders, thereby reducing overall cost of maintaining a robust treatment trials program.

Frequency of Response: The help desk and web site survey are collected annually. The OPEN survey is ongoing. Submission of forms varies depending on the purpose of the form and the activity of the local site.

Affected Public: CTSU's target audience is staff members at clinical sites and CTEP-supported programs. Respondent and burden estimates are listed in the Table below. The annualized burden is estimated to be 27,861 hours and the annualized cost to respondents is estimated to be $757,828. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Attach No.	Section/form or survey title	Use metrics/ month—# respond	Estimated time for site to complete (minutes)	Estimated burden (minutes/ hours)	Frequency of response	Total annual usage/annual burden hours
1a	CTSU IRB/Regulatory Approval Transmittal Form.	9,000	2	0.03	12.00	3,240
1b	CTSU IRB Certification Form	8,500	10	0.17	12.00	17,340
1c	CTSU Acknowledgement Form	500	5	0.08	12.00	480
1d	*Optional Form 1—Withdrawal from Protocol Participation Form.*	10	5	0.08	12.00	10
Roster Forms:						
1e	CTSU Roster Update Form	50	2–4	0.07	12.00	42
1f	CTSU Radiation Therapy Facilities Inventory Form.	20	30	0.50	12.00	120
Drug shipment:						
1g	CTSU IBCSG Drug Accountability Form.	11	5–10	0.17	12.00	22
1h	CTSU IBCSG Transfer of Investigational Agent Form.	3	20	0.33	12.00	12
Data Management:						
1i	Site Initiated Data Update Form (generic).	10	5–10	0.17	12.00	20
1j	N0147 CTSU Data Transmittal Form.	330	5–10	0.17	12.00	673
1k	Site Intimated Data Update Form (DUF), Protocol: NCCTG N0147*.	30	5–10	0.17	12.00	61
1l	TAILORX/PACCT 1 CTSU Data Transmittal Form.	1200	5–10	0.17	12.00	2,448
1m	Data Clarification Form	144	15–20	0.33	12.00	570
1n	Unsolicited Data Modification Form (UDM), Protocol:TAILORx/PACCT1.	30	5–10	0.17	12.00	61
1o	Z4032 CTSU Data Transmittal Form.	58	5–10	0.17	12.00	118
1p	Z1031 CTSU Data Transmittal Form.	54	5–10	0.17	12.00	110
1q	Z1041 CTSU Data Transmittal Form.	48	5–10	0.17	12.00	98
1r	Z6051 CTSU Data Transmittal Form.	12	5–10	0.17	12.00	24
1s	RTOG 0834 CTSU Data Transmittal Form*.	60	5–10	0.17	12.00	122
1t	CTSU 7868 Data Transmittal Form.	30	5–10	0.17	12.00	61
1u	Site Initiated Data Update Form, protocol 7868.	10	5–10	0.17	12.00	20
1v	MC0845(8233) CTSU Data Transmittal*.	40	5–10	0.17	12.00	82
1w	8121 CTSU Data Transmittal Form*.	40	5–10	0.17	12.00	82
1x	Site Initiated Data Update Form, Protocol 8121.	10	5–10	0.17	12.00	20
1y	USMCI 8214/Z6091: CTSU Data Transmittal *In Development.	50	5–10	0.17	12.00	102
1z	USMCI 8214/Z6091 Crossover Request/Checklist Transmittal Form.	5	5–10	0.17	12.00	10
Patient Enrollment:						
1aa	CTSU Patient Enrollment Transmittal Form.	600	5–10	0.17	12.00	1,224
1bb	CTSU P2C Enrollment Transmittal Form.	30	5–10	0.17	12.00	61
1cc	CTSU Transfer Form	40	5–10	0.17	12.00	82
Administrative:						

Attach No.	Section/form or survey title	Use metrics/ month—# respond	Estimated time for site to complete (minutes)	Estimated burden (minutes/ hours)	Frequency of response	Total annual usage/annual burden hours
1dd	CTSU System Account Request Form.	10	15–20	0.33	12.00	40
1ee	CTSU Request for Clinical Brochure.	35	10	0.17	12.00	71
1ff	CTSU Supply Request Form	130	5–10	0.17	12.00	265
Surveys/Web Forms:						
2	CTSU Web Site Customer Satisfaction Survey.	250	10–15	0.2500	1.00	63
3	CTSU Helpdesk Customer Satisfaction Survey.	300	10–15	0.2500	1.00	75
4	CTSU OPEN Survey	120	10–15	0.2500	1.00	30
Annual Totals		21,770				27,861

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are 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 Michael Montello, Pharm. D., CTEP, 6130 Executive Blvd., Rockville, MD 20852. At non-toll-free number 301–435–9206 or e-mail your request, including your address to: *montellom@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 7, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–17038 Filed 7–12–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0344]

Agency Information Collection Activities; Proposed Collection; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the 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 communication studies involving medical devices and radiation-emitting products regulated by FDA. This information will be used to explore concepts of interest and assist in the development and modification of communication messages and campaigns to fulfill the agency's mission to protect the public health.

DATES: Submit either electronic or written comments on the collection of information by September 13, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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 collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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.