FDA will conduct a pre-test of the survey with five respondents, and it is estimated that it will take a respondent 20 minutes (0.33 hours) to complete the pre-test, for a total of 1.65 hours. One hundred respondents will complete the survey. It is estimated that it will take a respondent 20 minutes (0.33 hours) to complete the survey, for a total of 33 hours. Thus, the total estimated annual reporting burden is 34.65 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar.

Dated: July 7, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010–16971 Filed 7–12–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0337]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Special Protocol Assessment

**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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance for industry on special protocol assessment.

**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:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, e-mail: *Elizabeth.Berbakos@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, including each proposed extension of an existing 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.

### Guidance for Industry on Special Protocol Assessment (OMB Control Number 0910–0470)—Extension

The "Guidance for Industry on Special Protocol Assessment" describes agency procedures to evaluate issues related to the adequacy (e.g., design, conduct, analysis) of certain proposed studies. The guidance describes procedures for sponsors to request special protocol assessment and for the agency to act on such requests. The guidance provides information on how the agency interprets and applies provisions of the Food and Drug Administration Modernization Act of 1997 and the specific Prescription Drug User Fee Act of 1992 (PDUFA) goals for special protocol assessment associated with the development and review of PDUFA products. The guidance describes two collections of information: (1) The submission of a notice of intent to request special protocol assessment of a carcinogenicity protocol, and (2) the submission of a request for special protocol assessment.

Notification of a Carcinogenicity Protocol

As described in the guidance, a sponsor interested in agency assessment of a carcinogenicity protocol should notify the appropriate division in FDA's Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) of an intent to request special protocol assessment at least 30 days prior to submitting the request. With such notification, the sponsor should submit relevant background information so that the agency may review reference material related to carcinogenicity protocol design prior to receiving the carcinogenicity protocol.

Request for Special Protocol Assessment

The guidance asks that a request for special protocol assessment be submitted as an amendment to the investigational new drug application (IND) for the underlying product and that it be submitted to the agency in triplicate with Form FDA 1571 attached. The guidance also suggests that the sponsor submit the cover letter to a request for special protocol assessment via facsimile to the appropriate division in CDER or CBER. Agency regulations (21 CFR 312.23(d)) state that information provided to the agency as part of an IND is to be submitted in triplicate and with the appropriate cover form, Form FDA 1571. An IND is submitted to FDA under existing regulations in part 312 (21 CFR part 312), which specifies the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of investigational drugs and biological products. The information collection requirements resulting from the preparation and submission of an IND under part 312 have been estimated by FDA and the reporting and recordkeeping burden has been approved by OMB under OMB Control Number 0910–0014.

FDA suggests that the cover letter to the request for special protocol assessment be submitted via facsimile to the appropriate division in CDER or CBER to enable agency staff to prepare for the arrival of the protocol for

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.*

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## 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