teleconference, the SEP will now convene at the Doubletree Hotel, 3342 Peachtree Road, NE., Atlanta, GA 30326.

Date and Time: 8:30 a.m.–3 p.m., May 10, 2007.

Contact Person for More Information: Juliana Cyril, M.P.H., PhD, Associate Director for Policy and Peer Review, CDC, 1600 Clifton Road, NE., Mailstop D–72, Atlanta, GA 30333, Telephone (404) 639–3098.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 25, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–8248 Filed 4–27–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed projects:

Title: Supporting Healthy Marriage (SHM) Project: Control Services Survey.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is conducting a demonstration and evaluation called the Supporting Healthy Marriage (SHM) Project. Supporting Healthy Marriage is designed to inform program operators and policymakers of the most effective ways to help low-income married couples strengthen and maintain healthy marriages. In particular, the project will measure the effectiveness of marriage education programs by randomly assigning eligible volunteer couples to SHM program groups and control groups.

In order to conduct a strong test of the SHM program, the researchers must understand whether marriage education services similar to SHM are readily accessible to control group members elsewhere in the communities where SHM is offered. To measure the difference between services received by the program group and control group, the evaluator will administer a brief survey to participants in each SHM demonstration pilot site. The purpose of this survey is to identify the kinds of services that participants have received over the last six months, either from the SHM program or from other agencies in the community. This survey will allow the research team to determine whether there is a sufficient differential between the services received by the participants in the program group and those in the control group to constitute a strong test of the SHM intervention.

Respondents: Low-income married couples with children.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SHM Control Services Survey	808	1	.17	137.4

Estimated Total Annual Burden Hours: 137.4.

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: *infocollection@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: April 23, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–2090 Filed 4–27–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0215]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Valid or Will Not Be Infringed

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 (the PRA).

DATES: Fax written electronic comments on the collection of information by May 30, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the OMB control number 0910–0513. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated NDAs Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed (OMB Control Number 0910–0513)—Extension

FDA is requesting that OMB revise and extend approval under the PRA for the information collection contained in the final rule entitled ''Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed'' (68 FR 36676, June 18, 2003) (the June 2003 final rule).

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, ''the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture[,] use, or sale of the drug.'' Section 505(c)(2) of the act imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the act, we publish patent information after approval of an NDA application in the list entitled ''Approved Drug Products with Therapeutic Equivalence Evaluations'' (the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the act directs us to publish the information upon its submission.

The June 2003 final rule clarified the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement. The June 2003 final rule also required persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using required forms (Form FDA 3542a and Form FDA 3542).

Certain sections of the June 2003 final rule regarding the application of 30-month stays on approval of certain abbreviated new drug applications (ANDAs) and certain other NDAs, known as 505(b)(2) applications, submitted under the act, were superseded by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Public Law 108–173), signed December 8, 2003. The affected sections of the regulations issued in the June 2003 final rule—under part 314 (21 CFR part 314), §§ 314.52(a)(3) and 314.95(a)(3)—were revoked by the technical amendment to the June 2003 final rule, published in the **Federal Register** of March 10, 2004 (69 FR 11309). Accordingly, FDA's request to extend approval under the PRA for the collection of information contained in the June 2003 final rule is revised to exclude the revoked sections of the regulations, §§ 314.52(a)(3) and 314.95(a)(3), and certain sections of the regulations, §§ 314.50(i)(1)(i) and 314.94(a)(12), which were included in the estimated annual reporting burden to describe an information collection burden associated with the revoked sections of the regulations.

The reporting burden for submitting an NDA, an amendment, or supplement in accordance with § 314.50(a) through (f), and (k) has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001, most recently until May 31, 2008, (70 FR 35099, June 16, 2005). In addition, the reporting burden associated with the previously-referenced §§ 314.50(i)(1)(i) and 314.94(a)(12), regarding patent certification requirements for 505(b)(2) applications and ANDAs also has been estimated and included within the collection of information approved by OMB under OMB control number 0910–0001. We are not re-estimating these approved burdens in this document. Only the reporting burdens associated with patent submission and listing in the final rule are estimated in this document.

The information collection reporting requirements are as follows:

Section 314.50(h) requires that an NDA, an amendment, or a supplement contain patent information described under § 314.53.

Section 314.53 requires that an applicant submitting an NDA, an amendment, or a supplement, except as provided in § 314.53(d)(2), submit on FDA Forms 3542 and 3542a, the required patent information described in the section.

Compliance with the information collection burdens under §§ 314.50(h) and 314.53 consists of submitting with an NDA, an amendment, or a supplement (collectively referred to as ''application'') the required patent declaration(s) on Form FDA 3542a for each ''patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product'' (§ 314.53(b)). Such patents claim the drug substance (active ingredient), drug product (formulation and composition), or method of use. If a patent is issued after the application is filed with FDA but before the application is approved, the applicant must submit the required patent information on Form FDA 3542a as an amendment to the application, within 30 days of the date of issuance of the patent.

Within 30 days after the date of approval of an application, the applicant must submit Form FDA 3542 for each patent that claims the drug substance (active ingredient), drug product (formulation and composition), or approved method of use for listing in the Orange Book. In addition, for patents issued after the date of approval of an application, Form FDA 3542 must be submitted within 30 days of the date of issuance of the patent.

In the **Federal Register** of June 2, 2006 (71 FR 32099), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment from the Pharmaceutical Research and Manufacturers of America (PhRMA). The comment stated, generally, that FDA underestimated the resources required to satisfy the collection of information. Further, the comment

suggested that the information collection burden could be reduced by clarifying several questions in FDA Forms 3542a and 3542, and deleting or revising questions in these forms that appear, to the comment, to serve no statutory purpose. In the following section of this document, FDA describes the comments submitted by PhRMA, and our responses (the word ''Response'' appears in parentheses before our response).

First, the comment stated that the information collection burden associated with FDA Forms 3542a and 3542 was underestimated ''in part because completion of each form may involve personnel from legal, patent, regulatory, medical, and scientific divisions within a company.''

(Response) FDA published for public comment its initial estimate of this collection of information in the proposed rule published in the **Federal Register** of October 24, 2002 (67 FR 65448 at 65458 and 65459). This estimate of the information collection burden was revised through the rulemaking process and further described in the preamble to the June 2003 final rule (68 FR 36676 at 36698 and 36699). In connection with the request that OMB extend approval for the collection of certain information described in the June 2003 final rule, FDA updated, unbundled, and revised its estimate of the burden associated with the collection of information on FDA Forms 3542a and 3542 to 20 hours and 5 hours, respectively. This proposed revision was based on FDA's experience and other information. The comment provides no data to support its statement that the burden was underestimated, and does not propose any alternative estimate. Accordingly, FDA declines to revise its estimate. We note, however, that clarifications and revisions to FDA Forms 3542a and 3542 described in this document would be expected to reduce the overall burden associated with this collection of information.

Second, the comment stated that question 4 on FDA Forms 3542a and 3542 ''requires completion of the form on a claim-by-claim basis.'' The comment further contended that ''[t]his is not authorized under the statute, it serves no statutory purpose, and it significantly increases the burden on applicants.'' In the alternative, the comment requested that FDA amend question 4.2 to ''specifically allow an applicant to list together multiple claims for the same or related labeled indications.''

(Response) FDA addressed comments related to listing individual patent claims for method-of-use patents in the response to comments 7 and 11 in the preamble to the June 2003 final rule. In the June 2003 final rule, we explained that the ''specific method-of-use claims are essential to our review because sections 505(j)(2)(A)(viii) and 505(b)(2)(B) of the act allow ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval [a ''section viii statement'']. The ANDA or 505(b)(2) applicant does not have to seek approval for all uses approved for the reference listed drug'' (68 FR 36676 at 36685). A method of use may be omitted for ANDA labeling if it is protected by exclusivity or a listed patent (§ 314.94(a)(8)(iv)). We further stated: ''Thus, the claim-by-claim listing of method-of-use patents will permit ANDA and 505(b)(2) applicants to assess whether they are seeking approval for a use claimed in the listed patent, and thus determine whether to submit a patent certification or a section viii statement. Additionally, we can verify that the certification or statement is correct, and that only the appropriate methods of use are included in the proposed labeling for the ANDA or 505(b)(2) drug product'' (68 FR 36676 at 36685).

In the alternative, PhRMA requested that FDA amend question 4.2 to ''specifically allow an applicant to list together multiple claims for the same or related labeled indications.'' FDA agrees, consistent with our regulations at § 314.53(b)(1), that an applicant may list together multiple patent claims for each pending or approved method of use. However, each pending or approved method of use must be separately identified and therefore will require separate listing(s) of method of use information in section 4 of FDA Forms 3542a and 3542. Therefore, if a patent claims one or more methods of use that apply to a pending application or approved product, each pending or approved method of use would need to be listed separately along with the patent claim number(s) for the patent claim(s) for the pending or approved method of use. A single Form FDA 3542a or Form FDA 3542, as appropriate, may be used to list a patent claiming more than one method of use, provided that each method of use is listed separately along with the patent claim number(s) for the patent claim(s) for the pending or approved method of use. This regulatory approach accomplishes the statutory objective of providing adequate information to permit ANDA and 505(b)(2) applicants to file statements which assert that the method-of-use patent does not claim a use for which the applicant is seeking approval.

FDA that the instructions and text of section 4 on FDA Forms 3542a and 3542 may warrant clarification in light of the text of the regulations at § 314.53(b)(1). FDA's regulations on submission of patent information state, in pertinent part: ''The applicant shall *separately identify each pending or approved method of use* and related patent claim'' (§ 314.53(b)(1) (emphasis added)). Section 4 of FDA Forms 3542a and 3542 states: ''Sponsors must submit the information in section 4 *separately for each patent claim* claiming an approved method of using the approved drug product. For each method of use claim referenced, provide the following information* * *'' (emphasis added). Currently, some applicants list multiple patent claims together for each separately identified pending or approved method of use. FDA is revising FDA Forms 3542a and 3542 to clarify that this is an acceptable practice and conform the text of these Forms to our existing regulations. The text of Section 4 of these Forms is being revised to delete the word ''separately'' from the first sentence of text and add other clarifying text. FDA also is adding clarifying text to the information and instructions for these Forms.

Third, the comment questioned the specific statutory purpose for requiring a sponsor to ''link'' the method of use claimed by the patent to language identifying the use in the approved (or, with respect to Form FDA 3542a, the proposed) labeling for the drug product.

(Response) FDA previously has explained the basis for requiring a description of each individual method of use for which a patent is submitted for listing, and identification of the corresponding language found in the labeling of the approved NDA that corresponds to that method of use. As discussed in more detail in the June 2003 final rule, this approach provides for effective implementation of the patent certification and ''section viii statement'' provisions of the act by enabling ANDA and 505(b)(2) applicants, and FDA, ''to assess whether the ANDA or 505(b)(2) applicant is seeking approval for a use the sponsor states is claimed in the listed patent, and thus determine whether the applicant must submit a patent certification or may submit a section viii statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii) of the act'' (68 FR 36676 at 36682). A ''section viii statement'' refers to a statement under section 505(b)(2)(B) or 505(j)(2)(A)(viii)

of the act asserting that a listed method of use patent does not claim a use for which the applicant is seeking approval. In addition, information regarding the approved labeling corresponding to a listed method of use patent assists FDA in determining which labeling should be omitted when a 505(b)(2) application or ANDA includes a ''section viii statement'' indicating that it is not seeking approval for the use claimed in the patent.

Fourth, with reference to section 4.2b of Form FDA 3542, the comment questioned the need for a sponsor to provide a proposed ''Use Code'' describing the approved indication or method of use for inclusion in the Orange Book. The comment stated that inclusion of ''Use Codes'' is not required by the act, and noted that ''although FDA has suggested that requiring NDA applicants to supply use codes is necessary to assist generic applicants, the agency also stated that a generic applicant should not rely on the information concerning method of use patents provided by the NDA applicant, but should conduct an independent review and evaluation of the relevant patent(s) and approved labeling'' (citing the June 2003 final rule, 68 FR 36676 at 36683 and 36685). Further, the comment stated that FDA has ''provided no guidance to innovators on appropriate content of 'use codes''' and such information may be duplicative of other information provided in the form.

(Response) As discussed in the previous response, section 505(b)(2)(B) and 505(j)(2)(A)(viii) of the act permit a 505(b)(2) and ANDA applicant, respectively, to assert that a listed method of use patent does not claim a use for which the applicant is seeking approval. FDA has consistently required that a 505(b)(2) or ANDA applicant filing a section viii statement must ''carve out'' from the proposed labeling, the labeling protected by the listed patent (see 68 FR 36676 at 36682). The regulatory requirement that an applicant provide a ''use code'' for method of use patents listed in the Orange Book facilitates the implementation of the certification and section viii statement provisions of the act (see section 701 of the act (21 U.S.C. 371)). Accordingly, the use code should contain adequate information, within the 240-character limitation of FDA's database system, to assist 505(b)(2) and ANDA applicants in determining whether a listed method of use patent claims a use for which the 505(b)(2) or ANDA applicant is not seeking approval and thus has been carved out of the proposed labeling.

Fifth, the comment states that ''Question 2 requires unnecessary information relating to patents that claim polymorphs.'' The comment contends that ''[t]he fact that a properly listed patent may also claim other forms is irrelevant * * * it is *only* if the patent claims only a different form that the agency needs to ask applicants to certify that the substance is, nevertheless, the 'same.''' The comment suggests that subquestion 2.2 should be revised accordingly to state: ''Does the patent claim *only* a drug substance that is a polymorph of the active ingredient in the pending NDA, amendment, or supplement?''

(Response) FDA's regulations at §§ 314.53(c)(2)(i)(M)(*2*) and 314.53(c)(2)(ii)(N)(*2*) require information on whether the patent claims a polymorph that is the same active ingredient that is described in the pending application or supplement. This requirement is described at section 2.2 of Forms 3542a and 3542. The revision that you have proposed would require revision of FDA's regulations. In continuing to implement Title XI of the MMA, FDA plans to initiate a rulemaking to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the act. FDA will further consider your request for clarification and revision to the regulations in the context of that rulemaking.

Sixth, the comment questioned the need for indicating in subsection 2.7 and 3.3 of FDA Forms 3542a and 3542 whether the product claimed in a product-by-process patent is novel. The comment stated that this information is not required by the act and the ''same listing criteria used for other product patents should apply to patents that include product-by-process claims.'' The comment further noted that ''including the term 'novel' in the form plunges FDA into complicated issues of patent law, which it has said repeatedly are beyond its expertise.''

(Response) In subsection 2.7 and 3.3 of FDA Forms 3542a and 3542, we require applicants to indicate whether the product claimed in the product-by-process patent is novel to help ensure that process patents are not submitted for listing (see June 2003 final rule, 68 FR 36676 at 36686). FDA's regulations at §§ 314.53(c)(2)(i)(L) and 314.53(c)(2)(ii)(M) codify this requirement. The June 2003 final rule and questions on FDA Forms 3542a and 3542 were intended to clarify which patents must and must not be submitted for listing, and avoid situations in which applicants may inadvertently submit patents that do not meet the statutory and regulatory requirements. We disagree with the comment's suggestion that inclusion of the term 'novel' in FDA Forms 3542a and 3542 ''plunges FDA into complicated issues of patent law.'' FDA's patent listing role remains ministerial. As discussed in the preamble to the June 2003 final rule, FDA ''will not evaluate a patent to assess whether the declaration is accurate or whether the patent has been appropriately submitted for listing. * * * We will, however, review the declaration for completeness and to determine that the information given by the NDA applicant or holder or patent owner indicates that the patent is eligible for listing'' (68 FR 36676 at 36687).

Seventh, the comment requested clarification of subsection 1f of FDA Forms 3542a and 3542, which states ''Is the patent referenced above a patent that has been submitted previously for the approved NDA or supplement referenced above.''

(Response) In the preamble to the June 2003 final rule, FDA discussed, in response to comment 12, its requirement for information on whether the patent being submitted has been submitted previously for the NDA or supplement referenced in the declaration. FDA stated: ''We require information on whether the patent being submitted has been submitted previously for the NDA or supplement referenced in the declaration. For example, an earlier listed patent may have included several method-of-use claims but only one method of use previously approved and submitted. A second method of use may be approved in a supplement and must be submitted for listing. Such information will assist the Orange Book staff with its administrative listing responsibilities'' (68 FR 36676 at 36686). FDA will further consider your request for clarification in the context of the rulemaking referenced previously.

Eighth, the comment suggested that FDA clarify that the ''purpose of questions 2.1, 3.1, and 4.1 [on Forms 3542a and 3542] is simply to differentiate the types of claims that appear in the patents in questions (i.e., drug substance, drug product, or method of use). In other words, question 2.1 should be answered 'yes' only if the patent contains 'drug substance' claims. Question 3.1 should be answered 'yes' only if the patent contains drug product claims. Question 4.1 should be answered 'yes' only if the patent contains method of use claims.''

(Response) FDA's regulations at § 314.53(c)(2) set forth reporting requirements for submission of patent information. These regulations require

the submission of information and verification of patent information to ensure not only that the patent contains drug substance, drug product, or method of use claims, but that the patent claims the drug substance, drug product, or method of using the drug product for which approval is sought or has been granted. The clarification that you have requested would require revision of FDA's regulations. FDA will further consider your request for clarification and revision to the regulations in the context of the rulemaking referenced previously.

Finally, the comment stated that the submission of FDA Forms 3542a and 3542 with submission and upon approval, respectively, of an NDA supplement is redundant where the information has not changed since the form last was filed, imposes a burden on sponsors, and serves no statutory purpose.

(Response) FDA's regulation at § 314.53(b)(1) requires any applicant who submits to FDA a supplement to an approved application that meets the criteria of § 314.53(d)(2) to submit FDA Forms 3542a and 3542, as appropriate. The revision that you have proposed would require revision of FDA's regulations. FDA will further consider your request for clarification and revision to the regulations in the context of the rulemaking referenced previously.

FDA estimates that the collection of information resulting from these regulations is as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Form FDA 3542a	114	3.2	365	20	7,300
Form FDA 3542	96	3.2	308	5	1,540
Total					8,840

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

Dated: April 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8141 Filed 4–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0155]

Defining and Implementing Quality in Clinical Investigations: From Design to Completion; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA) is announcing a public workshop cosponsored with the Drug Information Association (DIA) entitled ''Defining and Implementing Quality in Clinical Investigations: From Design to Completion.'' The purpose of the public workshop is to solicit constructive information on identifying attributes of quality in clinical investigations, approaches to quality from design to completion, and methods for measuring quality and ensuring data integrity during the conduct of clinical investigations. The public workshop will discuss the definition of quality, mechanisms for implementing quality in clinical investigations, and methods to improve the accuracy and reliability of collected data, which will enhance human subject protection. FDA also is requesting comments on these topics.

Dates and Time: The public workshop will be held on May 10 and May 11, 2007, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Washington Marriott Hotel, 1221 22d St. NW., Washington, DC 20037.

Contact Person: Kathleen Donner, DIA, 215–293–5810, FAX: 215–442–6199, or e-mail: *Kathleen.Donner@diahome.org*.

Registration: Registration will be accepted by mail, fax, or e-mail until May 10, 2007, and also onsite. Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person (see *Contact Person*). You may also register online at *www.diahome.org* (''Educational Offerings,'' keyword 07013). (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) There is a registration fee for the workshop: $1,165.00 for industry, $475.00 for charitable nonprofit organizations or academia, and $200.00 for Federal Government employees. The registration fees will be used to cover costs of the workshop, including program materials and food.

If you need special accommodations due to a disability, please contact Kathleen Donner (see *Contact Person*) at least 7 days in advance.

Comments: The deadline for submitting comments regarding this public workshop is July 10, 2007.

Interested persons may submit written or electronic comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the public workshop entitled ''Defining and Implementing Quality in Clinical Investigations: From Design to Completion'' is to solicit constructive information on identifying attributes of quality in clinical investigations, approaches to quality from design to completion, and methods for measuring quality and ensuring data integrity during the conduct of clinical investigations.

Over time, clinical investigations have evolved dramatically. In particular, clinical investigations are no longer primarily conducted at a single center; the use of electronic recordkeeping in the studies has increased dramatically; and the conduct of clinical investigations has become more complex. The public workshop will address the challenges of and potential solutions for maintaining quality during the conduct of clinical investigations to protect human subjects. The following