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

topics will be discussed: (1) The definition of quality, (2) mechanisms for implementing quality in clinical investigations, and (3) methods to improve the accuracy and reliability of collected data. As part of the Human Subject Protection/Bioresearch Monitoring Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*), this public workshop will help improve the safe conduct of clinical investigations and maximize efficiency in clinical investigations without compromising quality.

Dated: April 23, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–8137 Filed 4–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–07–8001]

Memorandum of Understanding Between the National Cancer Institute and the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the National Cancer Institute (NCI), part of the National Institutes of Health of the Department of Health and Human Services. The purpose of this MOU is to establish a formal collaboration between FDA and NCI regarding proteomics science and technology to accelerate proteomics technology development and application in clinical settings. FDA and NCI intend to collaborate in areas involving proteomics such as: Sample collection, preparation, storage and processing; bioinformatics and data analysis; discovery and validation of biomarkers; and surrogate biomarkers of cancer development and drug response, including standardization among technology platforms and assay standards development.

DATES: The agreement became effective April 5, 2007.

FOR FURTHER INFORMATION CONTACT: Francis Kalush, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0996, e-mail: *francis.kalush@fda.hhs.gov*.

or Henry Rodriguez, Office of the Director, (MSC–2580), National Cancer Institute, 31 Center Dr., rm. 10A52, Bethesda, MD 20892, 301–496–1550.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: April 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE

NATIONAL CANCER INSTITUTE

AND THE

U.S. FOOD AND DRUG ADMINISTRATION