conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application (IND) under 21 CFR part 312, and the associated information collections are covered in OMB control no. 0910–0014.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks.

Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3) and (c)(4)	FDA 2914	80	1	80	1	80
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1,190
361.1(d)(8)		50	6.8	340	0.1	34
Total Reporting						1,304

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Hours per Record	Total Hours
361.1(c)(2)	80	4	10	800
361.1(d)(5)	50	6.8	.75	38
Total Recordkeeping				838

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

Dated: September 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–18646 Filed 9–20–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0347]

Information Technology Strategic Planning; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to solicit views and information from interested persons on issues concerning how the agency can best plan and apply information technology (IT) resources to support the process for the review of human drug applications. In particular, FDA is seeking views and information from interested persons to identify and prioritize IT solutions that will support the process for the review of human drug applications. To help solicit such information and views, FDA is seeking responses to specific questions (see section IV of this document).

DATES: *Public Meeting*: The public meeting will be held on October 19,

2007, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

Registration and Participation: Registration on the day of the public meeting will be provided on a space available basis beginning at 7:30 a.m. Because seating is limited, we recommend arriving early. See section I of the **SUPPLEMENTARY INFORMATION** section of this document for information on how to participate in the meeting. If you need special accommodations due to a disability, please contact Carolyn Yancey (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

Comments: Submit written or electronic notices of participation and comments by 2 weeks prior to the public meeting. The docket for this meeting will remain open to receive additional comments until 15 days after the meeting date.

ADDRESSES: The public meeting will be held at the Advisors and Consultants Staff Conference Room, FDA, 5630 Fishers Lane, Rockville, MD 20857. Additional information on parking and public transportation may be accessed at *http://www.fda.gov/oc/pdufa/default.htm*.

Submit written notices of participation and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857. Submit electronic notices of participation and comments to *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm*. Identify all submissions to the docket with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carolyn Yancey, Office of Chief Information Officer (HFA–80), Food and Drug Administration, 5600 Fishers Lane, Rm. 16B–45, Rockville, MD 20857, 301–827–4302, *carolyn.yancey@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. How to Participate in the Meeting

If you wish to make an oral presentation during the meeting, you must submit a written notice of participation with the Division of Dockets Management (see **ADDRESSES**) no later than 2 weeks prior to the public meeting (see **DATES**). To ensure timely handling, any outer envelope should be clearly marked with the docket number found in brackets in the heading of this document, along with the statement ''Electronic Submission of Regulatory Information, and Creating an Electronic Platform for Enhanced Information Management.'' In the written notice, submit presenter's name and title, address, telephone and fax number, e-mail address, affiliation (if any), the sponsor of the presentation (e.g., the organization paying travel expenses or fees) (if any), and a brief summary of the presentation (including the discussion topic(s) that will be addressed or other pertinent information related to the topic in your presentation). If there are multiple participants please include the names and addresses of all individuals that plan to participate, and the approximate time requested for your presentation. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Participants should submit to the Division of Dockets Management two copies of each presentation. We will file the meeting schedule indicating the order of presentation and the time allotted to each person with the Division of Dockets Management (see **ADDRESSES**). We will also mail or telephone the schedule to each participant before the meeting. In anticipation of the meeting presentations moving ahead of schedule, participants are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called risk forfeiting their scheduled time.

II. Background

Over the years, FDA has agreed to several IT-related performance commitments, starting with computer assisted reviews in the Prescription Drug User Fee Act (PDUFA) I, and continuing with the PDUFA III Electronic Applications and Submission Goals in which FDA committed to implementing the electronic Common Technical Document (eCTD) and a common solution for the secure exchange of content, including secure e-mail and electronic submissions. FDA met these commitments by implementing the Electronic Submissions Gateway at *http://www.fda.gov/esg/* and an electronic system for facilitating the receipt and review of submissions in the eCTD format (*http://www.fda.gov/cder/regulatory/ersr/ectd.htm*). In addition, FDA implemented the first phase of the electronic labeling rule in the Center for Drug Evaluation and Research at *http://www.fda.gov/oc/datacouncil/spl.html*.

Simultaneously, the Federal Government has also been pursuing healthcare electronic standards. In 2004, the President issued Executive Order 13335 establishing the position of the National Coordinator for Health Information Technology within the Office of the Secretary of Health and Human Services (HHS). The primary purpose of this position is to aid the Secretary of HHS in achieving the President's goal for most Americans to have access to an interoperable electronic medical record by 2014. One of the key initiatives under the Office of the National Coordinator was the establishment of the Health Information Technology Standards Panel—a public-private partnership with broad participation across more than 300 health-related organizations—to identify and harmonize data and technical standards for healthcare. Adding to the complexity of the healthcare movement towards a standards-based approach is the impact this may have on the regulated entities, from the small startup companies and research organizations, to the large multinational companies who submit regulatory submissions globally and are requesting global coordination on healthcare standards.

During this timeframe FDA published IT plans to communicate FDA's overall direction and strategy in meeting IT-related performance goals and to describe our efforts in moving towards an electronic submission and review environment. In producing the previous IT plans FDA developed the plans internally and published the plans on the web—for example at *http://www.fda.gov/oc/pdufa/default.htm*. As FDA moves towards an automated standards-based electronic review environment, the agency is seeking public input on the type of information to be included in future IT plans that will provide our external stakeholders the information needed to be in alignment with the program direction and goals.

III. Purpose and Scope of the Meeting

The purpose of this public meeting is to provide stakeholders the opportunity to address specific topics (see section IV of this document) and present their views, recommendations, and any other pertinent information related to the scope of this public meeting. The scope of this public meeting includes the following areas:

1. The content of IT plans that is most useful to external stakeholders,

2. The data standards and guidance that best support available IT capabilities and any implementation considerations, and

3. How agency architecture and IT solutions can best be applied to support public health mission needs.

IV. Issues for Discussion

We are specifically interested in hearing comments regarding the following questions and any other pertinent information related to the feasibility of the electronic submission of premarket applications and other regulatory information related to the review of human drug applications including postmarket data sources:

1. What would help improve the quality of electronic submissions to the agency?
2. What would help increase the quantity of electronic submissions to the agency?
3. How would you prioritize these quality and quantity improvements?
4. What data standards are needed to implement these improvements?
5. How should FDA engage stakeholders while developing, testing, and implementing these solutions?
6. What topics are most useful to include in IT plans?
7. What lead time is needed for stakeholders to respond to and be in alignment with FDA initiatives?
8. How should FDA coordinate with stakeholders on the adoption and implementation of data standards?
9. What data standards areas provide the greatest challenge?
10. What approaches will facilitate the most effective and efficient adoption and implementation of data standards?
11. What key areas require new or expanded electronic submissions guidance?
12. What lessons learned and best practices should FDA consider as we transition from program-specific to enterprise IT solutions using a reusable and modular model?
13. What specific concerns (i.e., security, confidentiality, etc.) exist for a third party entity or entities providing services related to electronic submissions and review and how can they be addressed?

V. Notice of Public Meeting

The Commissioner of Food and Drugs is announcing that the public meeting will be conducted by FDA senior management. Persons who wish to participate in the meeting must file a written or electronic notice of participation with the Division of Dockets Management (see **ADDRESSES** and **DATES**). No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

VI. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration. To permit time for all interested persons to submit data, information, or views on this subject, the administrative record of the meeting will remain open until 2 weeks prior to the public meeting. Persons who wish to provide additional materials for consideration should file these materials with the Division of Dockets Management (see **ADDRESSES**). You should annotate and organize your comments to identify the specific questions to which they refer (see section IV of this document). Two paper copies of any mailed comments are to be submitted, 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VII. Transcripts

The meeting will be transcribed. Transcripts of the meeting will be available for review at the Division of Dockets Management (see **ADDRESSES**) and on the Internet at *http://www.fda.gov/ohrms/dockets* approximately 21 days after the meeting. You may place orders for copies of the transcript through the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rm. 6–30, Rockville, MD 20857, at a cost of 10 cents per page.

Dated: September 17, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–4692 Filed 9–18–07; 12:12 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Research Resources Special Emphasis Panel, Florida International University Site Visit.

Date: October 18–19, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Park Plaza Hotel, 415 North Monroe Street, Tallahassee, FL 32301.

Contact Person: Guo Zhang, PhD, MD, Scientific Review Administrator, National Center for Research Resources, or National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1064, MSC 4874, Bethesda, MD 20892–4874, 301–435–0812, *zhanggu@mail.nih.gov.*

Name of Committee: National Center for Research Resources Special Emphasis Panel, Tulane NPRC.

Date: October 29–31, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham New Orleans, 100 Rue Iberville, New Orleans, LA 70130.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Dem. Plaza, Room 1076, Bethesda, MD 20892, 301–435–0814, *lambert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: September 14, 2007.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07–4669 Filed 9–20–07; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice