DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 3090–0027, Contract Administration, Quality Assurance (GSAR Parts 542 and 546; GSA Form 1678, and GSA Form 308), in all correspondence.

Dated: May 20, 2008

Al Matera,

Director,Office of Acquisition Policy.

[FR Doc. E8–11849 Filed 5–27–08; 8:45 am]

BILLING CODE 6820–61–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Injury Prevention and Control/Initial Review Group, (NCIPC/IRG)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following meeting for the aforementioned review group:

Times and Date:

2 p.m.–2:30 p.m., June 18, 2008 (Open).

2:30 p.m.–4 p.m., June 18, 2008 (Closed).

Place: CDC, Chamblee Campus, Building 106, 4770 Buford Highway, Atlanta, GA 30341. Toll Free: 888–793–2154, Participant Passcode: 4424802.

Status: Portions of the meetings will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5, U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Section 10(d) of Public Law 92–463.

Purpose: This group is charged with providing advice and guidance to the Secretary, Department of Health and Human Services, and the Director, CDC, concerning the scientific and technical merit of grant and cooperative agreement applications received from academic institutions and other public and private profit and nonprofit organizations, including State and local government agencies, to conduct specific injury research that focuses on prevention and control.

Matters To Be Discussed: The meeting will include the discussion and voting of the peer reviews conducted in response to Fiscal Year 2008 Requests for Applications related to the following individual research announcements: RFA–CE–08–001, Youth Violence Prevention through Community-Level Change (U49); RFA–CE–08–002, Grants for Traumatic Injury Biomechanics and their Severity (R01); RFA–CE–08–003, Research for Preventing Violence and Violence-Related Injury (R01); RFA–CE–08–004, Translation Research to prevent Motor Vehicle-related crashes and Injuries to Teen Drivers and their Passengers (R01); RFA–CE–08–005, Dissertation Grant Awards for Doctoral Candidates for Violence-Related Injury Prevention Research in Minority Communities (R36); RFA–CE–08–006, Feasibility of Acute Concussion Management in the Emergency Dept (U49); RFA–CE–08–007, Assessing the Effects of Interpersonal Violence Prevention on Suicide (U49); RFA–TS–08–001, Program of Exposure-Dose Reconstruction and Computational Methods to Quantify Exposures to Hazardous Substances (U01); and RFA–EH–08–001, Program to Assess Health Effects Associated with Exposures to Volcanic Emissions and Environmental Air Pollutants (P78).

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Jane Suen, Dr. P.H., M.S., Executive Secretary, NCIPC IRG, CDC, 4770 Buford Highway, NE., M/S F–62, Atlanta, Georgia 30341, telephone 770/488–4281.

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: May 19, 2008.

Elaine L. Baker,

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

[FR Doc. E8–11720 Filed 5–27–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0280]

Potential for a Registry of Breast Cancer Treatment Using Thermal Ablation Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments on whether a registry could facilitate standardization of feasibility trials studying local treatment of small breast cancers with different thermal ablation devices and therapies (i.e. cryoablation, focused ultrasound, interstitial laser, microwave, radiofrequency ablation). FDA is specifically interested in understanding how breast cancer ablation feasibility trials can be constructed so that there exists standardized evaluation of tissue biopsy pathology, selection of tumors amenable to ablation, image guidance for ablation, post-ablation imaging and assessment, and tissue pathology of ablated specimens. The agency seeks to facilitate its understanding of local treatment for breast cancer using thermal ablation devices.

DATES: Submit written or electronic comments by November 24, 2008.

ADDRESSES: Submit written comments concerning this document 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.regulations.gov*. To ensure timelier processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail.

FOR FURTHER INFORMATION CONTACT: Binita Ashar or Long Chen, Center for Devices and Radiological Health (HFZ–500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3600, e-mail: *binita.ashar@fda.hhs.gov* or *long.chen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 24, 2003, FDA's General and Plastic Surgery Devices Advisory Panel discussed issues pertaining to the use of thermal ablation devices to percutaneously or non-invasively treat breast cancer by causing coagulation necrosis of the tumor. The panel discussed clinical trial issues pertaining to the local treatment of breast cancer using thermal ablation versus operative resection.

The panel addressed the following topics: (1) The level of evidence that would be required, in initial studies of treatment of primary breast cancer by minimally invasive ablation followed by immediate lumpectomy for pathologic examination of margins (i.e. ablate and resect studies), to permit initiation of studies that use minimally invasive ablation to definitively treat the cancer without followup resection (i.e., ablate and follow studies); (2) the type of pivotal study that could demonstrate the efficacy of a thermal ablation device to provide local breast cancer treatment in lieu of lumpectomy; (3) how to mitigate concerns regarding the effect of thermal ablation on surrounding breast tissue and radio/chemosensitivity; and (4) the limitations of breast imaging and its effect on patient selection and treatment followup. This panel's discussion of these issues has significantly affected FDA's regulation of these technologies.

Investigators studying the feasibility of thermal ablation devices for the treatment of breast cancers have refined their techniques. In fact, there have been small studies demonstrating nearly 100 percent ablation accuracy.

Unfortunately, the lack of uniformity among different feasibility study protocols has resulted in various study results that cannot be easily compared. Uniformity with respect to standardized evaluation of tissue biopsy pathology, selection of tumors amenable to ablation, image guidance for ablation, timing of ablation (with respect to lymph node biopsy, radiation therapy and chemotherapy), post-ablation imaging and assessment, and tissue pathology of ablated specimens would facilitate the assembly of results across both studies and ablation modalities and better allow the formulation of science-based hypotheses regarding best practices for breast cancer ablation therapy. The purpose of this critical path effort is to motivate the breast cancer ablation industry to standardize its feasibility study protocols so that data emerging are comparable in all respects except for the specific ablation modality. Such data could be used to hypothesize best practices and potentially serve as the basis for larger prospective clinical trials.

II. Registry Development and Implementation

FDA seeks comments on the possible role that a registry of breast cancer treatment using thermal ablation devices could have on advancing the development of thermal ablation devices. FDA is interested specifically on the role of such a registry on establishing standard imaging, pathological evaluation, and ablation timing protocols. In addition, FDA is interested in receiving comments on the feasibility, utility, benefits, and costs involved in the development and implementation of such standardization and on FDA's role in such a process.

A. Development of a Registry of Breast Cancer Treatment Using Thermal Ablation Devices

The agency believes that a registry for breast cancer treatments using thermal ablation devices would motivate the development and implementation of standardized protocols for pathology and imaging assessments for diagnosis and treatment of breast cancers, and followup of thermally ablated breast cancers. In addition, there would be a central place for information regarding patient selection factors, device attributes, device treatment settings and strategy, and device use integration into the multimodality treatment plan for patients with breast cancer. The patient selection, device attributes, device treatment settings and strategy, and patient treatment regimen information could include the following:

Patient Selection
- Demographics;
- Tumor imaging characteristics;
- Tumor size;
- Tumor nodal status;
- Tumor metastases;
- Tumor histology; and
- Tumor markers

Device Attributes
- Manufacturer, make, and model; and
- Unique device attributes (e.g., size, length, configuration, software version)

Device Treatment Settings and Strategy
- Thermal ablation modality;
- Tumor imaging modality for treatment localization;
- Treatment settings used to achieve ablation (relevant to modality used); and
- Treatment strategy (e.g. method for overlapping treatments, target ablation volume, method of catheter positioning)

Treatment Regimen
- Care path (i.e. timing of ablation with respect to chemotherapy, operative therapy and/or radiation therapy);
- Device application (e.g. time, target temperature, impedance, temperature achieved);
- Anesthesia;
- Chemotherapy treatment;
- Operative treatment;
- Radiation treatment; and
- Image guidance.

Patient Followup
- Duration;
- Imaging (e.g. MRI field, name of contrast agent, dose, pulse sequence used, post processing);
- Pathology assessment protocol of the ablated specimen;
- Adverse events; and
- Long term patient outcomes (i.e. overall survival, disease free survival, local recurrence).

B. Primary Benefits of Implementing a Registry of Breast Cancer Treatment Using Thermal Ablation Devices

We believe that the registry could be used to share experience. Practitioners could then refine best practices for imaging and pathologic assessment of breast cancers treated using thermal ablation. Such uniformity could identify conditions under which imaging might be a good surrogate for pathology and might serve to identify genotypes of responders versus nonresponders. This information could help our understanding of the safety and effectiveness associated with thermal ablation device use for breast cancer treatment and could better inform the decisions made by study investigators who are considering expanding their study into pivotal trials.

C. Ancillary Benefits

There may also be secondary or ancillary benefits from the use of a registry for thermal device ablation treatments for breast cancer. These benefits include improved data management across the industry of thermal ablation devices and associated healthcare cost savings. A registry could also facilitate the automatic capture of important information about the learning curve associated with thermal device use and patient factors affecting thermal ablation device use. This registry could also be used to help validate imaging findings with long term pathological assessments and patient outcomes.

III. Agency Request for Information

In light of the potential benefits highlighted previously, FDA is interested in gathering information about the feasibility, utility, benefits, and costs associated with the development and implementation of a registry of breast cancer treatment using thermal ablation devices. We are also interested in obtaining information about existing registries that may be modified to include breast cancer thermal ablation information and parties that would be interested in collaborating with the agency on this effort. Therefore, we invite comments and available data on the following questions:

Stakeholder Role and Involvement for Developing a Registry of Breast Cancer Treatment Using Thermal Ablation Devices

1. What should be the role, if any, of FDA in the development and implementation of a registry for breast cancer treatments using thermal ablation devices?
2. What are the incentives for establishing uniform, standardized imaging and pathological assessment techniques for such a registry?
3. What are the barriers for establishing a registry for breast cancer thermal ablation treatments? What suggestions would you have for overcoming these barriers?
4. Are there academic groups, industry groups, professional societies, or other organizations that would be interested in partnering with FDA and/or other entities to develop or implement a registry for breast cancer treatments using thermal ablation devices?
5. What existing databases could be feasibly modified to serve as the repository of a registry for breast cancer treatments using thermal ablation and meet the needs of all involved stakeholders?

Developing a Registry of Breast Cancer Treatments Using Thermal Ablation Devices

6. How should a registry for breast cancer treatments using thermal ablation devices be developed? What data analysis methods need to be considered when developing the registry data set?

7. Have you implemented some form of a registry for breast cancer thermal ablation treatments already? Please describe the extent of implementation, and type of data being collected.

8. Should a registry be considered for all thermal ablation device applications for cancer treatment? If yes, why? If not, what thermal ablation device uses should be considered for data capture in a registry?

9. What solutions have you developed or do you think could be developed for addressing the various technical use, pathological, imaging and other treatment assessment problems that might arise in developing and implementing a registry for breast cancer or other cancer treatments using thermal ablation devices?

Criteria for Data Inclusion from Breast Cancer Treatments Using Thermal Ablation Devices

10. What is the minimum data set that should be associated with a device use session? Would this minimum data set differ for different devices? If so, how?

11. How would the data in the minimum data set be used to improve patient safety? What other data would improve patient safety?

12. How and by whom should the registry and its associated minimum data set be obtained and maintained?

13. What information should be accessible by the public, healthcare providers, professional organizations, FDA, other Federal Agencies, the industry, and individual manufacturers? How would the information be accessible?

14. What type of proprietary information needs to be excluded?

15. Should data from all thermal ablation device investigators be included or should the data be limited to include only investigators that have received a certain level of training for device use?

Registry Benefits and Costs

16. From your perspective, how could a registry be best used among competing manufacturers of similar product lines? What obstacles do you see in using such an approach for justifying marketing claims?

17. From your perspective, should data previously collected or currently being collected be incorporated by investigators studying the effects of thermal ablation treatment for breast cancer be included in the registry? If so, why, and under what circumstances? If not, why not?

18. From your perspective, what specific public health and patient safety benefits could be gained from having a standardized registry for breast cancer treatments using thermal ablation devices? In addition, how would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

19. From your perspective, what are the startup costs measured in time and other resources associated with the development, implementation, and use of a registry for breast cancer treatments using thermal ablation devices? Please submit detailed data to support these cost estimates.

20. If you have already implemented a form of a registry for breast or other cancer treatments using thermal ablation devices, what investments in equipment, training, and other human and physical resources were necessary to implement the use of such a database? What factors influenced your decision to implement such a system?

21. From your perspective, what are the obstacles to implementing or using a registry for breast cancer treatments using thermal ablation devices?

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. Panel transcript and questions regarding percutaneous and thermal ablation treatment of breast cancer in lieu of operative resection (see *http://www.fda.gov/OHRMS/DOCKETS/AC/03/questions/3973q1_Breast%20ca%20Questions.htm* and *http://www.fda.gov/OHRMS/DOCKETS/AC/03/transcripts/3973t1.htm*.

2. Gliklich, R.E., N.A Dreyer, eds. ''Registries for Evaluating Patient Outcomes: A User's Guide.'' (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHSA29020050035I TO1.) AHRQ Publication No. 07–EHC001–1. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.

3. Goldberg, S.N., et al. ''Image Guided Tumor Ablation: Proposal for Standardization of Terms and Reporting Criteria,'' *Radiology* 2003; 228: 335–345.

4. Goldberg, S.N., et al. ''Image Guided Tumor Ablation: Standardization of Terminology and Reporting Criteria,'' *Journal of Vascular and Interventional Radiology* 2005; 16: 765–778.

Dated: May 19, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy and Planning.

[FR Doc. E8–11899 Filed 5–27–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2008–0050]

Data Privacy and Integrity Advisory Committee

AGENCY: Office of the Secretary, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Data Privacy and Integrity Advisory Committee will meet on June 11, 2008 in Arlington, VA. This meeting will be open to the public.

DATES: The Data Privacy and Integrity Advisory Committee will meet on Wednesday, June 11, 2008 from 9 a.m. to 12 p.m. and 1:30 p.m. to 4 p.m. Please note that the meeting may close early if the committee has completed its business.

ADDRESSES: The meeting will be held in Galleries I and II of the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, Virginia 22203. Send written materials, comments, and requests to make oral presentations to Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528. Written