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Dated: May 20, 2008

Al Matera,

Director, Office of Acquisition Policy.

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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]

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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.