

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Food and Drug Administration Critical Path Workshop on Clinical Trials for Local Treatment of Breast Cancer by Thermal Ablation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop to discuss the issues associated with the development and implementation of feasibility trials for local treatment of breast cancer by thermal ablation (i.e., cryoablation, focused ultrasound, interstitial laser, microwave, radiofrequency ablation). We are inviting individuals, companies, organizations, and other stakeholders to attend this public workshop to discuss how standardized protocols for 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 can be developed and used in breast cancer thermal ablation clinical trials. The public workshop will also serve as a forum for discussing where within the multispecialty care path involving operative therapy, chemotherapy, and radiation therapy, thermal ablation may play a role.

Date and Time: The public workshop will be held on September 15, 2008, from 9 a.m. to 6 p.m. Online registration is available at <http://www.blsm meetings.net/2008ThermalAblationWorkshop> until 5 p.m. on August 30, 2008 (see section III of this document for details).

Location: The public workshop will be held at the FDA White Oak Campus, conference rooms 2047 F and G (http://grouper.ieee.org/groups/scc34/sc2/meeting_info/Meeting_WhiteOak_15-18OCT2007/White_Oak_Campus_Info_2007.pdf) located at 10903 New Hampshire Ave., Silver Spring, MD 20993.

Contact: Binita Ashar, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3600, e-mail: Binita.Ashar@FDA.HHS.gov.

If you need special accommodations due to a disability, please contact Paula Gumbs at 301-594-4453 at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

On July 24, 2003, the 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 issues: (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., feasibility 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 contributed to FDA's evaluation 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 create a validated imaging tool that correlates pathological results with imaging findings of an ablated breast cancer and hypothesize best practices that could potentially serve as the basis for longitudinal prospective clinical trials.

We believe that there may be a variety of opinions and experiences regarding the information required to obtain 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 to 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. We therefore published a notice in the **Federal Register** of May 28, 2008 (73 FR 30619) (<http://www.access.gpo.gov>) requesting comments by November 24, 2008, to help the agency understand how a potential registry of breast cancer treatment using thermal ablation devices may motivate this effort.

II. Agenda

The purpose of the public workshop is to discuss the development and implementation of a rational, standardized approach for conducting feasibility trials (i.e., ablate and resect trials) examining thermal ablation of breast cancer as part of the treatment care path for patients with breast cancer. Representatives from various areas involved with the development, testing, and use of thermal ablation devices for breast cancer have been invited. There will be focused sessions, addressing the key issues of breast cancer thermal ablation treatment related to imaging, pathology, operative resection and axillary staging, chemotherapy and radiation therapy.

Participation in the workshop is open to both invited participants and audience members. The invited participants include medical experts from various specialties involved in the care of patients with breast cancer and use of thermal ablation devices. Invited participants will have completed a work assignment in advance of the public workshop in order to optimize the time

spent during the public workshop. Audience participation is open to all who are interested in clinical trials for local treatment of breast cancer by thermal ablation and will be scheduled throughout the sessions.

The agenda for this public workshop is available on the Internet at *http://www.blsm meetings.net/2008ThermalAblationWorkshop*.

III. Registration

Those interested in attending may register online at *http://www.blsm meetings.net/2008ThermalAblationWorkshop*. There is no registration fee to attend the public workshop, however all participants must submit a registration form. Space is limited, so please submit your registration early to reserve a space. Registrations will be accepted through August 30, 2008; however, onsite registration will be permitted on a space-available basis.

Persons without Internet access may call Paula Gumb at 301-577-0244, ext. 25 by September 12, 2008, to register for onsite workshop attendance.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at either *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* or *http://www.blsm meetings.net/2008ThermalAblationWorkshop*. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: July 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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