

Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 16, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0427]

Public Workshop on Medical Devices and Nanotechnology: Manufacturing, Characterization, and Biocompatibility Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Medical Devices & Nanotechnology: Manufacturing, Characterization, and Biocompatibility Considerations." The purpose of this workshop is to obtain information on manufacturing, characterization, and biocompatibility evaluation of medical devices containing or utilizing nanomaterials and nanostructures, including diagnostics. FDA is seeking input on these topics and requests comments on a number of related questions.

Date and Time: The workshop will be held on September 23, 2010, 8 a.m. to 5 p.m. Persons interested in attending, must register by 5 p.m. on September 15, 2010. Space availability permitting, on-site registration will be available on a first come first serve basis. If you would like your comments to be considered for workshop discussion, please submit your comments by September 15, 2010. Please submit all other comments by October 22, 2010.

Location: The public workshop will be held at the Hilton Washington DC/ North Gaithersburg, 620 Perry Pkwy, Gaithersburg, MD 20877. For directions, please contact the hotel at 301-977-8900 or refer to their Web page at: www.gaithersburg.hilton.com.

Contact Person: Daya Ranamukhaarachchi, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5574, Silver Spring, MD 20993, 301-796-6155, FAX: 301-

847-8510, email:

Daya.Ranamukhaarachchi@fda.hhs.gov.

Registration and Requests for Oral Presentations: Interested persons must register by September 15, 2010 at <http://www.fda.gov/MedicalDevices/NewsEvents/WorskshopsConferences/default.htm> (select the appropriate meeting from the list). Registrants must provide the following information: (1) Name, (2) title, (3) company or organization (if applicable), (4) mailing address, (5) telephone number, (6) email address, and (7) request to make an oral presentation or be a participant in round-table discussions (if applicable). There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you wish to make an oral presentation during any of the public comment sessions at the workshop (see section II of this document), you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in section III of this notice. You should also identify which discussion topic you wish to address in your presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should address only one discussion topic. FDA will do its best to accommodate requests to speak. Registered participants may send written material for oral presentations to the contact person by 5 p.m. on September 15, 2010.

If you would like to participate in the two planned round-table discussions (see section II of this document), you must indicate this interest at the time of registration, and also submit a brief statement that describes your experience or expertise with nanotechnology. There will be a limited number of round-table participants. FDA will attempt to have a range of constituencies represented in this discussion group. Others in attendance at the public workshop will have an opportunity to listen to each round-table discussion and provide public comments, time permitting.

If you need special accommodations due to a disability, please contact Susan Monahan at 301-796-5661 or email: susan.monahan@fda.hhs.gov at least 7 days in advance of the public workshop.

Comments: FDA is holding this public workshop to obtain information on a number of specific questions regarding manufacturing and characterization requirements and the biocompatibility evaluation for medical devices utilizing

nanotechnology. If you would like your comments to be considered for workshop discussion, please submit your comments by September 15, 2010. Please submit all other comments by October 22, 2010.

Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management either electronic or written comments on this document. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined below, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

Nanomaterials, measured in nanometers (a billionth of a meter), often possess physical and chemical properties that are different from their larger counterparts. Due to the high surface area to volume ratio, the small size, and the type of nanoscale material, these materials may exhibit altered magnetic, electrical, optical properties and altered chemical and biological activities. These characteristics provide the potential for nanomaterials to be used in a variety of medical device applications. However, some of these nanomaterial properties may also present safety concerns that are not found in their larger counterparts. The use of nanotechnology is increasingly applicable and provides novel opportunities in medical device development. The scientific hurdles (e.g., biocompatibility and toxicity) for safe use of nanomaterials in medical devices, including the processes and standards for their manufacture and characterization, are not understood.

In July 2007, FDA's Nanotechnology Task Force issued a report describing the state of the science and regulatory challenges in translating nanotechnology into FDA-regulated products (available at <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/NanotechnologyTaskForceReport2007/default.htm>). A general finding of the report is that nanoscale materials

present regulatory challenges similar to those posed by products using other emerging technologies and that these challenges may be magnified because nanotechnology can be used in, or used to make, any FDA-regulated product. In addition, the properties of a material with features in the nanoscale range might change, impacting the safety and effectiveness of the FDA-regulated products.

The objective of this public workshop is to obtain information on manufacturing, characterization, and evaluation of biocompatibility of medical devices containing or utilizing nanomaterials and nanostructures.

II. Public Participation

There are two types of opportunities for participation planned for the public workshop: Time limited oral presentations and round-table discussions.

If you wish to make an oral presentation during the public workshop, you must indicate this at the time of registration. The number of presentations may be limited based on the number of requests received during the public comment period. When registering, you will be required to identify the title of the topic you wish to address in your presentation and answer all the related questions on the registration form at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. FDA will do its best to accommodate requests to present and will focus discussion to the topics described in this document (see section III of this document). Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for joint presentations. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is to begin.

To close each of the two sessions, FDA will hold a round-table discussion between FDA staff and selected participants representing a range of constituencies. If you wish to be a participant in round-table discussions, you must indicate this interest at the time of registration, and also submit a brief statement that describes your experience or expertise with nanotechnology. FDA will attempt to have a range of constituencies represented in this discussion group. Others in attendance at the workshop will have an opportunity to listen during each round-table discussion and provide public comments, time permitting. FDA will determine the participants based on the requests

received. The participants in each round-table discussion will remark on the presentations given during the session, engage in a dialogue with each other and FDA staff, and provide closing thoughts on the session. Round-table participants will not be asked to develop consensus opinions during the discussion, but rather to provide their individual perspectives.

III. Issues for Discussion

The workshop will focus on two topics: (1) Manufacturing and characterization of medical devices containing or utilizing nanomaterials or nanostructures; (2) biocompatibility evaluation of medical devices containing or utilizing nanomaterials or nanostructures. The discussion on manufacturing and characterization will include the evaluation of physico-chemical properties of nanomaterials or nanostructures, characterization methods required, device manufacturing processes and evaluation of the final processed device after sterilization, and stability and aging studies. The discussion on biocompatibility evaluation will include testing for potential release of nanomaterials and additional testing considerations other than standard testing methods to determine the biocompatibility and toxicity of devices containing or utilizing nanomaterials or structures. For further information, please refer to the meeting registration Web page at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>.

IV. Transcripts

Please be advised that as soon as a transcript is available, it can be obtained in either hardcopy or on CD-ROM, after submission of a Freedom of Information Act request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857, approximately 15 working days after the public workshop. A transcript of the public workshop will be available on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm> (select the appropriate meeting from the list).

Dated: August 17, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute's Best Practices for Biospecimen Resources

AGENCY: National Institutes of Health (NIH), National Cancer Institute (NCI).

ACTION: Notice with request for comment.

SUMMARY: As part of the commitment to maintaining current and scientifically accurate best practices, the National Cancer Institute (NCI) is seeking public comment on a revised version of the *NCI Best Practices for Biospecimen Resources*. This revised version of the *NCI Best Practices* is intended to both respond to comments received from the biospecimen resource community and provide more current and detailed recommendations related to biospecimen and data quality. Major revisions include the addition of new sections on Biospecimen Resource Management and Operations and Conflict of Interest, expansion of recommendations related to Custodianship and Informed Consent based on NCI workshops, addition of current references throughout the document and harmonization with current federal guidance documents and recommendations from international biospecimen organizations.

DATES: Effective Date: The updated *NCI Best Practices for Biospecimen Resources* are open for public comment for a period of 30 days. Comments must be received by September 22, 2010 in order to ensure consideration. After the public comment period has closed, the comments received by NCI will be considered in a timely manner by the NCI Office of Biorepositories and Biospecimen Research. Subsequently, appropriate changes will be made on the Best Practices Web site <http://biospecimens.cancer.gov/bestpractices/>.

ADDRESSES: Comments submitted via e-mail should use nciobbr@mail.nih.gov and enter "NCI Best Practices" in the subject line. While NCI prefers that comments be sent by email, NCI will accept written comments. Written comments may be sent to: NCI/OBRR, NIH, 11400 Rockville Pike, Rockwall I Building, Bethesda, MD 20892, Attn: Dr. Nicole Lockhart.

FOR FURTHER INFORMATION CONTACT: Implementation assistance and inquiries should be directed to senior staff of the relevant NCI Extramural and Intramural Program offices.

SUPPLEMENTARY INFORMATION: The *NCI Best Practices for Biospecimen Research*