

Dated: August 4, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0107]

#### Food and Drug Administration-Regulated Products Containing Nanotechnology Materials; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public meeting; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) will hold a public meeting October 10, 2006, on FDA-regulated products containing nanotechnology materials, and has opened a docket on FDA-regulated products containing nanotechnology materials. The purpose of the meeting will be to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, and any other scientific issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

**DATES AND TIMES:** The public meeting will be held October 10, 2006, from 9 a.m. to 5 p.m.

**REGISTRATION:** You may register at <http://www.fda.gov/nanotechnology/>. We will also post the agenda at <http://www.fda.gov/nanotechnology/> prior to the meeting.

**ADDRESSES:** The public workshop will be held at the Natcher Auditorium, National Institutes of Health Campus, 9000 Rockville Pike, bldg. 45, Bethesda, MD. We will also post the address for the meeting at <http://www.fda.gov/nanotechnology/>.

Written or electronic comments may be submitted by November 10, 2006. Submit written comments 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.fda.gov/dockets/ecomments>. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: [poppy.kendall@fda.hhs.gov](mailto:poppy.kendall@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

#### I. Why Are We Holding a Public Meeting?

Nanotechnology is defined in a variety of ways. The National Nanotechnology Initiative (a U.S. Government research and development coordinating program) refers to nanotechnology as "the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications" (<http://www.nano.gov>). A nanometer is a billionth of a meter, and is approximately the width of 10 hydrogen atoms lined up side by side. (A human hair is about 80,000 nanometers in width. Deoxyribonucleic acid (DNA) is about 2.5 nanometers in width.)

Due to their small size and extremely high ratio of surface area to volume, nanotechnology materials often have chemical or physical properties that are different from those of their larger counterparts. Such differences include altered magnetic properties, altered electrical or optical activity, increased structural integrity, and increased chemical and biological activity. Because of these properties, nanotechnology materials have great potential for use in a vast array of products. Also because of some of their special properties, they may pose different safety issues than their larger counterparts. Of particular interest to FDA, nanotechnology materials may enable new developments in implants and prosthetics, drug delivery, and food processing, and may already be in use in some cosmetics and sunscreens. As part of its critical path initiative, FDA is interested in learning if there are opportunities for it to help overcome scientific hurdles that may be inhibiting the use of nanotechnology in medical product development.

We will be holding this meeting because we are interested in learning about the kinds of new nanotechnology material products under development in

the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to the safety of nanotechnology materials, and any other issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

The public meeting will be chaired by the FDA Nanotechnology Task Force. Acting FDA Commissioner Andrew von Eschenbach created this internal task force to help the agency evaluate the increasing use of nanotechnology materials in FDA-regulated products.

For more information about FDA's role regarding nanotechnology products, see our Web page at <http://www.fda.gov/nanotechnology/>.

#### II. How Can You Participate?

You can participate through oral presentation at the meeting or through written or electronic material submitted to the docket. In response to the first notice of this meeting (71 FR 19523, April 14, 2006) we received a large number of responses indicating interest in attending and presenting, and the responses indicated interest in a variety of topics. Therefore, in order to provide the most value to those attending who may be interested in a particular topic, we are likely to divide the meeting into topic areas (for separate, concurrent sessions on those topics) and one general session. Participants would be asked to express a preference for either one of the concurrent sessions or the general session in which to make a presentation. Time allotted for each presentation will depend on the presentation requests received for that session. Furthermore, given the number of responses received, it is likely that it will be necessary to limit presentations to one per individual/organization.

In addition to a session that has a more general focus, we are considering the following three breakout sessions: (1) Topically-administered drugs, biologics, devices and cosmetics; (2) other drugs, biologics and devices; (3) foods (including dietary supplements) and food and color additives, and animal feeds.

We ask that you register early (see **REGISTRATION**) if you intend to provide an oral presentation. The information provided during registration will help us determine further how to organize the day. The final agenda will depend

on the nature of the requests made for presentations.

### III. Will Meeting Transcripts Be Available?

Following the meeting, transcripts will be available for review at the Division of Dockets Management (see ADDRESSES).

### IV. How Should You Send Comments on the Issues?

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

Dated: August 1, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 06-6867 Filed 8-8-06; 3:14 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0292]

#### Unique Device Identification; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this notice to request comments to help the agency understand how the use of a unique device identification (UDI) system may improve patient safety, e.g., by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting. We are also interested in understanding the issues associated with the use of various automatic identification technologies (e.g., bar code, radiofrequency identification). We invite comments about specific UDI issues for medical devices.

**DATES:** Submit written or electronic comments by November 9, 2006.

**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.fda.gov/dockets/comments>.

#### FOR FURTHER INFORMATION CONTACT:

David Racine or Jay Crowley, Center for Devices and Radiological Health (HFZ-500), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-3400, e-mail: [CDRHUDI@fda.hhs.gov](mailto:CDRHUDI@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On February 26, 2004, we published a final rule (the "bar code rule") (69 FR 9120) requiring bar codes on certain human drug and biological products to help reduce medication errors in hospitals and other health care settings. The bar code is intended to enable health care professionals to use bar code scanning equipment in conjunction with computerized medication administration systems to verify that the right drug, in the right dose, is being given to the right patient at the right time. This rule (now codified at 21 CFR 201.25 and 610.67) requires that manufacturers encode the unique National Drug Code (NDC) number in a linear bar code on the product's label.

The bar code rule, however, does not apply to medical devices. In the bar code rule, we stated that, unlike drugs, medical devices do not have a standardized, unique identifying system comparable to the NDC number, and that the absence of such a system complicates efforts to put bar codes on medical devices for purposes of preventing medical errors (69 FR 9120 at 9132).

Since the issuance of the final bar code rule, various entities, including members of Congress and a consortium of hospital groups, have asked that we revisit the issue of bar coding medical devices to improve patient safety; improve quality of care; and encourage cost effectiveness, e.g., of health care by improving delivery and supply chain efficiency (Refs. 1 and 2).

##### A. Stakeholder Meetings

In response to the interest in revisiting the issue of bar coding medical devices, FDA met with various stakeholders, including device manufacturers and distributors, hospital associations, and other Federal agencies such as the Agency for Healthcare Research and Quality, Department of Defense, Department of Veterans Affairs, and Centers for Medicare and Medicaid Services to solicit information and comments about employing a uniform system for the unique identification of

medical devices. (References 3 and 5 contain summaries of some of these meetings). We were interested in hearing views about the value of a uniform system of unique identifiers for medical devices, what efforts or initiatives are currently ongoing among stakeholders, and the use of various automatic identification technologies. We were also interested in FDA's role related to the establishment and use of a UDI system and whether FDA should consider a voluntary or a mandatory approach for such a system.

As a result of these meetings, FDA learned that the majority of stakeholders support the development of a uniform system of unique identifiers as a way to improve patient safety and recognized other ancillary benefits such as better management of the purchase, distribution, and use of medical devices. However, there were a variety of opinions and experiences about how best to implement such a system.

##### B. Report on Automatic and Unique Identification of Medical Devices

In addition to holding stakeholder meetings, we commissioned two reports from outside experts to provide: A general overview of some of the most prevalent technologies available to support automatic identification of medical devices, the current published positions and standards of various stakeholders, and highlights of some of the general applications reported in the literature involving the use of such systems for medical devices. (See Refs. 4 and 6 and <http://www.fda.gov/cdrh/ocd/udi/>). The reports identified several potential benefits to widespread use of UDI, such as reducing medical errors, facilitating recalls, improving medical device reporting, and identifying incompatibility with devices or potential allergic reactions. The reports further indicated that many issues have to be addressed prior to successful implementation of UDI for devices, including determining the technology needed to utilize UDI effectively, identifying the data needed for patient safety; development, maintenance, and validation of a central data repository; and harmonizing UDIs for the international marketplace.

##### II. UDI Development and Implementation

We are interested in receiving comment on the possible role that a unique device identification system could have on improving patient safety, for example, by reducing medical errors, facilitating device recalls, and improving medical device adverse event reporting. In addition, we are interested