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*.

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

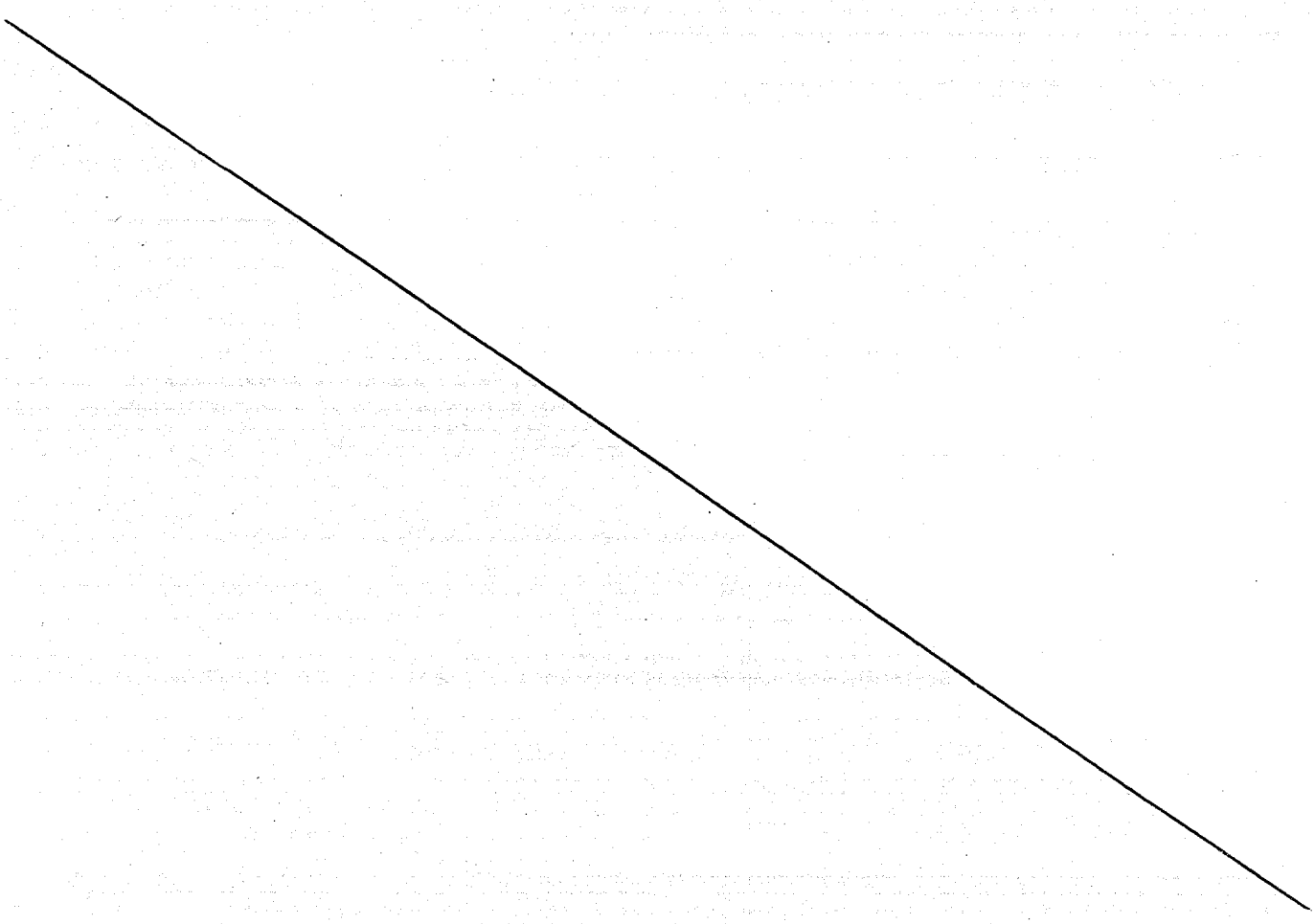
us determine further how to organize the day. The final agenda will depend on the nature of the requests made for presentations.

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: 8/1/06
August 1, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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