UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOOD AND DRUG ADMINISTRATION

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NANOTECHNOLOGY TASK FORCE

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PUBLIC MEETING ON NANOTECHNOLOGY MATERIALS IN FDA REGULATED PRODUCTS

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Tuesday, October 10, 2006

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The meeting came to order at 9:00 a.m. in the Natcher Auditorium, Building 45 of the National Institutes of Health, Bethesda, MD. Dr. Norris Alderson and Dr. Randy Lutter, co-chairmen, presiding.

PRESENT:

NORRIS ALDERSON CO-CHAIRMAN
RANDY LUTTERCO-CHAIRMAN

C-O-N-T-E-N-T-S

AGENDA ITEM PAGE

P-R-O-C-E-E-D-I-N-G-S

9:04 a.m.

CHAIRMAN LUTTER: Ladies and gentlemen, good morning. I'd like to welcome you to this public meeting on nanotechnology. I'm Randall

Lutter, Co-Chair of FDA's Nanotechnology Task Force and my Co-Chair, Dr. Norris Alderson and I are delighted to have the honor of chairing this meeting today.

The presence of all of you suggests that we'll benefit from a large number of comments about nanotechnology and FDA-regulated products and today we're looking forward to an informative and wide-ranging discussion. I'd like to sketch briefly FDA's efforts to protect and promote public health in a world where nanotechnology is no longer a topic only for basic research, then I'll lay out some procedural points for our meeting today and after that, we'll begin the different sessions.

By way of scientific background, nanotechnology materials often have chemical or physical properties that are different from those of their larger counterparts because of their small size and extremely high ratio of surface area to volume. 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 variety 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 sun screens. FDA also 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. FDA generally is responsible for overseeing the safety and effectiveness of drugs for humans and animals, biologics and

medical devices for humans and the safety of foods including dietary supplements, food and color additives, cosmetics and animal feeds.

It does so under a variety of laws and regulations and depending on product class under a variety of pre-market and post-market mechanisms. While most, if not all, of the key laws and regulations under which FDA operates were written before the advent of nanotechnology, most are general in nature by design. They, therefore, usually are able to accommodate products made with the use of new technologies or containing new kinds of materials. At this time, we're not aware of any adverse safety issues associated with the use of nanotechnology-based materials in FDA regulated products.

In fact, for some cancer drugs under development, the opposite may be true, with better targeting and lower doses of toxic drugs needed through use of nanotechnology delivery methods. Nanotechnology is also offering advances in things like lab on a chip, clinical diagnostic testing and I'm told that nanotechnology materials may soon greatly enhance our ability to see inside the body using MRI or other non-invasive techniques that would reduce the need for exploratory surgery.

As noted below, we're evaluating the effectiveness of the agency's regulatory approaches and authorities to meet any unique challenges that may be presented by the use of nanotechnology materials in FDA-regulated products. We look forward to gathering more information today and through submissions to the docket for this meeting to assist our evaluation, including information on safety considerations for use of nanotechnology materials in FDA-regulated products. Because of the generality of laws and regulations, FDA often finds it useful to develop guidance

processes. Such guidance documents, while not binding on industry or the agency, can illustrate how the agency interprets existing law and regulation with respect to new products or processes. It may also describe the kinds of information FDA considers appropriate to demonstrate the safety or effectiveness of products made with new kinds of materials or processes or describe new procedures for interacting with the agency to help facilitate the safe entry into the marketplace of new products.

We've not yet developed guidance for products using nanotechnology materials but part of the work of FDA's task force on nanotechnology is to evaluate whether such guidance might be useful for particular product areas. We're holding this meeting today because we're interesting in learning about the kinds of new nanotechnology material products under development in areas of food, including dietary supplements, food and color additives, animal feeds, cosmetics, drugs and biologics and medical devices. We're also interested in learning whether there are new or emerging scientific issues that should be brought to FDA's attention, including issues related to safety of nanotechnology materials.

Finally, we're interested in any other issues about which the regulated industry, academia, and the interested public may wish to inform us concerning the use of nanotechnology materials in FDA- regulated products. This meeting also helps us comply with tasks assigned to the FDA's nanotechnology task force which I will introduce shortly by Acting Commissioner Dr. Von Eschenbach on August 9th. Those tasks are as follows; first, assess the current state of scientific knowledge pertaining to nanotechnology materials for purposes of carrying out FDA's mission; second, evaluate the effectiveness of the agency's regulatory approaches and

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