meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 27, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 19, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 20, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt (301) 827–7001 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 29, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–18131 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0416]

Consideration of FDA-Regulated Products That May Contain Nanoscale Materials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and a request for comments including available data to gather information that will assist the agency in further implementing the recommendations of the Nanotechnology Task Force Report (the Report) relating to the development of agency guidances. The Report's recommendations covered foods (including dietary supplements), food and color additives (including food contact substances), animal drugs and feeds, cosmetics, human drugs and biologics, and medical devices. In addition to requesting comments in response to the questions in this notice and those that will be discussed at the public meeting, FDA is announcing a request for available data and information on the effects of nanoscale materials on quality, safety, and, where relevant, effectiveness of products subject to FDA oversight.

DATES: The public meeting will be held on September 8, 2008, from 8:30 a.m. to 5 p.m. Anyone who wishes to speak at the meeting must register and submit a summary of the presentation and an electronic copy of the presentation by Tuesday, September 2, 2008. See section IV of the **SUPPLEMENTARY INFORMATION** section of this document for details on how to register. Submit written or electronic comments by Friday, October 24, 2008.

ADDRESSES: The public meeting will be held at the University Systems of Maryland Shady Grove Center/Universities, 9630 Gudelsky Dr., Rockville, MD 20850 (*http://www.shadygrove.umd.edu/conference*).[1] There is parking near the building.

Submit written comments, available data, and other information 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.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Megan Clark, Office of Policy, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: *megan.clark@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Nanotechnology allows scientists to work on the scale of molecules to create, explore, and manipulate materials measured in nanometers; billionths of a meter. In July 2007, FDA issued the Report analyzing scientific and regulatory considerations relating to the safety and effectiveness of FDA-regulated products containing nanoscale materials regulated by FDA, and making recommendations regarding these considerations. Additionally, the Report summarized the state of the science for biological interactions with nanoscale materials. The Report also recommended that FDA coordinate with other Federal agencies and the private sector in research and other activities to increase general scientific understanding and facilitate assessment of data needs for regulated products. This coordination includes developing an infrastructure to share and leverage knowledge and build upon information from individual studies of nanoscale materials.

The agency has been considering development of guidances recommended in the Report and believes that holding a public meeting and announcing this request for comments and available data will provide information that will assist in this task. In addition, FDA is working with the National Institutes of Health (particularly the NanoHealth Enterprise) to explore methods for receiving and sharing data relating to, for example, general product development, including research on failed product candidates, and biological interactions of certain characteristics of nanoscale materials. Such a data repository could allow FDA and other stakeholders to share data and methods, and to develop models of biological interaction that could then inform product development and review.

II. Meeting Agenda

The primary purpose of the meeting is to determine what factors the agency should consider in providing guidance on:

1. The information and data that may be needed to demonstrate the safety and effectiveness of FDA-regulated products containing nanoscale materials and

[1] FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.

2. The circumstances under which a product's regulatory status might change due to the presence or use of nanoscale materials (for example, making a device no longer exempt from 510(k) submission requirements).

The meeting will begin with a plenary session at which FDA will review the goals of the meeting and give a general overview of the analysis and findings of the Nanotechnology Task Force and agency activities since publication of the Report in July 2007. The plenary session will frame topics that apply generally to all FDA-regulated products.

Immediately following the plenary session, FDA will hold breakout sessions that will be structured to allow brief presentations by those who have submitted requests to speak in accordance with the instructions in this document. We encourage those speaking to provide detailed comments, information, and available data to the docket, and use time at the meeting to give a general overview of the submitted comments to facilitate discussion during the product-specific sessions. There will be a brief period set aside during these sessions to allow attendees who did not register to speak an opportunity to offer comments. These breakout sessions will be organized around the following product categories identified in the Report for which the agency has been considering the need for guidance:

- Medical devices, including diagnostics (combination products may also be discussed in this session);
- Prescription drugs, including biological drugs, animal drugs and over-the-counter (OTC) drugs, including sunscreens;
- Food and color additives, including food contact substances;
- Dietary supplements; and
- Cosmetics.

These sessions will generally cover the following questions:

1. What characteristics of nanoscale materials in FDA-regulated products should be identified and evaluated to ensure the safety and, where relevant, effectiveness of these products?

2. What assessment tools are available (including test methods and standards) for evaluating the characteristics of nanoscale materials that may affect the safety, effectiveness, and quality of FDA-regulated products?

- How reliable are these tools?
- How widely available are these tools?
- Are these tools practical for regulatory use or do they have aspects that render them impractical?
- What additional tools should FDA and industry consider developing to evaluate the characteristics of nanoscale materials?

3. Are there unique features of the manufacturing process for products containing nanoscale materials? If so, how should these features be evaluated?

- Is the manufacturing process for nanoscale materials different from that of conventional materials? If so, how?
- What parameters are critical when manufacturing products containing nanoscale materials?
- What unique challenges are there for ''scale-up'' of manufacturing for products using nanoscale materials?
- How do potentially unique features of nanoscale materials, such as particle size, shape, and surface charge, affect what should be considered in the development of controls, standards, and specifications for manufacturing?

4. Are there particular aspects of product formulation, processing, or storage that can affect the quality, safety, or effectiveness of products containing nanoscale materials, including as excipients?

5. What has been your experience with products containing nanoscale materials? Have you avoided these products due to specific concerns about aspects of development, characterization, or manufacturing?

6. What additional questions focusing on characterization (including stability) and manufacturing aspects of products containing nanoscale materials should be addressed in this forum or otherwise brought to the attention of FDA?

The agency may develop additional questions for discussion during the breakout sessions and if so, they will be posted on the agency's Web site at *http://www.FDA.gov* by Monday, August 11, 2008, and posted to the FDA Docket No. FDA–2008–N–0416.

In addition to providing comments and information in response to the questions in this document and otherwise discussed at the public meeting, FDA is requesting that interested stakeholders submit comments which include available data and information on topics identified in the Report. We are requesting any available data that:

- Identify OTC drug products that contain or may contain nanoscale versions of ingredients included in an OTC monograph;
- Identify nanoscale versions of previously approved food and color additives;
- Address the effects of nanoscale materials on the safety and, where relevant, effectiveness of FDA-regulated products, including both existing products that are changed to contain (or contain greater proportions of) nanoscale materials and new products made with nanoscale materials;
- Address the effects that nanoscale versions of larger sized materials have on bioavailability; and
- Address whether and how the presence of nanoscale materials affects the manufacturing processes for the various types of FDA-regulated products, including both products that require premarket authorization and those products that do not.

Reporting Formats

We are not requesting a specific format or reporting structure for comments which include such available data. However, we prefer data in electronic form where possible, in order to facilitate access and to reduce paper use. We are asking for available data related to specific products and, therefore, request that any submitted data be identified as pertaining to a particular product or category of products. We also request that you identify your data submission as being a comment in response to this document, and refer to the docket number found in brackets in the heading of this document. See section IV. COMMENTS, on how to submit comments.

III. Meeting Registration, Agenda, and Transcript

Seating will be available on a first-come, first-served basis. If you need special accommodations because of a disability, please inform Megan Clark (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Registration for Speaking Attendees: If you wish to make an oral presentation at the meeting, you must register and submit a summary of your presentation to Megan Clark by Tuesday, September 2, 2008, via e-mail to *megan.clark@fda.hhs.gov*. When registering, you must provide the following information: (1) The product-specific breakout session at which you wish to present; (2) the specific topic or issue to be addressed; (3) your name, title, company or organization, address, phone number, and e-mail address; and (4) the approximate, desired duration of your presentation. FDA encourages persons and groups having similar interests to consolidate their information for presentation through a single representative. After reviewing the requests to present, we will contact each participant with the amount of time available and the approximate time the participant's presentation is scheduled to begin. Presenters must send electronic copies of their presentations in Microsoft PowerPoint,

Microsoft Word, or Adobe Portable Document Format (PDF) to Megan Clark at *megan.clark@fda.hhs.gov* by Tuesday, September 2, 2008.

Meeting Agenda and Transcript: The agenda for the public meeting will be available on FDA's Web site at *http://www.fda.gov/nanotechnology2008*. After the meeting, the agenda, presentations, and transcript will be placed on file in the Division of Dockets Management under the docket number found in the heading of this document and on FDA's Web site.

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. It may be viewed at the Division of Dockets Managment (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 Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857.

IV. Comments

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments related to the questions and the focus of this public meeting, as well as comments including available data and information submitted in response to the data call. All relevant data and information should be submitted with the written comments. 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 posted without change to *http://www.regulations.gov*, including any personal information provided. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS), FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 31, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18132 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Treatment; Notice of Meetings

Pursuant to Public Law 92–463, notice is hereby given that the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT) National Advisory Council will meet on August 21, 2008, from 1 p.m. to 3 p.m. and on September 9, 2008, from 1:30 p.m. to 2:30 p.m. via teleconferences.

The meetings will include discussion and evaluation of grant applications reviewed by Initial Review Groups. Therefore, the meetings will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2, Section 10(d).

Substantive program information, a summary of the meetings and a roster of Council members may be obtained as soon as possible after each meeting, either by accessing the SAMHSA Committee Web site at *http://www.nac.samhsa.gov,* or by contacting CSAT National Advisory Council's Designated Federal Official, Ms. Cynthia Graham (see contact information below).

Committee Name: SAMHSA Center for Substance Abuse Treatment National Advisory Council.

Dates/Times/Types: August 21, 2008, from 1 p.m. to 3 p.m.: CLOSED. September 9, 2008, from 1:30 p.m. to 2:30 p.m.: CLOSED.

Place: SAMHSA Building, 1 Choke Cherry Road, Great Falls Room, Rockville, Maryland 20857.

Contact: Cynthia Graham, M.S., Designated Federal Official, SAMHSA CSAT National Advisory Council, 1 Choke Cherry Road, Room 5–1035, Rockville, Maryland 20857, Telephone: (240) 276–1692, Fax: (240) 276–1690, e-mail: *cynthia.graham@samhsa.hhs.gov.*

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. E8–18130 Filed 8–6–08; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–0244]

Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers: 1625–0081 and 1625–0083

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this request for comments announces that the U.S. Coast Guard is forwarding two Information Collection Requests (ICRs), abstracted below, to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB) requesting an extension of their approval for the following collections of information: (1) 1625–0081, Alternate Compliance Program, and (2) 1625–0083, Operational Measures for Existing Tank Vessels Without Double Hulls. Our ICRs describe the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: Please submit comments on or before September 8, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2008–0244] to the Docket Management Facility (DMF) at the U.S. Department of Transportation (DOT) or to OIRA. To avoid duplication, please submit your comments by only one of the following means:

(1) Electronic submission. (a) To Coast Guard docket at *http://www.regulations.gov*. (b) To OIRA by e-mail via: *oira_submission@omb.eop.gov*.

(2) Mail or Hand delivery. (a) DMF (M–30), DOT, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. Hand deliver between the hours of 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329. (b) To OIRA, 725 17th Street, NW., Washington, DC 20503, to the attention of the Desk Officer for the Coast Guard.

(3) Fax. (a) To DMF, 202–493–2251. (b) To OIRA at 202–395–6566. To ensure your comments are received in time, mark the fax to the attention of the Desk Officer for the Coast Guard.

The DMF maintains the public docket for this Notice. Comments and material