written or electronic comments on the draft guidance by October 6, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Larry Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4125, Silver Spring, MD 20993, 301–796–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Residual Solvents in Drug Products Marketed in the United States.'' Beginning July 1, 2008, FDA will require that drug products marketed in the United States with an official USP monograph meet the residual solvents requirements in the revised General Chapter <467> ''Residual Solvents.''

For compendial drug products approved under a new drug application (NDA) or abbreviated new drug application (ANDA), changes made to the specifications in the approved application regarding the revised General Chapter <467> should be in accordance with applicable regulations described in 21 CFR 314.70 and the recommendations in the guidance for industry on ''Changes to an Approved NDA or ANDA, April 2004.'' FDA expects that in most cases, an annual report can be used to report changes.

FDA recommends that applicants who have submitted NDAs or ANDAs to the agency for drug products that are not the subject of an official USP monograph control and limit the presence of residual solvents in the subject drug product as described in the guidance on ''Q3C Impurities: Residual Solvents.''

Marketed compendial drug products that are not approved under an NDA or ANDA (for example, over-the-counter (OTC) drug products that are marketed under an FDA OTC monograph) are also subject to the provisions of the Federal Food, Drug, and Cosmetic Act, the revised General Chapter <467>, and current good manufacturing practice requirements in 21 CFR 211.165(e) and 211.194(a)(2).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on control of residual solvents in drug products marketed in the United States. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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.

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*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18127 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–0038]

Advisory Committee for Reproductive Health Drugs; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Reproductive Health Drugs.

General Function of the Committee: To provide advice and recommendations to theagency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 8, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Rockville, Plaza Ballrooms I and II, 1750 Rockville Pike, Rockville, MD. The hotel phone number is 301–468–1100.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2537. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22–242, proposed trade name FABLYN (lasofoxifene tartrate) Tablets, 0.5 milligrams (mg), Pfizer Inc., for the proposed indication of the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the

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**.