FOR FURTHER INFORMATION CONTACT: Robert Abugov, Center for Veterinary Medicine (HFV–105), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8168, *Robert.abugov@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #197 entitled ''Draft Guidance for Industry on Documenting Statistical Analysis Programs and Data Files.'' This draft guidance provides recommendations to study statisticians for documenting statistical analyses and data files submitted to the Center for Veterinary Medicine (CVM) for the evaluation of safety and effectiveness in new animal drug applications. These recommendations are intended to reduce the number of revisions that may be required for CVM to effectively review statistical analyses and to simplify submission preparation by providing a uniform documentation system.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control no. 0910–0032.

IV. 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.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: March 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5650 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Industry Exchange Workshop on Food and Drug Administration Drug and Device Requirements; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Chicago District, in cosponsorship with the Association of Food and Drug Officials (AFDO), is announcing a public workshop entitled ''Drugs and Devices—Promoting and Protecting the Public Health Through Risk Management and Product Cycle Improvement.'' This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

Date and Time: The public workshop will be held on Monday, June 8, 2009, from 10:20 a.m. to 5 p.m. and Tuesday, June 9, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Doubletree Hotel Chicago—Oakbrook, 1909 Spring Rd., Oak Brook, IL 60523, 800–222–TREE, 800–222–8733, or 630–472–6000, FAX: 630–573–1909.

Attendees are responsible for their own accommodations. To make reservations at the Doubletree Hotel Chicago—OakBrook, at the reduced conference rate, contact the Doubletree Hotel Chicago—OakBrook before May 5, 2009, citing meeting code ''AFDO Conference''.

Contact: William Weissinger, Food and Drug Administration, 550 W. Jackson Blvd., 15th Fl., Chicago, IL 60661, 312–596–4210, FAX: 312–596–4242, e-mail: *William.weissinger@fda.hhs.gov*.

Registration: You are encouraged to register by May 12, 2009. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

COST OF REGISTRATION

Affiliation	Fee
Government (AFDO/North Central AFDO Member)	$395.00
Government (Non-Member)	$495.00
Non-Government (AFDO/NCAFDO Member)	$450.00
Non-Government (Non-Member)	$550.00
To be added to registration fee for workshop registration postmarked after May 12,2009	$75.00

If you need special accommodations due to a disability, please contact William Weissinger at least 7 days in advance of the workshop.

Registration instructions: To register, please submit your name, affiliation, mailing address, phone, fax number, and e-mail, along with a check or money order payable to ''AFDO.'' Please mail your payment to: AFDO, 2550 Kingston Rd., suite 311, York, PA 17402. To register via the Internet, go to *www.afdo.org*. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**).

The registrar will also accept payment by major credit cards (VISA/MasterCard only). For more information on the meeting, or for questions on registration, contact AFDO, 717–757–2888, FAX: 717–755–8089, or e-mail: *afdo@afdo.org*.

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include the following:

- Risk management approach to consumer protection and industry regulation
- How quality management systems (including corrective and preventive action) contribute to product cycle improvement
- Supplier management and component controls for drugs and devices
- Adverse drug event reporting requirements
- Medical device reporting requirements
- Recalls, corrections and removals
- Complaint handling from the FDA investigator's perspective.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by Government agencies to small businesses.

Dated: March 4, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5648 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; 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: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on March 31, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Ronald P. Jean, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 240–276–3676, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. 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, make recommendations, and vote on a premarket approval application (PMA) for OP-1 Putty, sponsored by Stryker Biotech. This combination product is indicated for posterolateral spinal fusion procedures in skeletally mature patients with lumbar spondylolisthesis who have failed at least 6 months of conservative nonsurgical treatment.

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 2009 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 March 24, 2009. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the deliberations. 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 March 20, 2009. 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 March 23, 2009.

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 AnnMarie Williams, Conference Management Staff, 240–276–8932, 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: March 10, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–5644 Filed 3–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which