(2) Repeatedly misrepresented to the UP investigative panel the accuracy of one of the figures;

(3) Presented the false figures as true to members of the laboratory; and

(4) Falsified the record of revisions of the figures by deleting all prior versions from the laboratory server.

ORI has implemented the following administrative actions for a period of three (3) years, beginning on November 29, 2006:

(1) Dr. Park is debarred from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government as defined in the debarment regulations at 45 CFR Part 76; and

(2) Dr. Park is prohibited from serving in any advisory capacity to PHS, including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. E7–42 Filed 1–8–07; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0347]

In Vitro Diagnostic Multivariate Index Assays; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on In Vitro Diagnostic Multivariate Index Assays. The meeting is intended to provide a public forum during which FDA will hear presentations and comments from interested stakeholders regarding the draft guidance entitled ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.'' This draft guidance is intended to provide clarification on FDA's approach to regulation of in vitro diagnostic multivariate index assays. FDA is seeking comments on this draft guidance.

DATES: The public meeting will be held on February 8, 2007, from 8 a.m. to 5 p.m. Online registration is available until 5 p.m. on February 5, 2007; however, if space permits onsite registration will be permitted on February 8, 2007 (see the **Registration** section of this notice for details).

ADDRESSES: The public meeting will be held at the Grand Ballroom of the Hilton Washington DC/Gaithersburg Hotel located at 620 Perry Pkwy., Gaithersburg, MD 20877. Additional information about and directions to the facility are available by calling the hotel at 1–301–977–8900 or on the Internet at: *http://www.hilton.com* (under Find a Hotel, type in Gaithersburg, MD under city and State). (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**.)

The comment period on this draft guidance closes on March 5, 2007. 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 on the draft guidance to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sousan Altaie, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0450, ext. 106, e-mail: *Sousan.Altaie@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA announced the availability of a draft guidance entitled ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays,'' on September 7, 2006 (71 FR 52800). This draft guidance addresses the definition and regulatory status of a class of in vitro diagnostic devices referred to as In Vitro Diagnostic Multivariate Index Assays (IVDMIAs). The draft guidance also addresses premarket and postmarket requirements with respect to IVDMIAs. An IVDMIA employs clinical data, which may be derived in part from one or more in vitro assays, and an algorithm to integrate the variables, and reports a result that cannot be interpreted by the well-trained health care practitioner using prior knowledge of medicine without information from the test developer regarding its clinical performance and effectiveness.

FDA is seeking comments on this draft guidance and has extended the comment period to March 5, 2007 (71 FR 68822). FDA is announcing in this notice a public meeting on this draft guidance.

II. Agenda

FDA will start the meeting with a brief presentation on the draft guidance entitled ''Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on In Vitro Diagnostic Multivariate Index Assays.'' The purpose of this meeting is to obtain public input on this guidance. Hence, presentations by the public will make-up the remainder of the agenda. Interested persons who would like to make a presentation during the meeting will be given 10 minutes to do so if they submit their request (electronic or written) and a copy of the material to be presented by February 1, 2007, to the contact person, Sousan Altaie, at the address or the email above and to the docket for this draft guidance. Depending upon the number of presenters submitting requests to present, the allotted time may be expanded or shortened to provide appropriate representation by all interested parties. Presentations and comments are to be identified with the docket number found in brackets in the heading of this document.

This public meeting agenda will be available on the Internet on February 7, 2007, at *http://www.fda.gov/cdrh/oivd/meetings/020807agenda.html*.

III. Registration

Those interested in attending may register online at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfSUD/oivd_meeting.cfm*. There is no registration fee to attend the meeting. Please submit registration early in order to reserve a space, as space is limited. You may register online until February 5, 2007; however, onsite registration will be permitted if space remains. If you require special accommodations due to a disability, please contact the Hilton Washington DC/Gaithersburg Hotel directly at 1–301–977–8900, at least 7 days in advance.

Persons without Internet access may call Sousan Altaie at 240–276–0450 ext. 106, by February 5, 2007, to register for onsite meeting attendance.

IV. Request for Input and Materials

FDA is interested in receiving input from stakeholders on the draft guidance. Send suggestions or recommendations to the Division of Dockets Management (see **ADDRESSES**). FDA will place an additional copy of any material it

receives on the docket (Docket Number 2006D–0347). Suggestions, recommendations, and materials may be seen at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Transcripts

Following the meeting, transcripts will be available for review at *http://www.fda.gov/cdrh/oivd/presentations.html#r*, and the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 3, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–93 Filed 1–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices 101: An Educational Forum; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in cosponsorship with the FDA Medical Device Industry Coalition (FMDIC) and the Risk Management Small Business Development Center (RMSBDC), is announcing a public workshop entitled ''Medical Devices 101: An Educational Forum.'' This public workshop is intended to provide an overview on FDA's medical device requirements to entrepreneurs, startup companies, and small businesses.

Date and Time: The public workshop will be held on February 9, 2007, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Hoblitzelle Auditorium at the Bill Priest Campus of El Centro College, 1402 Corinth St. in Dallas, TX.

Contact Person: David Arvelo, Food and Drug Administration, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, e-mail: *oraswrsbr@fda.hhs.gov*.

Registration: Registration by January 26, 2007, is strongly encouraged. The RMSBDC has a $75 early registration fee to cover the cost of facilities, materials, and refreshments. Please submit your registration as soon as possible. Registration at the site may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration after January 26, 2007, is $99 payable to RMSBDC. If you need special accommodations due to a disability, please contact David Arvelo (see *Contact Person*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the RMSBDC registration form and submit along with payment to RMSBDC, Attn: Saira Roberts, 1402 Corinth St., Dallas, TX 75215. You may fax the completed registration form to RMSBDC at 214–860–5867. To obtain a copy of the registration form, please call RMSBDC at 214–860–5887 or 214–860–5849. The registration form is also available online at *http://www.ntsbdc.org/*.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The workshop is being held in response to the interest in the topics discussed from small medical device entrepreneurs and startup manufacturers in the Dallas District area. FDA presents this workshop in cosponsorship with FMDIC and RMSBDC to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is also consistent with the purposes of FDA's Regional Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as an outreach activity by Government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with the Medical Device QSR. The following topics will be broadly covered at the workshop: (1) Medical device classification, (2) establishment registration, (3) device listing, (4) premarket notification, (5) premarket approval, (6) Quality System Regulation, (7) labeling, and (8) postmarket surveillance.

Dated: January 3, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–92 Filed 1–8–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products 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 January 25, 2007, from 8 a.m. to 5 p.m.

Location: Doubletree Hotel, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: In Session I, the committee will hear presentations and make recommendations on the safety and immunogenicity of PENTACEL (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine Combined (DTaP-IPV/Hib)), manufactured by Sanofi Pasteur, Ltd. In Session II, the committee will hear an overview of the research programs in the Office of Vaccines Research and Review, Center for Biologics Evaluation and Research (CBER). In the closed session, the committee will discuss the