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