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

report of the Office of Vaccines Research and Review Office Site Visit of May 19, 2006.

FDA intends to make background material available to the public no later than 1 business day 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 2007 and scroll down to the appropriate advisory committee link.

Procedure: On January 25, 2007, from 8 a.m. to 4:25 p.m., the meeting is open to the public. 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 January 19, 2007. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 11:45 a.m. and 3:55 p.m. to 4:25 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 January 11, 2007. 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 January 12, 2007.

Closed Committee Deliberations: On January 25, 2007, from 4:25 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the May 19, 2006, review of internal research programs in the Office of Vaccines Research and Review, Division of Viral Products and Division of Bacterial, Parasitic, and Allergenic Products, CBER.

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 Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

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

Dated: January 3, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. 07–28 Filed 1–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Education Assistance Loan (HEAL) Program Regulations (OMB No. 0915–0108): Extension

The Health Education Assistance Loan (HEAL) Program has regulations that contain notification, reporting and recordkeeping requirements to insure that the lenders, holders and schools participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under the OMB number referenced above, much of the burden associated with the regulations is cleared under the OMB numbers for the HEAL forms and electronic submissions used to report required information. The table listed at the end of this notice contains the estimate of burden for the remaining regulations.

The estimates of burden are as follows:

Number of respondents	Number of transactions	Total transactions	Hours per response (minutes)	Total burden hours
Reporting Requirements				
17 Holders	5	78	12	17
190 Schools	.4	76	10	13
Total Reporting				30
Notification Requirements				
7,930 Borrowers	1	7,930	10	1,322
17 Holders	7,910	134,470	10	22,412
190 Schools	.89	170	14	40
Total Notification				23,774