to demonstrate the effectiveness of antiseptic products used in health care settings. The discussion will also focus on related public health issues, trial design, and statistical issues. The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to NDAC).

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 by March 16, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 23, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 16, 2005 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.

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 LaNise Giles, 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: February 10, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–3115 Filed 2–17–05; 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). The meeting will be open 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 March 15, 2005, from 8:30 a.m. to approximately 5:40 p.m.

Location: Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD.

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: The committee will review safety and immunogenicity for two Tetanus Toxoid, Reduced Diptheria Toxoid and Acellular Pertussis Vaccine, Absorbed (Tdap) vaccines. In the morning the committee will review safety and immunogenicity data for a Tdap vaccine manufactured by GlaxoSmithKline Biologicals. In the afternoon the committee will review safety and immunogenicity data for a Tdap vaccine manufactured by Aventis Pasteur Ltd.

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 by March 8, 2005. Oral presentations from the public will be scheduled between approximately 11:10 a.m. and 11:40 a.m., and approximately 4:10 p.m. and 4:40 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 8, 2005, 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.

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: February 10, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–3180 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0043]

Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy; Draft Revised Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised guidance for FDA staff and industry entitled ''Compliance Policy Guide (CPG) Sec. 310.210 Blood Pressure Measurement Devices (Sphygmomanometers)—Accuracy (CPG 7124.23).'' This draft CPG provides guidance concerning accuracy and exhaust rate criteria for sphygmomanometers. This draft guidance is being issued for public comment only and will not be implemented until a final CPG is announced in the **Federal Register**.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FAX your request to 240–632–6861. 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section

for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6851.

SUPPLEMENTARY INFORMATION:

I. Background

In 1992 and 1994, the Association for the Advancement of Medical Instrumentation (AAMI) issued two revised standards that were approved by the American National Standards Institute (ANSI) namely, ''ANSI/AAMI SP9–1994 American National Standard Non-Automated Sphygmomanometers'' and ''ANSI/AAMI SP10–1992 American National Standard for Electronic or Automated Sphygmomanometers.''

As amended by the FDA Modernization Act of 1997 (FDAMA), section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)) allows FDA to recognize consensus standards, established by international and national standard development organizations, for use in satisfying portions of device premarket review submissions or other requirements. FDA now recognizes the complete standards ANSI/AAMI SP9–1994 and ANSI/AAMI SP10–1992 for the purpose of premarket clearance (63 FR 55617, October 16, 1998; 67 FR 1774, January 14, 2002). To be consistent with current industry practice, FDA intends to use the accuracy and exhaust rate criteria identified in these recognized consensus standards as guidance for testing, surveillance, and compliance purposes, as well as for premarket clearance. Therefore, this draft revised guidance reflects the accuracy and exhaust rate criteria in the currently recognized revisions of these two voluntary standards.

II. Significance of Guidance

This draft guidance represents 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.

In accordance with FDA's good guidance practices regulation (21 CFR 10.115), this draft document is considered a level 1 guidance. This draft guidance is being issued for public comment only and is not in effect at this time. Only after a notice of availability is published in the **Federal Register** for the final document will the agency implement the guidance.

III. 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. The agency will review all comments, but in issuing final guidance, need not specifically address each comment. If appropriate, the agency will make changes to the guidance in response to comments. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ora/compliance_ref/revisions.htm*.

Dated: February 10, 2005.

John Marzilli,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 05–3116 Filed 2–17–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0047]

Draft Guidance for Industry: Considerations for Plasmid Deoxyribonucleic Acid Vaccines for Infectious Disease Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications'' dated February 2005. The draft guidance document is intended to assist manufacturers and/or sponsors in the development and testing of deoxyribonucleic acid (DNA) vaccines to prevent infectious diseases. The draft guidance, when finalized, will update and replace the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996.

DATES: Submit written or electronic comments on the draft guidance by May 19, 2005, to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Considerations for Plasmid DNA Vaccines for Infectious Disease Indications'' dated February 2005. The draft guidance is intended to assist manufacturers and/or sponsors in the development and testing of DNA vaccines to prevent infectious diseases. The document describes the manufacturing information that should be submitted to CBER for a new DNA vaccine product for clinical study under an investigational new drug application (IND). Plasmid DNA products intended for non-infectious therapeutic indications are not addressed in the draft guidance. The draft guidance, when finalized, will update and replace the guidance document entitled ''Points to Consider on Plasmid DNA Vaccines for Preventive Infectious Disease Indications'' dated December 1996.