ICH was organized to provide an opportunity for tripartite harmonisation initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonisation of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization (WHO), Health Canada's Health Products and Food Branch, and the European Free Trade Area.

In the **Federal Register** of June 14, 2002 (67 FR 40951), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''Q1F Stability Data Package for Registration in Climatic Zones III and IV.'' In the same notice, the agency announced that when the Q1F guidance was finalized, the Q1A guidance, originally published in the **Federal Register** of September 22, 1994 (59 FR 48754), and revised (as Q1A(R)) in 2001 (66 FR 56332, November 7, 2001), would be revised to incorporate the relevant information from the Q1F guidance. The notice gave interested persons an opportunity to submit comments by August 20, 2002.

After consideration of the comments received and revisions to the guidance, a final draft of the Q1F guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on February 6, 2003. On the same date, the ICH Steering Committee endorsed the revised Q1A guidance incorporating the Q1F recommendations.

II. The Guidances

There are four climatic zones in the world that are distinguished by their characteristic prevalent annual climatic conditions, based on the concept described by P. Schumacher (*Pharmazeutische Zeitung*, 119:321–324, 1974). The Q1A guidance defines the stability data package for the ICH tripartite regions (the EU, Japan, and the United States), which are in climatic zones I or II. The WHO has published a guideline on ''Stability testing of pharmaceutical products containing well established drug substances in conventional dosage forms'' (WHO technical report series, no. 863, annex 5), updated in the ''Report of the thirty-seventh meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations,'' Geneva, October 22–26, 2001. The WHO guideline defines stability testing recommendations, including storage conditions, for all four climatic zones.

A. The Q1F Guidance

The Q1F guidance establishes harmonized global stability testing recommendations based on the Q1A guidance and the WHO guideline and defines an approach for broader use of Q1A recommendations for territories in climatic zones III and IV. For territories in climatic zones III and IV, the data package as described in the Q1A guidance can be considered applicable except for certain storage conditions. The Q1F guidance recommends the ''room termperature'' long-term storage conditions and other considerations as part of the data package considered sufficient for a registration application for drug substances and products intended to be marketed in climatic zones III and IV.

B. The Revised Q1A Guidance

In concert with the Q1F recommendations, the intermediate storage condition for the ''general case'' in the Q1A guidance has been changed from 30 °C ± 2 °C/60 percent relative humidity (RH) ± 5 percent RH. The new intermediate storage condition for the general case is now 30 °C ± 2 °C/65 percent RH ± 5 percent RH. This change, from 60 percent RH to 65 percent RH, is intended to harmonize the intermediate storage condition for zones I and II with the long-term condition for zones III and IV. Furthermore, this modified intermediate condition can be used as an alternative long-term condition to 25 °C ± 2 °C/60 percent RH ± 5 percent RH for zones I and II.

These guidance documents represent the agency's current thinking on this topic. They do not create or confer any rights for or on any person and do 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. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidances. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidances and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm*, or *http://www.fda.gov/cber/publications.htm*.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29103 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood 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: Blood 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 December 11, 2003, from 8 a.m. to 6:30 p.m.; and on December 12, 2003, from 8 a.m. to 3 p.m.

Location: Hilton DC North—Gaithersburg, Grand Ballrooms A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line

for up-to-date information on this meeting.

Agenda: On December 11, 2003, the committee will hear presentations and discuss and provide recommendations on these topics: The American Association for Blood Banks (AABB) abbreviated donor questionnaire; and blood donor deferral for exposure to Leishmaniasis. In the afternoon, the committee will hear an update on the West Nile Virus (WNV) epidemic and donor testing in 2003 including updates on WNV testing under investigational new drug applications and plans for 2004. On December 12, 2003, the committee will hear updates on these topics: The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), the use of secure e-mail, a summary of the factor VIII inhibitor workshop, platelet testing and evaluation guidance, and freezing and storage temperatures for source plasma (-25 °C and -30 °C). The committee will also hear presentations and discuss and provide recommendations on the review of plasma collection nomograms.

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 November 21, 2003. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m., 2 p.m. and 2:30 p.m., and 5:30 p.m. and 5:45 p.m. on December 11, 2003; and between approximately 9:30 a.m. and 10:15 a.m., and 12 noon and 12:30 p.m. on December 12, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 21, 2003, 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 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 Linda A. Smallwood, or Pearline K. Muckelvene at 301–827–1281 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: November 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–29075 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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). At least one portion of the meeting will be closed 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 December 11, 2003, from 8:30 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, ext. 176, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12521. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on the reclassification of the intervertebral body fusion device (cage) intended for spinal fusion procedures in skeletally mature adults with degenerative disc disease at one or two levels from C2–C7 and L2–S1 using autogenous bone graft. The device does not include combination products, such as the intervertebral body fusion device using morphogenic proteins and scaffolds. Background information for the topic, including the agenda and questions for the committee, will be available to the public no later than 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

Procedure: On December 11, 2003, from 9 a.m. to 6 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 by December 1, 2003. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 1, 2003, 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.

Closed Committee Deliberations: On December 11, 2003, from 8:30 a.m. to 9 a.m., the meeting will be closed to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future device issues. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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 Shirley Meeks, Conference Management Staff, at 301–594–1283, ext. 105, 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: November 14, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–29070 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting.