SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Electronic Records; Electronic Signatures'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 23, 2003 (68 FR 43531), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0303. The approval expires on May 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets.*

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29071 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2000D–1598]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of notice.

SUMMARY: This document withdraws a Food and Drug Administration (FDA) notice that published in the **Federal Register** of October 31, 2003 (68 FR 62086).

DATES: This notice is withdrawn on November 21, 2003.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION: FDA published a notice in the **Federal Register** of October 31, 2003, informing interested parties that the proposed collection of information entitled ''Suggested Documentation for Substantiating Whether Foods Have or Have Not Been Developed Using Bioengineering'' had been submitted to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. However, this request for comments was issued prematurely. Thus, FDA is withdrawing the proposed collection of information at this time. FDA will reissue the request for comments when appropriate.

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–29074 Filed 11–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0231 and 1993D–0139]

International Conference on Harmonisation; Stability Data Package for Registration Applications in Climatic Zones III and IV; Stability Testing of New Drug Substances and Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidances prepared under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The first is a guidance entitled ''Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV'' (the Q1F guidance). The second is a revised guidance entitled ''Q1A(R2) Stability Testing of New Drug Substances and Products'' (the Q1A guidance). The Q1F guidance, which is an annex to the Q1A guidance, defines an approach for broader use of the Q1A guidance for territories in climatic zones III and IV. The revised Q1A guidance incorporates relevant Q1F recommendations.

DATES: The guidance is effective November 21, 2003. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidances 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.* Submit written requests for single copies of the guidances to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or 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, 301–827–3844, FAX: 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidances: Chi-wan Chen, Center for Drug Evaluation and Research (HFD–830), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2001; or Andrew Shrake, Center for Biologics Evaluation and Research (HFM–345), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20052–1148, 301–402–4635.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonisation of regulatory requirements. FDA has participated in many meetings designed to enhance harmonisation and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

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