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 April 16, 2008.

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 Teresa Watkins at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: March 20, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–6193 Filed 3–25–08; 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). At least one portion of the meeting will be closed 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 May 1, 2008, from 8:30 a.m. to 5:30 p.m. and on May 2, 2008, from 8:30 a.m. to 4 p.m.

Location: Hilton Hotel, Washington DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike (HFM–71), 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 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of May 1, 2008, the committee will hear updates on the following: (1) Summaries of August 22–23, 2007, and January 9–10, 2008, meetings of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability; (2) 2007 West Nile Virus Epidemiology and the use of nucleic acid tests to reduce the risk of transmission of West Nile Virus in Whole Blood and blood components for transfusion and Human Cells, Tissues, and Cellular and Tissue-based products (HCT/Ps); (3) implementation of blood donor screening for infection with *Trypanosoma cruzi* and the use of serological tests to reduce the risk of transmission of *T. cruzi* infection in Whole Blood and blood components for transfusion and HCT/Ps; (4) FDA's proposal to lower the minimum recommended lot release titer for measles antibodies in Immune Globulin Intravenous (Human) and Immune Globulin Subcutaneous (Human); (5) Gambro/Fenwal Post Approval Surveillance Study of Platelet Outcomes, Release Tested (PASSPORT) Post Marketing Study—7 Day Platelets; (6) Experience with 7 Day Platelets Versus 5 Day Platelets; and (7) FDA Perspective on the PASSPORT Study. These updates will be followed by informational presentations on FDA's Center for Biologics Evaluation and Research Safety Teams related to blood and tissue. In the afternoon, the committee will discuss the Biomedical Excellence for Safer Transfusion Committee Report on red blood cell recovery standards. On the morning of May 2, 2008, the committee will discuss Lev Pharmaceutical's plasma-derived C1 esterase inhibitor (CINRYZE). Then, in the afternoon the committee will review the research programs in the Laboratory of Hepatitis and Related Emerging Agents, Division of Emerging and Transfusion Transmitted Diseases, Office of Blood Research and Review, CBER Site Visit of November 8, 2007.

FDA intends to make background material available to the public no later than 2 business days 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 2008 and scroll down to the appropriate advisory committee link.

Procedure: The entire day of May 1, 2008, and on May 2, 2008, from 8:30 a.m. to 3:15 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 April 23, 2008. Oral presentations from the public will be scheduled between approximately 11:50 a.m. and 12:20 p.m. and between approximately 4:20 p.m. and 4:50 p.m. on May 1, 2008, and between approximately 10:40 a.m. and 11:10 a.m. and 2:40 p.m. and 3 p.m. on May 2, 2008. 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 April 15, 2008. 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 April 16, 2008.

Closed Committee Deliberations: On May 2, 2008, between 3:15 p.m. and 4 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 reports of intramural research programs and make recommendations regarding personnel staffing decisions.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

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

Dated: March 20, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–6208 Filed 3–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0158] (formerly Docket No. FDA–2008–N–0131)

Frozen Concentrate for Lemonade Deviating From Identity Standard; Temporary Permit for Market Testing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of February 29, 2008 (73 FR 11095). The document announced that a temporary permit has been issued to Florida's Natural Growers, to market test a product designated as ''Frozen Concentrate for Lemonade 3+1 Ratio.'' The document was published with an incorrect value for the Brix (measure of concentration of sugars in juice). This document corrects the error.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, 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: In FR Doc. E8–3912, appearing on page 11095 in the **Federal Register** of Friday, February 29, 2008, the following correction is made:

1. On page 11095, in the second column, in the **SUPPLEMENTARY INFORMATION** section, line twenty-two, the number ''56°'' is corrected to read ''37.6°''.

Dated: March 18, 2008.

Barbara Schneeman,

Director, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. E8–6056 Filed 3–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0178]

International Conference on Harmonisation; Draft Guidance on S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance updates and combines information from two ICH guidances, ''S2A Specific Aspects of Regulatory Genotoxicity Tests for Pharmaceuticals'' and ''S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals.'' The draft guidance is intended to help facilitate drug development programs, ensure patient safety, and reduce animal usage.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 12, 2008.

ADDRESSES: 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.regulations.gov*. Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; 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. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance*: David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993–0002, 301–796–0175.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization 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 harmonization 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 harmonization 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