

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 Donald W. Jehn or Pearline K. Muckelvene 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. E8-6208 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 CBERT 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

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, Health Canada, and the European Free Trade Area.

In February 2008, the ICH Steering Committee agreed that a draft guidance entitled "S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use" should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

The draft guidance provides guidance on optimizing the standard genetic toxicology battery for the prediction of potential human risks, and on interpreting the results. The ultimate goal of this guidance is to improve risk characterization for carcinogenic effects induced by changes in the genetic material. The draft guidance is intended to help facilitate drug development programs, ensure patient safety, and reduce animal usage.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

## III. Electronic Access

Persons with access to the Internet may obtain the document 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: March 21, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 08-1076 Filed 3-21-08; 3:05 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0145]

#### Preparation for International Conference on Harmonization Meetings in Portland, Oregon; Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting entitled "Preparation for ICH Meetings in Portland, Oregon" to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Portland, Oregon. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Portland, Oregon, June 2-5, 2008, at which discussion of the topics underway and the future of ICH will continue.

**Date and Time:** The meeting will be held on Friday April 4, 2008, from 12:30 pm to 5 p.m.

**Location:** The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Room G and H, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 12:25 p.m., as you will be escorted from the front

entrance of 5600 Fishers Lane to Conference Room G and H.

**Contact Person:** All participants must register with Tammie Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by e-mail: [Tammie.bell@fda.hhs.gov](mailto:Tammie.bell@fda.hhs.gov) or FAX: 301-480-0003.

**Registration and Requests for Oral Presentations:** Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations, to the contact person by April 3, 2008.

If you need special accommodations due to a disability, please contact Tammie Bell at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

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 medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization 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, Labor 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