

Advisory Committee	10-Digit Access Number
Molecular and Clinical Genetics Panel	3014510231
Neurological Devices Panel	3014512513
Obstetrics-Gynecology Devices	3014512524
Ophthalmic Devices Panel	3014512396
Orthopaedic and Rehabilitation Devices Panel	3014512521
Radiological Devices Panel	3014512526
National Mammography Quality Assurance Advisory Committee	3014512397
Technical Electronic Product Radiation Safety Standards Committee	3014512399
<b>Center for Veterinary Medicine</b>	
Veterinary Medicine Advisory Committee	3014512548
<b>National Center for Toxicological Research (NCTR)</b>	
Science Advisory Board to NCTR	3014512559

The hotline will provide the most recent information available on upcoming advisory committee meetings, guidance for making an oral presentation during the open public hearing portion of a meeting, and procedures on obtaining copies of transcripts of advisory committee meetings. Because the hotline will communicate the most current information available about any particular advisory committee meeting, this system will provide interested parties with timely and equal access to such information. The hotline should also conserve agency resources by reducing the current volume of inquiries individual FDA offices and employees must handle concerning advisory committee schedules and procedures.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: May 28, 2007.

**Randall W. Lutter,**

*Associate Commissioner for Policy.*

[FR Doc. E7-10738 Filed 6-4-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0206]

#### Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices; Availability

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

#### **ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices." The guidance sets forth the agency's recommendations for ensuring the safety of refrigerated carrot juice and other low-acid refrigerated juices. The guidance is in response to six recent cases of botulism poisoning linked to refrigerated carrot juice that occurred in the United States and Canada.

**DATES:** This guidance is final June 5, 2007. Submit written or electronic comments on the guidance document at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Food Safety (HFS-317), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2022, FAX: 301-436-2651. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the 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 guidance document.

**FOR FURTHER INFORMATION CONTACT:** Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-305), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park,

MD 20740, 301-436-2022, or e-mail: [michael.kashtock@fda.hhs.gov](mailto:michael.kashtock@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance document entitled "Guidance for Industry: Refrigerated Carrot Juice and Other Refrigerated Low-Acid Juices." The purpose of the document is to provide guidance that will assist industry in processing and labeling refrigerated carrot juice and other refrigerated low-acid juices, which are subject to the pathogen reduction provisions of the Hazardous Analysis and Critical Control Point regulation for juice (21 CFR part 120) (the juice HACCP regulation), in a manner intended to provide for the safety of the juice when offered for sale by the processor and during handling by the consumer after purchase. This guidance is in response to six cases of botulism poisoning linked to refrigerated carrot juice that occurred in the United States and Canada in September and October 2006. *Clostridium botulinum* is a bacterium commonly found in soil. Botulism is a rare but serious paralytic illness caused by botulinum toxin, a nerve poison that under certain conditions is produced by *C. botulinum*. Botulism can be fatal and is considered a medical emergency. Foodborne botulism is not common in the United States.

FDA is issuing this guidance as level 1 guidance consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)). Consistent with FDA's good guidance practices regulation, the agency will accept comment, but is implementing the guidance document

immediately in accordance with § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate in light of the need to respond expeditiously to the recent cases of botulism linked to refrigerated carrot juice. This guidance represents the agency's current thinking on important practices for ensuring the safety of refrigerated carrot juice and other low-acid refrigerated juices subject to the juice HACCP regulation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance (see **FOR FURTHER INFORMATION CONTACT**).

## II. Comments

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

## III. Electronic Access

Persons with access to the Internet may obtain the guidance document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: May 25, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-10792 Filed 6-4-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007D-0213]

### Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Receipt Date; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Receipt Date." This draft guidance provides information on what FDA will consider to be the receipt date for certain submissions provided in electronic format to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The receipt date of these submissions has a number of important regulatory implications. Under the draft guidance, FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

**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 August 6, 2007.

**ADDRESSES:** 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, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. Submit written comments on the 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 document.

### FOR FURTHER INFORMATION CONTACT:

Gary Gensinger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1112, Silver Spring, MD 20993-0002, 301-796-0589; or

Michael Fauntleroy, Center for Biologics Evaluation and Research (HFM-25), 11400 Rockville Pike, Rockville, MD 20852, 301-827-5132.

## SUPPLEMENTARY INFORMATION:

### I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Receipt Date." This draft guidance provides information on what FDA will consider to be the receipt date for submissions provided in electronic format to CDER and CBER. When FDA receives a submission, the receipt date is used to determine important regulatory milestones (e.g., 30-day safety review cycle for an investigational new drug application, review performance goal date for a new drug application or biologics license application). Occasionally, however, submissions in electronic format have technical deficiencies that prevent FDA from being able to open, process, and archive them. When this occurs, FDA's review cannot begin until these technical deficiencies are corrected. To encourage sponsors to ensure that electronic submissions are free of technical deficiencies that can delay FDA review of the submission, FDA is changing its policy on the receipt date for submissions provided in an electronic format. The guidance provides that FDA will not consider a submission to be received until it has passed a technical validation check to ensure that the submission can be opened, processed, and archived.

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 determining the receipt date for submissions in electronic format. 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 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.