

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0206]

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Certifier L. CLAWSON  
DDM

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

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

**ACTION:** Notice.

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**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 [*insert date of publication in the Federal Register*]. 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

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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: 5/25/07  
May 25, 2007.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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