

DMEB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier D. Hawkins

**Guidance for Industry: Exemptions From the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction; 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 entitled “Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction.” This guidance is intended to provide revised FDA guidance to small and very small fruit and vegetable juice processors for effectively achieving a 5-log pathogen reduction that is the basis for exempting juice products from the warning label requirement established by the final rule entitled “Food Labeling: Warning and Notice Statement: Labeling of Juice Products” (“the juice labeling rule”). A 5-log pathogen reduction is also a requirement of the final rule entitled “Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice” (the “juice HACCP rule”).

**DATES:** Submit written or electronic comments concerning the guidance at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance entitled “Guidance for Industry: Exemptions from the Warning Label Requirement for

Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction” to Jennifer A. Burnham (see **FOR FURTHER INFORMATION CONTACT**).

Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Jennifer A. Burnham, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740, 301–436–2030, FAX: 301–436–2632.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On December 21, 2001, FDA issued a draft guidance document that outlined the agency’s current recommendations for effectively achieving a 5-log pathogen reduction in juice. The purpose of this draft guidance was to encourage processors who are not subject to the juice HACCP rule and who are performing a 5-log pathogen reduction to attain exemption from the warning label requirement to apply effective 5-log pathogen reduction treatments based upon FDA’s most current scientific understanding. In the **Federal Register** notice of December 21, 2001 (66 FR 65978), announcing the availability of the draft guidance document, FDA provided a 60-day period for comment on the draft guidance.

FDA received four comments in response to the December 21, 2001, draft guidance document. These comments represented the views of trade

associations representing small farm family citrus operations, commercial fresh citrus shippers, juice and juice beverage producers and suppliers, and a public health group. The comments suggested changes or modifications to FDA's revised recommendations for effectively achieving a 5-log pathogen reduction. FDA has considered the submitted comments and determined that the suggested changes or modifications are beyond the scope of this guidance or are not consistent with FDA's current scientific understanding of pathogen reduction. On its own initiative, FDA is making certain editorial changes in the guidance.

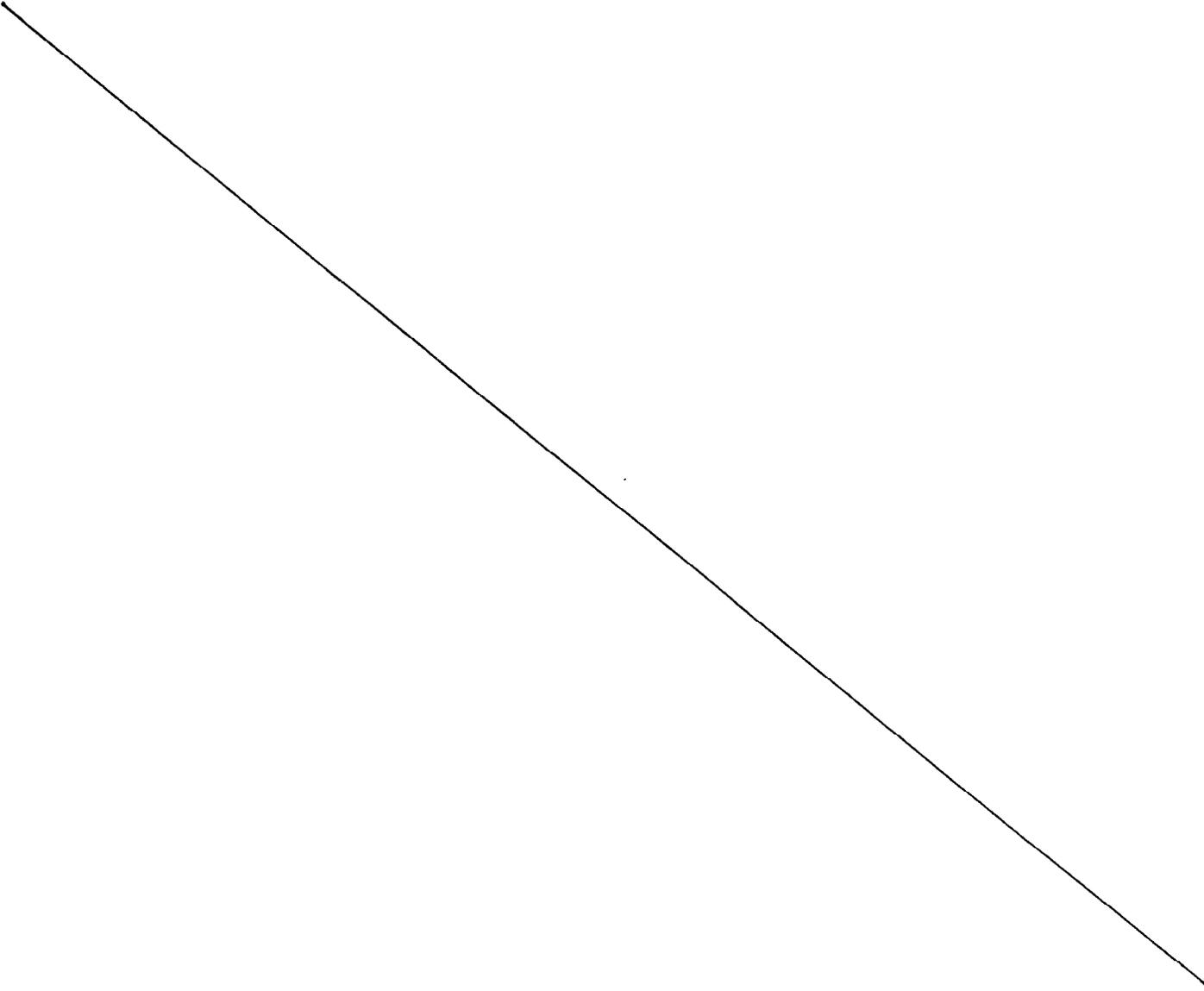
## **II. Conclusion**

The agency is adopting the revised recommendations for effectively achieving a 5-log pathogen reduction that is the basis for exempting juice products from the warning label requirement as presented in the draft guidance document. After considering the comments the agency received, the agency has determined that no changes are warranted.

The guidance entitled "Guidance for Industry: Exemptions from the Warning Label Requirement for Juice—Recommendations for Effectively Achieving a 5-Log Pathogen Reduction" is being issued as a level 1 guidance, consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current recommendations for effectively achieving a 5-log pathogen reduction in juice. 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.

### III. Comments

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



**IV. Electronic Access**

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

Dated: 9/27/02  
September 27, 2002.

  
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Margaret M. Dotzel,  
Associate Commissioner for Policy.

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