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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 99N-1979]

Apple Cider Food Safety Control; Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

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SUMMARY: The Food and Drug Administration (FDA) is announcing a workshop on food safety controls for the apple cider industry. The workshop will clarify issues related to the implementation of the agency's regulations requiring a warning statement for certain juice products. Specifically, the workshop will address pathogen reduction interventions that may be effective for apple cider production and the methods used to measure and validate such interventions. Results of research conducted by Federal, State, private, and academic institutions will be presented.

DATES: The workshop will be held on Thursday, July 15, 1999, from 9 a.m. to 4 p.m., and Friday, July 16, 1999, from 9 a.m. to noon. Written comments and requests to distribute materials and scientific studies at the meeting will be accepted until Friday, July 2, 1999. Submit written notices of registration by July 8, 1999.

ADDRESSES: The workshop will be held at the Department of Health and Human Services, Hubert Humphrey Bldg., conference room 705-A, 200 Independence Ave. SW., Washington, DC 20201. Submit registration and written notices of participation to Darrell J. Schwalm (address below). Submit written comments, written requests to distribute materials, and materials regarding relevant scientific studies to be distributed at the workshop to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two

copies of any comments and materials to be distributed are to be submitted, except that individuals may submit one copy. Comments and materials to be distributed are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Darrell J. Schwalm, Center for Food Safety and Applied Nutrition (HFS-625), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202-205-4040, FAX 202-205-4121 or e-mail “dschwalm@bangate.fda.gov”.

Registration for the workshop will be provided on a first come first served basis. Persons interested in attending this workshop should, by Friday, July 8, 1999, fax their name, title, firm name, address, telephone and fax number, and e-mail address to Darrell J. Schwalm (fax number above). If you need special accommodations due to a disability, please contact Darrell J. Schwalm (address above) at least 7 days in advance.

Interested persons should note that additional information regarding the workshop will be posted on FDA’s web site “www.cfsan.fda.gov”, as it becomes available. Accordingly, such persons are encouraged to visit that web site on a regular basis until the workshop convenes.

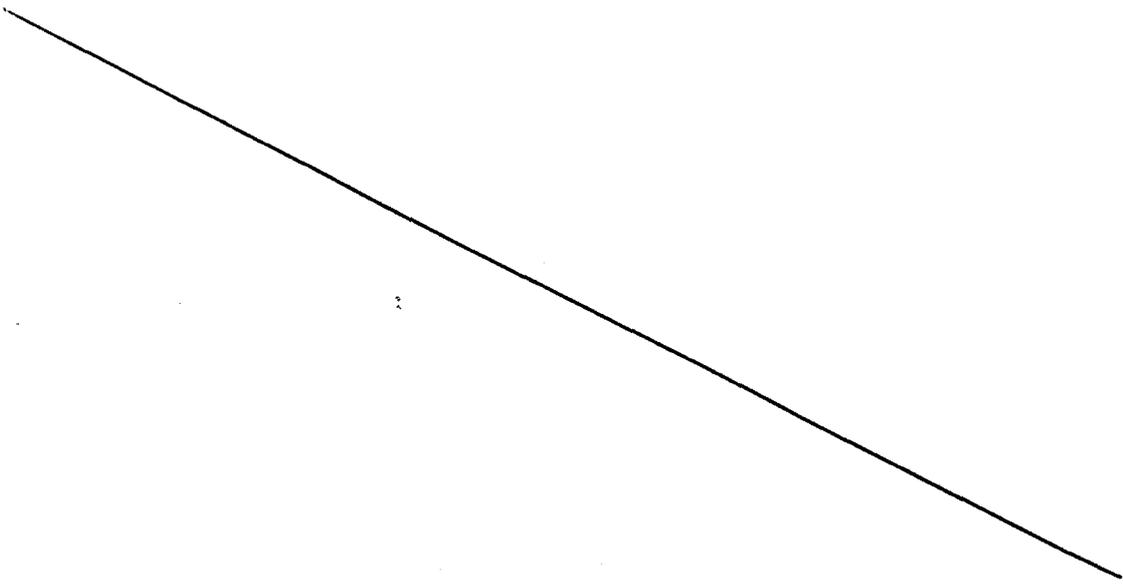
SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final regulation that required a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present in such juices. The regulation provides that the warning statement requirement does not apply to a juice that has been processed in a manner that will result in, at a minimum, a reduction in the pertinent microorganism of at least a 5-log magnitude (i.e., 100,000 fold). In the preamble to the proposed rule (63 FR 20486, April 24, 1998), FDA recognized that pasteurization is a process that can produce the 5-log reduction. The agency also noted that manufacturers may be able to use other technologies and practices, individually or in combination, to achieve the 5-log reduction, provided that the manufacturer’s process is validated to achieve the 5-log reduction in the target microorganism.

In the preamble to the final regulation, FDA indicated it would be willing to meet with manufacturers or groups of manufacturers to discuss and evaluate their proposed processes. FDA also stated that in order to help processors meet the pathogen reduction standard, the agency would make available, in accordance with part 20 (21 CFR part 20) of its regulations, information received by the agency regarding processes that have been validated to achieve a 5-log reduction.

The July 15 and 16, 1999, workshop will include a discussion of the control measures, that FDA is aware of, that can be used for apple cider production and of the methods for measuring and validating the effectiveness of measures in reducing pathogens. At the beginning of the workshop, a proceedings document will be provided to registered participants.

FDA believes that this workshop will also provide an opportunity for industry representatives and other members of the public to discuss information regarding control measures that are believed to achieve the 5-log reduction. Participants are requested to bring to the workshop at least 50 copies of any written or published materials they wish to distribute. Agency experts will be available to answer technical food safety questions.

A video recording of the proceedings will be prepared; copies of the video may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15-working days after the meeting.



The video recording of the meeting, submitted comments, and materials for distribution will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/21/99

June 21, 1999



Margaret M. Dotzel
Acting Associate Commissioner for
Policy Coordination

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