application for benefits. If you do not qualify as a child of the insured under that version of State law, we look at all versions of State law that were in effect from the first month for which you could be entitled to benefits up until the time of our final decision and apply the version of State law that is most beneficial to you.

(4) *Insured is deceased.* If the insured is deceased, we apply the law of the State where the insured had his or her permanent home when he or she died. We apply the version of State law in effect when we make our final decision on your application for benefits. If you do not qualify as a child of the insured under that version of State law, we will apply the version of State law that was in effect at the time the insured died, or any version of State law in effect from the first month for which you could be entitled to benefits up until our final decision on your application. We will apply whichever version is most beneficial to you. We use the following rules to determine the law in effect as of the date of death:

(i) If a State inheritance law enacted after the insured's death indicates that the law would be retroactive to the time of death, we will apply that law; or

(ii) If the inheritance law in effect at the time of the insured's death was later declared unconstitutional, we will apply the State law which superseded the unconstitutional law.

4. Section 404.356 is amended by adding a sentence at the end to read as follows:

§ 404.356 Who is the insured's legally adopted child?

* * * We apply the adoption laws of the State or foreign country where the adoption took place, not the State inheritance laws described in § 404.355, to determine whether you are the insured's legally adopted child.

[FR Doc. 98–28707 Filed 10–27–98; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

Food Labeling: Warning and Notice Statement; Labeling of Juice Products; Technical Scientific Workshops; Requests for Additional Time to Achieve the Pathogen Reduction Standard

AGENCY: Food and Drug Administration, HHS.

ACTION: Technical scientific workshops; requests for additional time to achieve the pathogen reduction standard; rule related.

SUMMARY: The Food and Drug Administration (FDA) is announcing two technical scientific workshops to discuss and clarify issues related to the implementation of the agency's rule requiring a warning statement for certain juice products. In particular, the workshops will address the pathogen reduction interventions that have been developed for citrus juice production and the methods for measuring and validating such systems. FDA is also announcing a process by which individual manufacturers of citrus juices may request additional time, beyond the current compliance date of November 5, 1998, to implement a validated system of control measures that achieves the required reduction in pathogenic microorganisms. Manufacturers who implement such control measures will not be required to use the warning statement on their juice products. These actions are being taken in response to requests from several fresh citrus juice manufacturers that have indicated they want to implement improved controls but need additional time to do so.

DATES: The technical scientific workshops will be held on November 12, 1998, and on November 19, 1998. Both workshops will be from 8:30 a.m. to 5:30 p.m. Registration for the workshops will be provided on a first come, first served basis and must be received by November 6, 1998.

Individual fresh citrus juice producers may request additional time to comply with the pathogen reduction standard in § 101.17(g)(7)(i) (21 CFR 101.17(g)(7)(i)) until December 19, 1998. For requests for additional time, see the FDA District Directors listed under the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: The technical scientific workshops will be held at the following locations:

The November 12, 1998, workshop will be held at the Citrus Research and Education Center, University of Florida, Lake Alfred, FL 33850, 941–956–1151 and

the November 19, 1998, workshop will be held at the FDA District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 90015–2486, 949–252–7592.

For requests for additional time, see the FDA District Directors listed under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

To register for a technical workshop, please contact Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, FAX 202–205–4970 or e-mail ''cderoeve@bangate.fda.gov''. Registration information (including name, title, firm name, address, telephone and fax numbers) must be received no later than November 6, 1998.

For information on requests for additional time to achieve the pathogen reduction standard, please contact, as listed in the **SUPPLEMENTARY INFORMATION** section of this document, the Director of the FDA District Office in which the firm is located.

If you need special accommodations due to a disability, please contact Catherine M. DeRoever at the previous address at least 7 days in advance.

Interested persons should note that additional information regarding the technical scientific workshops, making requests for additional time and other relevant information will be posted on CFSAN's web site, ''www.cfsan.fda.gov,'' as it becomes available. Accordingly, such persons may wish to visit that web site on a regular basis until the workshop convenes.

SUPPLEMENTARY INFORMATION: Requests by individual citrus firms for additional time to implement control measures and validate that the process achieves the pathogen reduction in § 101.17(g)(7)(i) should be addressed to the Director of the FDA District in which the firm is located. For firms in Florida, Texas, Arizona, and California the addresses are:

Douglas Tolen, District Director, FDA Florida District Office, 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809, 407–475–4700;

Joseph Baca, District Director, FDA Dallas District Office, 3310 Live Oak St., Dallas, TX 75204, 214–655–5315; or

Elaine C. Messa, District Director, FDA Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612–2445, 949–798–7714.

In the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final regulation that requires 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 produce, 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 (such as a combination of eliminating use of drops, brushing, washing and using sanitizers) 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 stated its expectation that citrus juice processors should be able to achieve and validate a 5-log reduction without pasteurization (63 FR 37030 at 37042). FDA also indicated that it would be willing to meet with manufacturers or groups of manufacturers to discuss and evaluate their proposed processes. In addition, FDA stated that in order to help processors meet the pathogen reduction standard, the agency would make available, in accordance with 21 CFR part 20 of its regulations, information received by the agency regarding processes that have been validated to achieve a 5-log reduction.

FDA has received requests from several manufacturers of fresh citrus juice for 18-additional months beyond the November 5, 1998, compliance date for the warning statement requirement to permit such firms to develop and to validate procedures that will achieve the 5-log reduction in citrus juices. In discussions with the agency, there was evidence of widespread confusion among juice manufacturers as to how FDA expects the 5-log reduction to be achieved.

Upon consideration of the fresh citrus juice manufacturers' request and in light of other information before the agency regarding progress made by some citrus juice manufacturers in identifying effective mechanisms for pathogen reduction, FDA has developed a two-part strategy to respond to these requests. First, FDA will sponsor two technical scientific workshops for the citrus juice industry, open to the public, on November 12 and November 19, l998. Each workshop will include a discussion of the control measures of which FDA is aware that are being used for citrus juice production and of the methods for measuring and validating the effectiveness of the measures in reducing pathogens. FDA believes that these workshops will provide an opportunity for industry representatives and other members of the public to share information regarding control measures that are believed to achieve the 5-log reduction. Participants are requested to bring to the workshop at least 150 copies of any written or published materials they wish to distribute at the workshop. Agency experts will be available to answer technical questions.

Second, as noted, several firms have requested that FDA extend the final rule's compliance date for citrus juices to permit those firms additional time to develop and validate intervention measures that achieve the 5-log pathogen reduction standard. FDA believes that a formal extension of the rule's compliance date is not feasible in the current circumstances because such extension would arguably require notice and comment rulemaking. Nevertheless, FDA believes that under certain conditions (which are enumerated as follows), it would be an appropriate exercise of the agency's enforcement discretion to suspend enforcement of the final rule for a limited period of time. In particular, FDA will consider such an exercise of its enforcement discretion for those citrus juice producers who no later than December 19, 1998, request such consideration and who make the following commitments in writing:

(1) The firm agrees to use the time period between November 4, 1998, and July 8, 1999, to develop, adapt, and validate procedures that are sufficient to achieve a 5-log reduction in the pertinent microorganism; and,

(2) The firm agrees to establish interim protection measures in the form of a system that applies hazard analysis and critical control point (HACCP) principles. This interim system will include, at a minimum, good manufacturing practices and specific control measures such as chemical washing and brushing of the fruit, sanitizing, culling of damaged fruit, and utilization of only those types of fruit with skins that are sufficiently smooth and durable to be cleanable and to remain intact after cleaning; and,

(3) The firm agrees to comply with the provisions of the warning label regulation (§ 101.17 (g)) no later than July 8, 1999. As a result of this commitment, the firm will use the warning label on its products beginning July 8, 1999, if it has been unable to implement validated control measures that achieve the 5-log reduction.

FDA believes that this two-part strategy is reasonable and will provide appropriate public health protection. As noted in the warning statement rulemaking, because the warning statement provides consumers with important information about the risk of foodborne illness, the warning requirement contributes to public health protection in that it allows consumers to make informed purchase decisions. In FDA's view, this warning statement requirement is primarily an interim step designed to reduce the risk of fresh juice consumption pending completion of a final HACCP rule and its implementation. However, because the warning statement requirement may nevertheless allow contaminated juice products to reach the marketplace, FDA does not expect the statement to be as effective in protecting consumers as would a validated 5-log reduction program. FDA believes it is appropriate to consider exercising its enforcement discretion where, as a result of such exercise, the agency can provide an incentive for citrus juice processing firms to produce safe juice earlier than such firms would otherwise do.

Because of the relationship between particular provisions in the warning statement regulation and the HACCP proposal, FDA is announcing its intention to reopen the comment period on the juice HACCP proposal (63 FR 20450) entitled ''Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice.'' This reopening will allow information and data presented at the workshop to be included in the record of the HACCP rulemaking. A **Federal Register** document announcing the reopening of the juice HACCP proposal comment period will be published at a later date.

Transcripts of the workshops will be prepared. Copies of the transcripts 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 meetings at a cost of 10 cents per page.

Dated: October 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–28901 Filed 10–23–98; 3:47 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 97F–0388]

Food Additives Permitted For Direct Addition to Food For Human Consumption; Polydextrose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996. This action is in response to a petition filed by Cultor Food Science, Inc.

DATES: This regulation is effective October 28, 1998; written objections and requests for a hearing by November 27, 1998. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51 of certain publications in § 172.841(b) (21 CFR 172.841(b), October 28, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3107.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1997 (62 FR 50387), FDA announced that a food additive petition (FAP 7A4556) had been filed by Cultor Food Science, Inc., 205 East 42d St., New York, NY 10017, proposing that § 172.841 *Polydextrose* (21 CFR 172.841) be amended to permit aqueous transition metal catalytic hydrogenation in the production of polydextrose and to adopt the specifications for polydextrose of the Food Chemicals Codex, 4th ed., 1996, pp. 297–300.

The proposed optional transition metal catalytic hydrogenation step in the production of polydextrose yields a partially reduced form of polydextrose in which the glucose moiety of glucose-terminated polydextrose polymers and the residual glucose monomers are converted to sorbitol moieties. The petitioner submitted data demonstrating that this partially reduced form of polydextrose is functionally equivalent to the currently regulated polydextrose and that no new chemical species are formed as a result of the proposed hydrogenation step. These data also show that the components of polydextrose produced by the proposed hydrogenation step are the same as the compounds of the currently regulated polydextrose and that only the relative amounts of sorbitol-terminated polydextrose and of free sorbitol are changed. The proposed adoption of the specifications for polydextrose in the Food Chemicals Codex, 4th ed., will allow the partially reduced form of polydextrose, with increased residual free sorbitol, to meet the specifications for polydextrose.

No new uses and no changes in current use levels of polydextrose are proposed in the petition. Polydextrose produced by the proposed hydrogenation step is expected to be used as a replacement for the currently regulated polydextrose. Therefore, FDA concludes that there will be no increase in dietary exposure to polydextrose from the promulgation of this amendment to the regulation (Ref. 1).

Based on its evaluation of the data in the petition and other relevant material in its files, FDA concludes that the reduced form of polydextrose produced by the proposed optional hydrogenation step is safe, that it will achieve its intended technical effect, and that therefore, the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before November 27, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated September 27, 1997, from M. DiNovi, Division of Product Manufacture and Use, FDA, to R. M. Angeles, Division of Product Policy, FDA.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner