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Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Final Rule

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Extension of Comment Period; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

RIN 0910–AA43

Food Labeling: Warning and Notice Statement; Labeling of Juice Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising its food labeling regulations to require 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. FDA is taking this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these products.

DATES: Effective September 8, 1998; however, compliance for juice other than apple juice or apple cider is not required until November 5, 1998.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 28, 1997 (62 FR 45593), FDA published a notice of intent (''the notice of intent'') that announced a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juice and ultimately to address the safety of all juice products. In the notice of intent, the agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory Hazard Analysis and Critical Control Point (HACCP) program for some or all juice products; (2) propose that the labels or the labeling of juice products not specifically processed to prevent, reduce, or eliminate pathogens bear a warning statement informing consumers of the risk of illness associated with consumption of the product; and (3) initiate several educational programs to minimize the hazards associated with consumption of fresh juices. The agency stated that it would address comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency and would consider all comments to the notice of intent received after 15 days in any final rulemaking.

FDA considered the comments received within 15 days of the notice of intent and other information available to the agency. Based on this information, FDA tentatively concluded in a proposed rule (''the HACCP proposal'') (63 FR 20450, April 24, 1998) that the most effective way to ensure the safety of juice products is to process the products under a system of preventive control measures. Consequently, in the HACCP document, the agency proposed to require that juice products be processed under HACCP programs.

Although FDA had tentatively concluded that HACCP is the most effective means of ensuring the safety of juice products, it also tentatively concluded in a proposed rule (''the juice labeling proposal'') (63 FR 20486, April 24, 1998), that there is an immediate need to inform consumers of the health risks associated with the consumption of juice products not processed to prevent, reduce, or eliminate pathogens that may be present. As fully discussed in the juice labeling proposal, FDA proposed that packaged untreated juice products[1] bear a warning statement informing at-risk consumers of the hazard posed by untreated juices to allow them to make informed decisions on whether to purchase and consume such products. Interested parties were given until May 26, 1998, to comment.

FDA prepared a single Preliminary Regulatory Impact Analysis (PRIA) that addressed both the juice labeling proposal and the HACCP proposal (63 FR 24254, May 1, 1998). Interested parties were given until May 26, 1998, to comment on aspects of the PRIA relating to the juice labeling proposal and until July 8, 1998, to comment on aspects of the PRIA relating to the HACCP proposal. Elsewhere in this issue of the **Federal Register**, FDA is announcing a 30-day extension of the comment period on the juice HACCP proposal to August 7, 1998.

FDA received approximately 85 responses to the notice of intent, each containing one or more comments. FDA addressed some of these comments in the juice labeling proposal. FDA subsequently received approximately 150 responses to the juice labeling proposal, each containing one or more comments. Responses to the notice of intent and to the juice labeling proposal were received from industry, trade organizations, consumers, consumer interest groups, academia, and State government agencies. Some of the comments supported the proposal. Other comments opposed the proposal or suggested modifications of various provisions of the proposal. The agency discusses below the significant comments bearing on the proposed labeling regulation and, when applicable, any revisions to the proposed regulation made in response to these comments. Responses to the notice of intent that bear on the juice labeling proposal and that were not addressed in that proposal are also addressed in this document. For simplicity, the agency's discussion does not categorize comments with regard to whether they were received in response to the notice of intent or in response to the juice labeling proposal.

Proposed § 101.17(g)(6) of the juice labeling proposal states that the requirements of that regulation would not apply to juice processed in a manner that will produce, at a minimum, a 5-log (i.e., 100,000-fold) reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, where the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice. This provision is directly linked to the process controls for pathogen reduction (the pathogen reduction performance standard; proposed § 120.24 that is part of the agency's HACCP proposal. This standard is pivotal in both the juice labeling and juice HACCP proposals, and interested persons could comment on the standard in response to either or both proposals.

FDA received several requests to extend the comment period, e.g., for an additional 30 days, for an additional 45 days, or for an additional 60 days. Some of these requests discussed the fact that the proposed pathogen reduction performance standard was an important

[1] As discussed in the juice labeling proposal, the terms ''juice'' and ''juice products'' are used interchangeably. Thus, ''juice'' refers both to beverages that are composed exclusively of an aqueous liquid or liquids extracted from one or more fruits or vegetables and those beverages that contain other ingredients in addition to juice. Similarly, ''juice product'' refers both to beverages that contain only juice and beverages that are composed of juice and other ingredients.

In the remainder of this document, products not processed to prevent, reduce, or eliminate pathogens will be referred to as ''untreated juice products.'' In addition, processing to ''prevent, reduce, or eliminate'' pathogens will be referred to as processing to ''control'' pathogens.

provision of both the juice labeling proposal and the HACCP proposal and stated that 30 days was an insufficient time to address that standard. In a memorandum dated June 5, 1998, from the Deputy Director of FDA's Regulations Policy and Management Staff to the Dockets Management Branch, FDA extended the comment period until June 22, 1998, for those persons who had requested an extension, in accordance with § 10.40(b)(3) (21 CFR 10.40(b)(3)). Thereafter, in a memorandum dated June 10, 1998, FDA extended the comment period until June 22, 1998, for all interested persons. The agency's memoranda noted that comments submitted to the juice labeling rule must be received in the Dockets Management Branch on or before 4:30 p.m., e.d.t., June 22, 1998, and that no other extensions would be considered. The public was notified of both extensions by placing copies of the two memoranda in the agency's public docket.

In this document FDA addresses those comments that were received on or before 4:30 p.m., e.d.t., June 22, 1998, in response to the notice of intent, in response to the juice labeling proposal, or in response to the HACCP proposal that bear on the proposed warning statement requirement or on the proposed pathogen reduction performance standard. However, in this document, FDA does not address any comments, received either in response to the notice of intent or in response to the juice labeling proposal, that bear on aspects of the HACCP proposal other than the pathogen reduction performance standard (proposed § 120.24). Those comments will be addressed in any final rule that the agency issues with respect to the HACCP proposal.

As noted, since the publication of the notice of intent in August 1997, FDA has intended to propose two regulations, a juice HACCP regulation and a juice warning statement regulation, that in combination with one another, as well as certain educational programs, would establish a comprehensive program to ensure the safety of fresh juice. As discussed in the juice labeling proposal, the warning statement requirement is designed to provide public health information during the development and implementation of a HACCP rule. FDA recognizes that as a result, certain provisions of the juice labeling proposal and the juice HACCP proposal are very closely linked, including the scope of each rule (e.g., what is defined as ''juice'') and the pathogen reduction standard (the so-called ''5-log standard''). See also comment 40. The agency is also aware that the comment period announced in the juice HACCP proposal is continuing, and in fact, elsewhere in this issue of the **Federal Register**, the agency is announcing a 30-day extension of that comment period to August 7, 1998. Thus, comments are likely to be made on the HACCP proposal, including on these common issues, after the publication of this final rule.

Although there are these overlapping issues in the two juice rulemakings, FDA believes that the public health risk presented by untreated juice is such that it is essential that the warning statement rulemaking be completed and the rule implemented promptly. In order to complete the warning statement rulemaking, the agency must consider and respond to all significant comments on the juice labeling proposal, including those comments that relate to issues presented in both the HACCP and warning statement rulemakings. Thus, this final rule addresses and responds to all significant comments made on the juice labeling proposal; the resolution of these comments is based upon the administrative record of this proceeding at this time. Once the comment period closes on the HACCP proposal, FDA will evaluate all comments received on that proposal and utilize such information to develop a final HACCP rule for juice, if such a rule is supported by the record. To the extent that the agency's analysis of the record for the HACCP proceeding results in the resolution of a common issue or issues in a way that differs from the issue's resolution in this final rule, FDA will initiate the amendment of the juice labeling regulation to ensure conformance with any final HACCP rule.

II. Rationale for Warning Statement

A. Risk Associated with Consumption of Juices

In the notice of intent and the juice labeling proposal, FDA documented that certain juices have been the vehicle for outbreaks of foodborne illness (62 FR 45593). Consequently, in the juice labeling proposal, FDA proposed to require a warning statement for juice products to alert consumers, especially those at greatest risk, of the potential hazard so that they may make informed decisions on whether to purchase and consume such juice products.

1. Some comments contended that FDA has not conducted an adequate risk assessment and, therefore, has no basis to require a warning statement.

The agency performed a detailed evaluation of the hazards posed by untreated juices, which was filed in the administrative record of the HACCP proposal and was included as an appendix to the PRIA (Ref. 1). This evaluation was based on available scientific information and was appropriate to the circumstances. FDA believes that this evaluation provided an adequate assessment of risks and a sufficient basis for requiring a warning statement.

2. Many of the comments contended that the health hazard associated with juice products is not sufficient to justify a warning statement. Some of the comments asserted that the health hazard is limited to apple juice and, therefore, the remedies should be limited to apple juice. Another comment asserted that FDA's estimate of the risk of foodborne illness is inaccurate because that estimate did not consider recent steps taken by members of the juice industry to address microbial contamination. Some comments argued that most of the outbreaks have occurred because of poor manufacturing practices and suggested that FDA increase its inspection of food manufacturers rather than issue regulations to require a warning statement.

The agency does not agree with the comments that contend that the health hazard associated with the consumption of fresh juices is insufficient to justify requiring a warning statement. Risk is a function of two factors: Likelihood of occurrence of an event and severity of the event. As discussed in the HACCP proposal (63 FR 20450 at 20459), severity is the seriousness of the consequences of exposure to the hazard. Considerations of severity (e.g., impact of sequelae and magnitude and duration of illness or injury) can be helpful in understanding the public health impact of the hazard. Likelihood of occurrence of a hazard is generally judged based on processing experience, epidemiological data, and information in the technical literature.

As discussed in the juice labeling proposal, there are documented cases of foodborne illness associated with the consumption of various juice products contaminated with microorganisms such as *Escherichia coli* O157:H7, *Salmonella* species, *Cryptosporidium*, and *Vibrio cholerae*. These various microorganisms, which were found in apple juice, apple cider, orange juice, and frozen coconut milk, were associated with foodborne illness throughout the United States (e.g., in CA, CO, MA, NY, CT, NJ, MD, and WA) over a 6-year period (i.e., 1991 to 1996).

Furthermore, some of the illnesses associated with certain untreated juice have been very severe (e.g., cases of long-term reactive arthritis and severe chronic illness); in one case, consumption of contaminated juice has resulted in death. As is the case with most food associated disease, because of the likelihood of underreporting, it is assumed that these outbreaks represent a fraction of the outbreaks and sporadic cases that actually occur.

Importantly, the comments did not provide the agency with additional data that either contradict FDA's detailed hazard evaluation (Ref. 1) or that could be used to reevaluate the health risks associated with consumption of untreated juice products. Therefore, the comments have not persuaded FDA that there is insufficient risk to warrant requiring a warning statement for untreated juice products.

The agency recognizes the recent steps taken by members of the juice industry to address microbial contamination. However, FDA notes that industry practices may vary. The agency is not aware that all members of the juice industry are addressing the potential for microbial contamination in an equally effective manner. Accordingly, the agency continues to see a need for a comprehensive Federal regulatory approach for all juice products.

FDA tentatively concluded in the HACCP proposal (63 FR 20450 at 20456) that a preventive system, such as HACCP, appears to offer the most effective long-term solution to control the significant microbial hazards, along with other hazards, that have become a problem with juice. Increased inspection, while having some beneficial impact on the safety of juices, is resource intensive to the agency. Even if funds were available to the agency for this purpose, the agency tentatively concluded in the HACCP proposal that increased inspection likely would not be the best way for the agency to utilize its resources to protect the public health. It is ultimately the responsibility of manufacturers to ensure that their products are safe.

Current good manufacturing practices (CGMP's) are plantwide operating procedures that also address sanitation. Although FDA supports the use of CGMP's, the agency also tentatively concluded in the proposed HACCP rule that the use of CGMP's alone would not be sufficient to control the problems with juices because CGMP's do not concentrate on the identification and prevention of food hazards.

Based on information the agency has received in response to the juice labeling proposal, FDA has concluded that the use of CGMP's and increased FDA inspections by themselves do not adequately address the safety of juices. Labeling addresses the need to provide a warning to consumers until juice processors implement measures to control pathogens.

3. Comments stated that the results of FDA's 1997 national cider mill survey indicate that the health risk posed by cider is not sufficient to warrant a warning label. Although the results of the survey have not been published, these comments asserted that no pathogenic bacteria were found in the cider samples evaluated by the agency.

These comments refer to a 1997 assignment in which FDA inspected fresh unpasteurized apple cider operations and collected in-line product for microbiological analysis at 237 establishments in 32 States. Although FDA has not issued its summary of results from this assignment, the agency notes that this assignment generated microbiological data at several stages of operation in these facilities including the incoming apples, wash water, apples taken after washing but before processing, and finished cider both preserved and unpreserved. The microbiological analyses at these various steps were for pathogens such as *E. coli* 0157:H7 and *Salmonella sp*. and also for fecal coliforms and generic *E. coli*, which are not foodborne pathogens, but are used as indicators of fecal contamination that could be a potential source for contamination by pathogens. It was the agency's intent to consider all of the data generated to assess microbiological safety factors for cider. The agency does not consider it appropriate to focus on any one aspect of its findings, i.e., the lack of any positive finding for pathogens in finished product, for drawing conclusions about the microbiological safety of cider.

This assignment did not result in the detection of any pathogens in a finished cider product intended to be sold to the public. However, FDA's preliminary findings from this assignment show that one firm's incoming apples tested positive for *Salmonella sp.* indicating that microbial hazards that necessitate effective control measures are reasonably likely to occur on incoming apples. Moreover, FDA's preliminary findings show that fecal coliforms and *E. coli* were found in the wash water used at several firms, indicating that the water is of poor quality. In addition a small number of finished cider products tested positive for fecal coliforms and generic *E. coli* was found in 14 percent of the finished product samples.

These findings further support the agency's action here in that they establish that risk factors such as pathogenic bacteria and fecal coliforms can exist in cider processing operations and could give rise to microbiological safety hazards in finished cider products. The findings of this FDA assignment clearly do not support the comment's contention that the health risk posed by cider is insufficient to justify a warning label.

4. Several of the comments that opposed warning statements on juice products contended that they are unnecessary. Two of these comments asserted that FDA should educate the consumer that the problem is not the juice, but rather, the fact that the juice is contaminated with animal feces and not properly processed.

FDA does not agree with this comment to the extent that it asserts that a warning statement should not be part of the Federal response to the problem of contaminated juice. Juice products that contain pathogenic microorganisms can be a vehicle for foodborne illness regardless of whether the microbial contamination arises from the source fruit or vegetable or from insanitation during manufacture. FDA's HACCP proposal is designed to ensure the safe and sanitary processing of juice. The warning statement, which is itself a form of education, is required only for those juices that have not been processed to achieve the pathogen reduction performance standard. Consumers, particularly those at greatest risk, need to know that untreated juice may contain harmful bacteria that could cause serious illness so that they may make informed choices. FDA expects that the warning statement will reduce the risk of illness because some of the at-risk consumers likely will choose not to expose themselves to the hazard.

B. Juice Products Versus Other Food Products That May Contain Pathogens

5. Several comments claimed that the agency's actions were discriminatory in nature and not proportional to the health hazard posed by unpasteurized juices. These comments questioned why other food products associated with recent foodborne illnesses are not required to bear warning statements (i.e., fruits, berries, eggs, melons, poultry, hamburgers, meat products, seafood, etc.).

The agency disagrees with these comments. Juice products historically have been consumed by individuals without treatment to control pathogenic microorganisms. In addition, the presence of some of the pathogens (i.e., *E. coli* O157:H7 and *Crytosporidium*)

that have been responsible for recent outbreaks of foodborne illnesses associated with untreated juice products is a relatively new phenomenon. Therefore, consumers do not associate such pathogens, and the risk that they present, with the consumption of untreated juice. Accordingly, in the juice labeling proposal, the agency tentatively concluded that a juice warning statement is needed to protect the public health because consumers are unaware of the nature and magnitude of the hazard.

In contrast, other mechanisms are in place to reduce the risk of foodborne illness from consumption of many of the foods discussed in the comments. First, consumers have some awareness that meat and poultry products have the potential to contain harmful microorganisms; also, these foods ordinarily are cooked prior to consumption. Moreover, meat and poultry products that are regulated by the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) are subject to that agency's HACCP regulations. In addition, regulations issued by USDA/FSIS require safe handling instructions on raw meat and poultry products advising consumers to thoroughly cook the products.

Other products mentioned in the comments are regulated with the goal of ensuring microbial safety. For example, seafood products are now required to comply with FDA's HACCP program for seafood products. Recently, FDA issued draft guidelines for good manufacturing practices and good agricultural practices regarding raw agricultural commodities (63 FR 18029, April 13, 1998). In addition, the agency recently requested public comment on its plan to implement a comprehensive ''farm to table'' strategy to decrease food safety risks associated with shell eggs (63 FR 27502, May 19, 1998).

Thus, FDA's requirement for a warning statement on untreated juice products has a rational foundation and is part of a comprehensive approach to solve a larger problem. The agency therefore finds no merit in the assertion that the agency's proposed actions are discriminatory when compared to the regulatory approaches that are already in place or that are being considered for other food products that have been associated with foodborne illness.

C. Regulatory Approach

6. Some comments asserted that the purpose of the juice labeling rule is to force manufacturers to pasteurize juices, particularly apple cider. Comments from some cider manufacturers contended that their customers don't want pasteurized cider, and a few of these comments contended that pasteurizing cider converts the product to apple juice.

While pasteurization is an effective and proven mechanism that has been shown to satisfy the pathogen reduction standard, it is not the only mechanism capable of achieving a 5-log reduction. As discussed in the HACCP proposal, the pathogen reduction performance standard is a performance-based, rather than process-based, standard. Thus, as addressed in response to comment 35, mechanisms other than pasteurization may be used to satisfy the pathogen reduction performance standard. Thus, FDA disagrees with these comments.

7. Some of the comments argued that a warning statement will not reduce the hazards associated with unpasteurized juice or make a safer juice industry.

The agency agrees that a warning statement will not directly reduce the hazards associated with juice products. However, the purpose of the warning statement is to provide consumers with information regarding the potential hazards associated with untreated juice and thereby to allow consumers, including those most vulnerable, to make informed choices. Thus, FDA expects that the warning statement will reduce the risk of illness because some of the at-risk consumers likely will choose not to expose themselves to the hazard.

The agency also acknowledges that warning statements will not directly make a safer juice industry. Indeed, it is for that very reason that the agency concurrently proposed a HACCP program to reduce or eliminate the hazards associated with juice products.

8. One comment contended that warning labels will encourage producers to ignore good manufacturing practices (GMP's) because of their belief that the presence of the warning statement will remove the producer's liability for the product.

The agency rejects the comment. The presence of the warning statement does not remove the manufacturers' responsibility of adhering to GMP's or his liability for the finished product. Regardless of this final rule, a juice product that is found to contain harmful bacteria would be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) and thus, illegal.

9. One comment asserted that the requirement for a warning statement is contrary to agency policy of disallowing adulterated products to be sold. This comment also asked whether a juice product that bears the warning statement would be subject to recall if it were found to be contaminated with pathogenic microorganisms.

The evidence available at this time documents that there is a risk of foodborne illness from consumption of untreated juice. The agency does not contend, nor does the validity of the juice labeling proposal require, a showing that all unpasteurized juice is adulterated. Thus, FDA disagrees that requiring a warning statement essentially permits adulterated food to be marketed. As noted, the warning statement is intended to provide consumers important information not otherwise available on the label or in labeling (namely, that a risk of serious illness exists if the products are consumed by certain groups of the population.) Upon the effective date of this final rule, a covered product that does not comply with the labeling requirement would be misbranded under sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n) and 343(a)(1)). Regardless of this final rule, a juice product that is found to contain harmful bacteria would be adulterated under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)) and thus, illegal. This adulterated status would persist regardless of whether product labeling included the warning statement.

Similarly, although FDA has no express authority to mandate the recall of adulterated foods, FDA fully expects that any manufacturer who has distributed an adulterated juice product would voluntarily recall that product as soon as a microbial contamination problem was identified.

10. Several comments suggested that FDA should implement HACCP requirements immediately rather than require warning labels on untreated juice products. Other comments supported the use of a warning statement on food products only as an interim measure until the agency establishes a more comprehensive solution to the problem of microbial contamination in juice.

In each of the recent agency documents regarding juice (i.e., the notice of intent (62 FR 45593 at 45594), the juice labeling proposal (63 FR 20486 at 20487), and the HACCP proposal (63 FR 20450 at 20457)), FDA tentatively concluded that the implementation of its proposed HACCP program is the most effective long-term measure for controlling pathogens and other safety concerns related to the production and distribution of juice products. As discussed in the juice labeling proposal, warning statements are intended to serve as a short-term alternative for almost all untreated juice products until

HACCP programs that ensure that the juice will be processed in a manner that meets the pathogen reduction performance standard can be developed and implemented by the juice industry. Once such HACCP programs are in place, the agency does not presently foresee the need for a warning statement on products processed in a manner that meets the pathogen reduction performance standard, and this final rule is consistent with that view. However, the agency's proposed HACCP regulations would not cover: (1) The operation of a retail establishment; or (2) the operation of a very small business that is also a retail establishment and that makes juice on its premises, provided that the establishment's total sales of juice and juice products do not exceed 40,000 gallons per year, and provided that the establishment sells such juice directly to consumers or other retail establishments. Thus, it is likely that not all juice products will be produced under a HACCP system. In addition, a program as comprehensive as the agency's proposed HACCP program requires more time to implement than a labeling requirement. This is particularly true in light of the provision in the juice labeling proposal that the warning statement requirement may be met, in the short term, by labeling (i.e., a sign or placard that is displayed at the point of sale) rather than by application of the warning statement to the product label (proposed § 101.17(g)(3)). FDA believes that the warning statement, together with HACCP, makes the agency's response to this problem a comprehensive solution. Therefore, the agency is making no changes to its regulatory approach in response to these comments.

11. Several comments expressed the opinion that use of the terms ''pasteurized'' or ''unpasteurized'' alone is sufficient to inform consumers of potential risks associated with consumption of juice products. Some of these comments maintained that use of the term ''fresh, unpasteurized'' would more clearly indicate that the juice is unprocessed.

Other comments agreed with the agency's rationale in the juice labeling proposal that a warning statement that merely characterizes juice as ''pasteurized'' or ''unpasteurized'', without also including the information about the nature and magnitude of the hazard, would be incomplete. Some comments noted that unpasteurized juice may have a reputation among many consumers for being a particularly fresh and healthful food. These comments contended that it is important to ensure that product labeling meets both the needs of consumers who are at risk of serious illness as well as the needs of consumers who prefer to purchase untreated juice because they perceive such products to be healthful.

In the juice labeling proposal, the agency fully discussed its rationale for tentatively concluding that not providing information about the nature and magnitude of the hazard presented by untreated juices would constitute misbranding of the product. The agency is concerned that some consumers do not know the significance of pasteurization and, therefore, would not be able to make an informed decision on whether to purchase and consume the products. In focus group research, FDA determined that, while most participants had a good understanding of what pasteurization was, a significant number of the participants did not. The agency acknowledged that indicating whether a product is ''pasteurized'' or ''unpasteurized'' may be useful to consumers who are seeking to purchase either type product. However, FDA tentatively concluded that use of the terms ''pasteurized'' or ''unpasteurized,'' alone, informs the consumer on the type of treatment, or lack of treatment, that a product has received and would not give consumers information about the risks presented by untreated juices. In reaching this tentative conclusion, the agency considered comments to the notice of intent that expressed opinions similar to the comments subsequently submitted to the juice labeling proposal. The latter comments provided no new information to provide a basis for FDA to change that tentative conclusion. Therefore, FDA is not adopting the suggested approach that, instead of the warning statement requirement, the agency require all juice products to be labeled as ''pasteurized'' or ''unpasteurized.'' Nonetheless, as a general matter, statements that are truthful and not misleading are always permitted under the act. Thus, manufacturers who choose to make a statement, on the product label or in labeling, that describes a juice product as ''pasteurized'' or ''unpasteurized'' may do so as long as the statement is factually accurate and is not presented in a manner that would cause the statement to be misleading.

12. One comment questioned FDA's proposal to require that untreated juice products bear a warning statement in light of the fact that the agency does not require foods containing known allergens, such as peanuts, to bear a warning statement.

FDA disagrees with the suggestion contained in this comment. The purpose of a warning statement is to provide consumers with important information that did not otherwise appear on the product label or in labeling. FDA recognizes that many foods contain substances (e.g., peanuts) that cause an allergic response in those persons sensitive to the substance. Current food labeling regulations require, in virtually all cases, a complete listing in the ingredient statement of all of the ingredients of the food. Consequently, the label of foods containing such substances already provides sufficient information to allow sensitive individuals to avoid food products that contain substances to which they are allergic. Thus, as a general rule, a statement warning about the potential for an allergic reaction is not needed to protect the public health. With untreated juice, there is no other disclosure regarding the potential presence of pathogens in unprocessed juice, and, due to the relatively recent nature of such risk, sensitive individuals (which may be as much as 25 percent of the general population) (Ref. 2) are not aware of the hazard.

13. Some comments contended that warning statements are not generally effective at preventing the targeted behavior, pointing to the failure of warnings on other commodities, such as cigarettes and alcohol, to have the desired effect. Other comments considered it likely that the proposed warning statements would be effective because the risks associated with consuming untreated juice are not widely known or understood and consumers would use the new information to make informed choices that they were unable to make without the new information. Some comments advocated the use of brochures or pamphlets outlining the risks associated with consumption of untreated juices as an alternative to a warning statement.

In its focus group research on juice labeling, and in recent survey results (Ref. 3), FDA confirmed that consumers are largely unaware of the potential hazards of consuming untreated juice. Thus, the proposed warning statement contains information that is new to consumers. This fact separates the proposed warning statement from warning statements on other commodities such as alcohol or tobacco where the information contained in the statement is already widely known and familiar to most people. Research on warning statement effectiveness has identified the lack of new information in the warning statement as the principal reason that warning

statements are ineffective (Ref. 4). Participants in the focus groups said that the information about the risks of untreated juice was new and would have a substantial impact on their juice product choices.

The agency agrees that the effectiveness of the warning statement would be enhanced by an educational campaign that provides consumers with materials such as brochures or pamphlets containing information giving a fuller context to the hazard. FDA is continuing to provide educational information to consumers concerning juice. However, the FDA focus group participants strongly expressed a need for product specific information that clearly identified a product, on its label, as ''unpasteurized'' and that described the nature of the hazard. The reasons given by the focus group participants were that this was new information to them and they considered such information necessary to make informed choices. Educational materials could be an adjunct to a warning statement, and the agency encourages firms to develop and provide them where possible. However, FDA believes that the warning statement required by this final rule is necessary to adequately and efficiently communicate to consumers the risks presented by unprocessed juice. Therefore, FDA declines the suggestion in the comments that educational materials such as brochures or pamphlets should substitute for the warning statement.

14. Several of the comments asserted that, in general, a warning statement would remind consumers of products such as cigarettes, which are well known to be a health hazard for the general population, or alcoholic beverages, which are well known to be harmful to the general population when consumed in excess or to a developing fetus when consumed by a pregnant woman. In essence, these comments contended that a warning statement on a juice product, which consumers perceive as healthful, is inappropriate because it casts that product in the same light as products that are a known health hazard.

FDA agrees that products such as cigarettes and alcohol have characteristics that present a known health hazard to the general population. However, these products also are subject to regulatory control mechanisms, other than warning statements, commensurate with their risk. Relative risk aside, FDA believes that the level of risk associated with untreated juice justifies the requirement for a warning statement. The focus group research reflects the importance of this information in that many focus group participants said that the risk information would have a substantial impact on their juice product selection. Even participants who said that they would continue to drink untreated juice products because of the perceived benefits also said that the information would influence whether they would give such products to their children.

15. Some comments maintained that a warning statement on covered juice products would be tantamount to stating that the products contain pathogens.

FDA does not agree with these comments. The agency's warning statement is carefully worded to state that the products in question ''may contain'' harmful bacteria. This statement is factually accurate.

16. Some comments pointed out that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) did not support warning statements.

The agency disagrees with the comments' view that NACMCF did not support a warning statement for juice products. In fact, NACMCF stated that it lacked sufficient data to evaluate the effectiveness of labeling statements as safety interventions or to help consumers make informed choices. Therefore, NACMCF declined to endorse labeling as an interim safety measure and instead endorsed implementation of a comprehensive HACCP program as a preventive system of hazard control to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. As already discussed, the agency has likewise tentatively concluded in the HACCP proposal that a HACCP program for juice products is the best long-term strategy for public health protection; the juice warning statement is intended largely as an interim measure to inform consumers about the potential risk associated with untreated juice products until the application of HACCP principles increases the safety of juice products. Thus, FDA is making no changes to its regulatory approach in response to these comments.

17. Several comments questioned the precedent set by FDA in applying a warning label to fresh juice. The comments noted that requiring this warning label establishes a regulatory trend which, if continued, would result in virtually all foods carrying warnings. Having too many warnings on food would make the warnings meaningless.

FDA agrees that too many warning labels on foods could result in loss of consumer credibility and effectiveness. However, the agency does not agree that it is establishing a trend toward too many warning labels. The agency has used the authority under sections 201(n) and 403(a)(1) of the act only rarely to require warnings or other cautionary label statements. FDA cannot require labeling unless the need for it meets the statutory criteria of being necessary either to clarify existing label statements or because of consequences that may result from customary or usual use of the food.

18. A few comments cited an agency memorandum that is part of the administrative record of the juice labeling proposal (Ref. 5). These comments interpreted the memorandum to reflect the agency's opinion that warning statements are an ineffective method for communicating with consumers or that the agency does not have data that show that warning statements are effective in convincing target populations to avoid a particular substance.

The agency does not agree with these comments. The key point of the memorandum is that warning statements need to be evaluated in consumer testing because it is difficult for experts to anticipate consumers' assumptions and prior beliefs about a product and its potential hazards. The memorandum identified communication problems encountered with a variety of proposed warning statements and concluded that the remedy to these kinds of potential problems is to subject proposed warning statements to consumer testing to determine if they communicate as intended. The memorandum underscored the need to test proposed options for the juice warning statement, and the agency did so, with the results summarized in a report that is in the administrative record of this rulemaking. This consumer testing helped the agency to identify a statement that can inform consumers about a previously unrecognized hazard without being overly alarming.

In addition, these comments incorrectly suggest that FDA has no basis for believing that warning statements can be effective. In fact, the memorandum focuses on the communication effectiveness of warning statements rather than the broader policy question of how well warning statements work in the marketplace. The intent of warning statements is to provide consumers with information necessary to make informed choices. Qualitative research suggests that warning statements are effective in alerting vulnerable populations to potential risks but that consumers' ultimate decisions are based on a variety

of considerations, including their prior experiences, personal preferences, the tradeoffs they are willing to make, and their awareness of particular risks gained by reading warning statements.

Because these comments misinterpret FDA's position, the agency is making no changes to its regulatory approach in response to these comments.

19. Some comments expressed the opinion that FDA acted contrary to public relations research theory by developing script guidelines used by focus group moderators. This comment asserted that, as a result, the focus group results were biased by FDA.

FDA disagrees with the assumption underlying this claim of bias—i.e., that the moderator of the focus groups was given a script. The agency has extensive experience conducting focus group studies, which are a qualitative type of research that generates discussion on the issues in question, allowing for many points of view and differing levels of interest and knowledge. The agency's goals in conducting focus group research are to understand how consumers think about the subject issues, to see how they react to language that the agency and other interested parties have suggested to convey health-related messages, and to uncover erroneous beliefs and assumptions about how consumers will think and respond to proposed communications. In FDA-sponsored focus group research, the moderator is a professionally trained neutral party, who is briefed on the subject matter of the study to the extent necessary to lead the discussion. The moderator works closely with FDA to ensure that the materials and questions meet the highest standards for the conduct of qualitative research. The moderator's guide is a primer to help the moderator cover the topics of interest rather than a ''script.'' Accordingly, the agency finds no merit in the assertion in the comment that the focus group studies were biased.

20. Some comments contended that a warning statement could have a potentially negative impact on consumers by discouraging the consumption of all fruit and vegetable juice products, regardless of whether the products had been processed to control pathogenic microorganisms. Some of these comments expressed the opinion that this negative impact could potentially carry over to other healthful products such as fruits and vegetables.

These comments provided no data or other information to substantiate the assertion that a warning statement on untreated juice products will result in a decreased consumption of all juice products or of fruits and vegetables generally. Nonetheless, FDA will seek to minimize any remote possibility that consumers' reaction to the juice warning statement would be to avoid all juice products or to avoid fresh fruits and vegetables by emphasizing in the agency's ongoing consumer education initiative that: (1) Most juice products are processed to control pathogenic microorganisms and therefore are safe; (2) the warning statement has a limited and targeted scope based on the distinctive characteristics of untreated juice products; and (3) the warning statement will be a reliable cue to tell whether a product has or has not been processed to control pathogenic microorganisms. Accordingly, FDA concludes that the concerns raised in these comments provide no basis to alter the agency's regulatory approach.

In the juice labeling proposal, FDA acknowledged that it would take time for manufacturers to make label changes and deplete existing label inventories. Accordingly, FDA proposed that, as a temporary alternative to providing the information on the label, firms could provide the warning statement in labeling, e.g., signs or placards, at the point of purchase.[2] Under proposed § 101.17(g)(3)(i), manufacturers could provide the warning statement in labeling until January 1, 2000, the next uniform compliance date for other food labeling changes. To relieve the burden on small businesses, proposed § 101.17(g)(3)(ii) provided that small businesses could provide the warning statement in labeling until January 1, 2001.

21. Some comments contended that consumers may not notice the warning in a sign or placard at all. Other comments expressed concern that the message would not be apparent to the consumer when the product was ready to be consumed or would not be apparent to other members of the household who did not have the opportunity to see the sign at the point of purchase.

Other comments expressed concern that consumers would not correctly link the warning message with the appropriate juice product. The comments stated that, for example, a sign may be placed outside a refrigerator that contains both pasteurized and untreated juice products and the label of many juice products does not inform the consumer as to whether the product has been pasteurized. As a consequence, consumers could choose not to purchase any product at all.

The majority of comments that addressed the issue of labeling as an interim means of compliance with the warning statement requirement opposed the length of time that labeling would be allowed. Some comments pointed out that, if the urgency of the public health concern justified the shortening of the comment period, then FDA should not allow an extended time for the warning statement to appear on the label. Other comments contended that FDA's notice of intent provided ample notice to firms to prepare for label changes because FDA urged voluntary compliance at that time.

Some of these comments also opposed the additional time allowed for small businesses to place the warning statement on the labels of their products. The comments asserted that the public health concern existed whether or not the firm was small.

FDA finds merit in these comments. The agency agrees that placards and signs may be less effective than package labels for the purpose of communicating product-specific information to consumers. FDA's experience with the voluntary labeling of fresh fruits and vegetables in supermarkets also indicates that this is the case. While the agency found high levels of voluntary nutrition labeling in supermarkets, consumer research showed that only a small proportion of consumers reported that they had seen this labeling in stores (Ref. 6).

However, as a practical matter, producers of unpasteurized juice need time to modify their labels to include the warning statement. In response to the concerns about the effectiveness of signs and placards, FDA is reducing the length of time that it will permit manufacturers to provide the warning statement in labeling. The label change being required is not complex. FDA believes that small business will not experience more difficulty than large businesses in making the change. Therefore, FDA is giving small and large businesses the same amount of time to make the change. Accordingly, the effective date of this final rule applies equally to all manufacturers of packaged juices, regardless of size. Thus, this final rule (§ 101.17(g)(4)) provides that, except for unpackaged juices (which have no label), the required warning statement may be provided in labeling at point of purchase, until 1 year from the date of compliance with the final rule. In essence, this provision provides

[2] The term ''label'' means any written, printed, or graphic matter on the immediate container of an article (section 201(k) of the act). The term ''labeling'' means all labels and other written, printed, or graphic matter either on any article or its containers or wrappers, or accompanying such article (section 201(m) of the act). Thus, signs and placards that appear at point-of-sale are a type of labeling.

manufacturers the alternative of using labeling for a single juice season. This flexibility will postpone by a juice season a manufacturer's need to revise and reprint labels that would be affixed to packaged untreated juice products.[3] During this interim period, the agency's ongoing food safety education campaign will help consumers to look for, and understand, juice labeling posted at the point of purchase.

The agency acknowledges that there are some costs associated with this revision to the proposed rule. FDA's analysis of the economic impact of this revision is discussed in section VIII of this document.

22. Some comments suggested that a more appropriate interim measure than the use of signs or placards would be the application of the warning statement to the product label via stickers. One comment estimated the cost of placing stickers with the warning statement on packaged containers. For 1,000 bottles, the comment estimated the cost to be $28.25. The estimate in the comment was based on several assumptions. First, the time and cost to design the sticker is negligible. Second, the total cost to pay the bottle supplier to apply the 1,000 labels is 70 cents. Third, there are no printing charges beyond the basic per unit cost of the label.

FDA acknowledges that firms could comply with the warning statement requirement through the use of stickers. Many manufacturers may find it more convenient to apply the warning statement to packaged product by means of stickers than to provide signs or placards to all retailers who sell their product.

However, there are costs associated with using stickers to revise a label. FDA disagrees with the estimate included in the comment because FDA disagrees with the underlying assumptions presented in the comment. First, there are always costs of specifying to the printer what the sticker will say and the way it will look, as well as costs of finding the printer to produce the stickers. The agency estimates that these administrative costs are $100. Second, it is not feasible to have bottle suppliers place labels on bottles this close to the beginning of the juice seasons. As some comments noted, bottles and labels for this season are already in inventory and waiting for the beginning of processing. The agency estimates the cost of applying the labels by multiplying the average rural hourly cost of labor ($13.00) by the number of hours it would take to label 10,000 gallon size packages (the average size of plant that will be using the warning statement) and the cost of extra equipment needed to apply this volume of labels. The agency estimates this cost to be $600. Third, printers levy one time charges for set-up in addition to the basic per unit cost of labels. The agency has estimated total printing costs for a 10,000 gallon operation to be $250. Thus, the agency's estimate of the cost of achieving compliance within 60 days through use of stickers is approximately $1,000. This is in contrast to the $100 agency estimate of the cost of achieving compliance through use of signs or placards. Thus, while FDA considers stickers an acceptable means of revising a label, in light of the cost differential between labels and placards, the agency is not persuaded that it should mandate the use of labels with stickers for the 1998 juice season. Accordingly, FDA is making no additional changes to its provisions for interim compliance with the warning statement requirement through labeling in response to these comments.

23. Some comments that objected to allowing juice product manufacturers to use labeling while they change labels noted that the USDA requirement for safe handling instructions on raw meat and poultry, which was issued in response to a similar public health concern, was effective 60 days after its publication, with no temporary allowance for labeling.

FDA acknowledges that the final regulation requiring safe handling label statements on meat and poultry products (59 FR 14528, March 28, 1994) became effective for comminuted products 60 days after publication, with no temporary allowance for labeling. However, the comment failed to fully describe the circumstances surrounding the FSIS rulemaking. On August 16, 1993 (58 FR 43478), FSIS published an interim final rule requiring the safe handling statements, with opportunity for comment. On October 12, 1993 (58 FR 52856), FSIS published a final rule requiring the safe handling statements, with an immediate effective date. On November 4, 1993 (58 FR 58922), FSIS withdrew the October 12, 1993, rule as a result of litigation and reproposed its regulations requiring safe handling instructions. Finally, FSIS published the final rule cited by the comments, with an effective date of 60 days—i.e., May 27, 1994—for comminuted products.[4] Because the safe handling statements did not change between October 12, 1993, and March 28, 1994, the meat and poultry industry had approximately seven and one half months to prepare new labels. Moreover, in its rulemaking and subsequent FSIS Directives, FSIS allowed the use of any labels that bore the safe handling instructions proposed in August 1993, until the inventory was depleted.

Given these circumstances, the alternative provided by§ 101.17(g)(4) that manufacturers may comply with the warning statement requirement through labeling is, as a practical matter, similar to the added time that manufacturers received to comply with the FSIS rule requiring safe handling statements as a result of FSIS' withdrawal of the October 12, 1993, rule. The agency believes that these comments require no changes to the provisions of § 101.17(g)(4).

III. Covered Products

A. Unpackaged Juices

In the juice labeling proposal, FDA proposed to require a warning statement on packaged juice products not processed to prevent, reduce, or eliminate pathogens. FDA specifically noted that the agency's proposal excluded unpackaged juice sold for immediate consumption (e.g., juice sold by the glass in restaurants, grocery stores or other food establishments). Comments from the restaurant industry supported the exclusion from the warning statement requirement of unpackaged juice sold for immediate consumption. Other comments requested that the warning statement requirement not exclude unpackaged juice products. In general, these comments asserted that unpackaged fresh juices pose the same risk as fresh juices sold in containers.

24. A few comments pointed out that unpackaged juices have accounted for some of the cases of serious illness that have been associated with consumption of fresh cider. Another comment expressed the view that contamination of fresh juices may be more likely in retail establishments that prepare unpackaged juices than in manufacturing facilities that prepare packaged juices because personnel who work in retail establishments may lack relevant training that ordinarily is provided to personnel who work in manufacturing facilities. Other comments contended that the agency's proposal that the warning statement

[3] As discussed in section VI of this document, this final rule establishes a compliance date for apple juice and apple cider that will closely coincide with the 1998 fresh apple juice season. This final rule also establishes a compliance date for juice products other than apple juice and apple cider that will closely coincide with the 1998 fresh citrus juice season.

[4] The effective date for all other meat and poultry products was July 6, 1994.

requirement apply only to packaged juices would create consumer confusion. For example, consumers would be unable to distinguish, in all circumstances, between unlabeled juice that had been processed to control pathogenic microorganisms and unlabeled juice that had not been so processed. Most of these comments asserted that the warning statement requirement should apply equally to packaged and to unpackaged juices.

As part of its decision to propose to require a warning label on untreated juice, FDA considered, among other things, the issues raised in these comments, and tentatively concluded not to specifically require the labeling of unpackaged juice. As stated in the juice labeling proposal, this approach is consistent with the agency's food labeling regulations which do not apply to food distributed to consumers in unpackaged form unless specifically noted in the regulations (63 FR 20486 at 20487). Because these comments did not provide any information that the agency had not considered at the time it published the proposal, the agency is maintaining its position to not include unpackaged juice in the scope of the warning labeling requirement.

B. Apple Juice Products versus Non-Apple Juice Products

Several comments, almost exclusively from citrus juice interests, asserted that the labeling requirement should apply only to apple juice and apple juice products and should not apply uniformly to juices of other fruits, especially citrus fruits, or to vegetable juices. The comments provided a number of reasons as justification for a differential application of the warning statement requirements. FDA discusses these specific comments, and the agency's response, below.

25. Some comments claimed that the extraction methods for citrus juices justify excluding such juices from the warning statement requirement. Specifically, comments asserted that the extraction of apple juice necessarily involves contact of the expressed juice with a substantial portion of the peel surface for an extended period of time, during which pathogenic organisms on the peel can pass into the juice. The comments asserted that, in contrast, the extraction of citrus juice involves contact of the expressed juice with a small fraction of the peel surface for a period of time much shorter than that for the extraction of apple juice, thereby limiting the opportunities for microorganisms on the peel to pass into the juice. In addition, one comment stated that the smooth surface and disposable outer peel of citrus fruit make it easier to sanitize and prepare citrus fruit for juice extraction. This comment also stated that drops (i.e., fruit that has fallen to the ground) are not used in the fresh citrus juice industry, the extraction method typically used allows less than 2 percent of the presanitized peel surface to come into contact with the juice, and the interior of the citrus fruit is sterile.

FDA does not agree that the described differences in juice extraction methods, with concomitant differences in peel/juice exposure, justify the selective application of the warning statement requirement. The agency acknowledges that the physical characteristics of citrus fruits may help to facilitate safe and sanitary citrus juice extraction operations. However, the comments did not include sufficient data to demonstrate that these factors are sufficient to ensure the safe and sanitary processing of citrus juices. Moreover, the significance of the peel-juice contact as a source of pathogens that may be present in the juice depends on the microbial load on the peel; that initial microbial load may vary with preextraction conditions. In addition, the comments provided no substantive information to establish the rate of transfer of pathogens from peel to expressed juice; thus, a minimum timeframe for contamination remains unknown.

26. One comment asserted that citrus juices should be exempt from the warning statement requirement because the citrus industry is rapidly adopting the following practices to achieve, at a minimum, a 3-log reduction in microbial count: (1) A grading line to remove compromised fruit; (2) rinsing stations; (3) washing fruit with commercial cleaning agent and brush scrubbing; (4) application of sanitizer; (5) heat dryers; (6) extraction equipment that minimizes the amount of peel that contacts the juice; and (7) imposition of good manufacturing practices (GMP's) set out in part 110 (21 CFR part 110).

The agency agrees that the described operations are major pathogen reduction steps and would likely result in a reduction of pathogen levels. Indeed, in the HACCP proposal, the agency acknowledged that it is possible that whole oranges with an intact skin may be processed so that pathogens on the surface of the fruit are destroyed (63 FR 20450 at 20478). However, once again, the comments provided no data or other substantive information to verify that such operations have been adopted industry-wide. In addition, the comments claimed only that these processing practices allowed the citrus industry to achieve, at a minimum, a 3-log reduction in microbial count. As noted, both in the proposed rule (proposed § 101.17(g)(6)) and in this final rule (§ 101.17(g)(7)), the pathogen reduction performance standard would require a 5-log reduction in pathogens. Moreover, consistent with customary scientific practices, the method that produces the 5-log reduction should be validated. Thus, the comments do not establish that the citrus juice industry is universally or automatically meeting the pathogen reduction standard established in this final rule. Accordingly, the comments did not provide a basis for the agency to exclude citrus juices from the warning statement requirement. However, as discussed later in this document (see comment 42), the agency believes that citrus processors should be able to achieve and validate a 5-log reduction.

27. Some comments asserted that the chemical composition of certain fruits and vegetables justifies differential application of the warning statement requirement.

The agency recognizes that various fruits and vegetables differ in their indigenous chemical composition. In fact, even within a variety of a particular fruit or vegetable, there can be some variation in composition depending on growing conditions. However, the comments provided no data to show how chemical composition of a juice bears on its safety. The comments also provided no data to show how chemical attributes that are unique to citrus products will ensure the safety of fresh citrus juices. Therefore, FDA does not agree that differences in chemical composition of various fruits and vegetables and their juices justify the comments' request that certain juices not be subject to the warning statement requirement.

28. Finally, some comments asserted that differences in the degree to which citrus juices have been associated with illness outbreaks justify exempting citrus juices from the warning statement requirement.

The agency disagrees. A 1997 study of recombinant *E. coli* 0157:H7 growth in apple juice and orange juice indicated that citrus juices provide an environment for growth of this microorganism (Ref. 9). In the study, there was only a small decline in numbers of *E. coli* 0157:H7 inoculated into orange juice over a 24-day period at refrigeration temperatures. The fact that *E. coli* 0157:H7 can survive in citrus juice and the fact that human illnesses from other pathogens have been traced epidemiologically to citrus juice demonstrates that, if contaminated,

these juices have potential to cause human illness. Therefore, the agency finds no basis in the comments to conclude that the level of association of citrus juices with illnesses of public health significance is so low as to justify their exclusion from the warning statement requirement.

29. A few comments questioned whether the warning statement requirement should apply to carrot juice because there have been no outbreaks of illness linked to this product.

FDA acknowledges that there are no documented incidents of illness associated with carrot juice sold commercially. This lack of reported incidences may be due to lower exposure because of the total amount of carrot juice consumed. [5]

FDA believes that this absence of documented instances of illness does not justify exempting carrot juice from this final rule. According to information available to FDA, carrot juice is one of the top three fresh juices sold, following orange and apple juice. Because it is derived from a root vegetable, carrot juice has the potential to be directly contaminated with soilborne pathogens. In addition, carrot juice has a higher pH (i.e., it is less acidic) than juices such as apple juice or orange juice, and thus, will better support the growth of microorganisms, including pathogens, which a juice with a more acid pH is more likely to inhibit. In addition, carrot juice itself is a rich source of nutrients that will support microbial growth. Therefore, the agency concludes that there is no basis to exclude carrot juice from § 101.17.

30. Several comments requested clarification on which products are covered by the proposed rule. Comments asked whether a final product that contained a diluted pasteurized juice needed to be labeled if the final product itself is not pasteurized. Other comments inquired about citrus oils, juice concentrates not packaged directly for consumer sale, and lemon and lime juice concentrates that are not sold as beverages. A few comments asked whether certain juices were subject to the warning statement requirement because such juices are sold for use as ingredients in other beverages, such as wine or hard cider.

In considering these comments, FDA identified three questions that bear on whether a particular juice product is subject to the warning statement requirement. First, does the product meet the definition of ''juice'' in § 101.17(g)(1)? With respect to the specific products described in the comments, FDA advises that juice concentrates not packaged for retail sale to consumers meet the definition of ''juice'' in § 101.17(g)(1). Likewise, lemon and lime concentrates, which often are sold for use as ingredients in beverages such as a blend or ''punch,'' also meet the definition of ''juice'' under § 101.17(g)(1). Finally, juices sold for use as an ingredient in either wine or hard cider, which are beverages, are ''juice'' within the meaning of § 101.17(g)(1). In contrast, citrus oils are not ''juices'' under § 101.17(g)(1) because they are not aqueous liquids.

The second question that bears on whether a particular juice product is subject to the warning statement requirement is whether a product that is ''juice'' within the meaning of § 101.17(g)(1) has been processed in a manner that satisfies the pathogen reduction performance standard in § 101.17(g)(7); if so, such ''juice'' is exempt from the warning statement requirement. Thus, neither a pasteurized juice concentrate nor a beverage containing such a concentrate would be subject to the warning statement requirement, as proposed, because a pasteurized ''juice'' satisfies the pathogen reduction performance standard.

The third question that bears on whether a particular juice product is subject to the warning statement requirement is whether the product is intended for retail sale to consumers or is being sold for use as an ingredient in the manufacture of another beverage. FDA acknowledges that, under proposed § 101.17(g)(1), the requirement for a warning statement applied to any juice sold as such or used as an ingredient in another beverage. FDA's proposal to require the warning statement on juice sold for use as an ingredient in another beverage was intended to ensure that manufacturers of beverages had access to information about whether a juice ingredient that they include in their product had been processed in a manner to satisfy the pathogen reduction performance standard. Such information is necessary to allow manufacturers of beverages to comply with the warning statement requirement. However, after consideration of the comments that questioned whether juice sold for use as an ingredient is subject to the warning statement requirement, FDA has reconsidered its proposal.

The warning statement is intended to inform consumers of the hazards presented by untreated juices so that they may make informed choices. Although the use of this warning statement on the label or in labeling of a juice product that is being shipped for use solely in the manufacture of other foods or that is to be processed, labeled, or repacked at a site other than originally processed could serve to inform manufacturers who receive the ingredient that the juice is untreated, the same goal of providing information to manufacturers could be accomplished by customary trade practices. For example, a statement that describes whether the juice has, or has not, been processed in a manner to meet FDA's pathogen reduction performance standard could be included on an invoice or product specification sheet.

Accordingly, in this final rule FDA is adding new § 101.17(g)(3) to clarify that juice that is not for distribution to retail consumers in the form shipped and that is for use solely in the manufacture of other foods or that is to be processed, labeled, or repacked at a site other than originally processed, is exempt from the warning statement requirement, provided that for juice that has not been processed in the manner described in § 101.17(g)(7), the lack of such processing is disclosed in documents accompanying the juice, in accordance with the practice of the trade.

C. The Proposed Pathogen Reduction Performance Standard

As discussed in section I of this document, proposed § 101.17(g)(6) of the juice labeling proposal is directly linked to the pathogen reduction performance standard that is part of the agency's HACCP proposal (proposed § 120.24). As discussed in both the juice labeling proposal and the HACCP proposal, these two proposed regulations would function together as a comprehensive program to address the incidence of foodborne illness related to consumption of fresh juices and to ultimately address the safety of all juice products.

31. Several comments opposed the pathogen reduction performance standard that FDA included in both the juice labeling proposal and the HACCP proposal. Under proposed § 101.17(g)(6), the requirement for a warning statement would not apply to juice processed in a manner that

[5] Alternatively, it is possible that this lower rate of reported incidences is related to some inherent characteristics of this product. The agency is aware that research shows that carrot juice contains a broad spectrum of antimicrobial activity due to the presence of phytoallexins. This activity may be useful as a barrier to kill or prevent the growth of *Listeria monocytogenes* in particular, and may possibly also function to keep in check other foodborne pathogens and spoilage microorganisms. Nonetheless, the conditions under which the antimicrobial effects of carrot juice are manifested have not been fully defined. Accordingly, at this time, such research does not establish a basis to exclude carrot juice from the warning statement requirement.

satisfies the pathogen reduction performance standard—i.e., juice processed such that there is, at a minimum, a 5-log (i.e., 100,000-fold) reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions. (The proposals defined the ''pertinent microorganism'' as the most resistant microorganism of public health significance that is likely to occur in the juice.) Some comments asserted that the 5-log performance standard is unnecessary and unreasonable and questioned the scientific basis of the NACMCF recommendation of that standard.

Based on information the agency has received in response to the juice labeling proposal, FDA has concluded that the pathogen reduction performance standard in proposed § 101.17(g)(6) is the most appropriate standard to ensure that juice is safe. The agency advises that no food processing method can be shown scientifically to achieve a ''zero'' probability that a pathogenic microorganism will be present in the processed food. However, food processing methods can be shown scientifically to reduce, by mathematical increments (i.e., by ''logs''), the level of pathogens that may be present in food and as a result to reduce any potential risk of illness from the food. As explained in the HACCP proposal (63 FR 20450 at 20477), the 5-log reduction is a performance standard intended to provide assurance that juice produced consistent with this standard does not pose more than a tolerable level of risk of illness. FDA notes that the 5-log value was arrived at by consensus of the Fresh Produce Working Group of the NACMCF, and subsequently adopted by the NACMCF, as a target that would provide adequate public health assurances while minimizing the impact of treatments on the sensory attributes of the juices (Ref. 10).

With respect to the comment that questioned the basis for the NACMCF's recommendation, FDA advises that the agency relied on the collective judgment of this group of experts. The comment did not present specific challenges to the scientific basis underlying NACMCF's recommendation, nor did it provide a basis, data, or other information to support any other performance standard.

For these reasons, these comments have not persuaded FDA to make any changes to the pathogen reduction performance standard in proposed § 101.17(g)(6).

32. One comment suggested that a zero tolerance for *E. coli* O157:H7 would be more appropriate than the adoption of a performance standard. Another comment requested that a ''safe harbor'' bacterial load level be added to or used in lieu of the 5-log reduction criteria.

FDA disagrees with these comments. In general, FDA would consider a food product that contains pathogenic microorganisms to be adulterated under section 402(a)(1) of the act because it would contain a poisonous or deleterious substance that may render the food injurious to health. In contrast, FDA considers a total bacterial plate count as an indication that the food may have been prepared, packed or held under insanitary conditions. FDA would generally conduct an inspection of the processing facility to determine whether insanitary conditions exist in the facility. If insanitary conditions are found in the facility, any food produced under such conditions would be adulterated under section 402(a)(4) of the act.

The agency advises that while it could conceivably issue a tolerance for *E. coli* O157:H7, FDA has authority under section 402(a)(1) of the act to take regulatory action against any juice that contains a pathogenic microorganism that may render the juice injurious to health. Further, it would be impractical for juice processors to establish procedures to ensure actual compliance with such a tolerance because it would be necessary to channel a significant portion of the end product into testing to provide a statistically valid indication of compliance. Finally, a zero tolerance means the pathogens are undetectable in the food. For microbiological methods this is about one pathogen per 100 grams. For *E. coli* O157:H7, this is not a safe level. In contrast, the performance standard is a way to ensure that the presence of *E. coli* O157:H7 is much lower than that. In addition, the performance standard required in proposed § 101.17(g)(6) is a tool that can be applied in a practical manner to processing to ensure that all the juice has been processed to control pathogens.

Regarding the use of a ''safe harbor'' bacterial load level, FDA considers a ''safe harbor'' bacterial load level to mean a maximum total bacterial count. As discussed, under section 402(a)(4) of the act, very high aerobic plate counts may indicate that the food has been prepared, packed, or held under insanitary conditions, which may contribute to increased risk of pathogen occurrence and outgrowth. FDA has established regulations in part 110 concerning CGMP in manufacturing, packing, or holding human food that already apply to juice. Because these regulations directly address appropriate conditions for preparing, packing, and holding food, a ''safe harbor'' bacterial load level would not directly address such conditions, FDA concludes, based on comments received in response to the juice labeling proposal, that establishing a ''safe harbor'' bacterial load level is not necessary.

33. One comment stated that the proposed pathogen reduction performance standard is premature given that the source of *E. coli* 0157:H7 contamination in apples is not known. Additional comments questioned whether E. coli 0157:H7 could be found anywhere other than in bovine manure.

The agency disagrees that the proposed pathogen reduction performance standard is premature because the source of *E. coli* O157:H7 is unknown. First, although *E. coli* will likely be the ''pertinent'' microorganism of public health concern for apple juice, it may not be the ''pertinent'' microorganism for other juices. Second, in some outbreaks, a likely source has been determined (Ref. 11). Although *E. coli* O157:H7 may be found in bovine manure, there are other possible sources for this pathogen, such as deer manure (Ref. 12). Third, regardless of its source, *E. coli* O157:H7 is a pathogen that has been found to be present in fresh juice, including apple juice (Ref. 12). In fact, the agency's proposed pathogen reduction performance standard is a logical response to the comment's assertion that the source of *E. coli* O157:H7 in products such as apple juice is unknown. The knowledge that *E. coli* and other pathogens have been found in juice and have caused illness indicates that a processor must take steps (i.e., pathogen reduction steps to achieve the performance standard) to ensure that juice is safe. These steps must include prevention of contamination, destruction of any pathogens of concern that may be present, or both. If future research determines new sources of *E. coli* O157:H7 or other pathogens in juice products, processors could then develop appropriate measures to prevent contamination from these sources and apply measures that are determined to be effective toward the pathogen reduction performance standard.

34. Several comments requested clarification on which aspects of a process could be included for the purpose of meeting the proposed pathogen reduction performance standard. Respondents asked about the appropriate place in the production operation to start measuring pathogen reduction and whether specific farming,

harvesting, and processing practices may be counted toward meeting the proposed pathogen reduction performance standard.

The pathogen reduction process control can begin at the point at which the processor has control over the preparation of the product. The 5-log reduction may be accomplished cumulatively (e.g., through a combination of special culling, use of appropriate sanitizers, and specific extraction methods) or by a one-step process (e.g., pasteurization). The 5-log reduction standard is designed to achieve appropriate microbial risk reduction under all conditions that may be encountered in the manufacture of juice, including the conditions in which the fruit is grown and harvested. Therefore, farming, harvesting, and processing practices may be considered in achieving the 5-log reduction, so long as the processor has control over these activities and the control measures are effective.

35. FDA received a number of comments regarding achievement of the proposed pathogen reduction performance standard. Some comments expressed the opinion that the rule would in essence require pasteurization. Other comments asked about options for achieving the 5-log reduction, such as ultraviolet (UV) radiation, pulsed light, or sodium benzoate. Additionally, several comments indicated that instituting a ''no dropped fruit'' policy, using potable water, and following CGMP's would provide an adequate measure of safety for juice products.

FDA disagrees that the proposal would require pasteurization of juice products. While pasteurization currently may be the most practical process to achieve the proposed pathogen reduction performance standard, it is not the only alternative. A manufacturer who demonstrates that the measures discussed in the comments (i.e., use of UV radiation, pulsed light, and sodium benzoate) are effective in controlling pathogenic microorganisms may apply such measures in achieving the pathogen reduction performance standard.

FDA agrees that the various steps proposed in the comments (e.g., ''no dropped fruit'') have the potential to contribute to the reduction of microbial contamination. Animal manure, whether applied as fertilizer or from animals (e.g., cows, deer) present in orchards, can be a source of *E. coli* O157:H7. Not using produce that has come into contact with the ground reduces the risk of this contamination. However, there are other possible sources of contamination that may not be avoided as easily. For example, dust, insects, and birds may be vectors of contamination. Likewise, a water supply that does not meet the requirements of § 110.37(a) (21 CFR 110.37(a)) that any water that contacts food or food-contact surfaces be safe and of adequate sanitary quality may also be a source of contamination.

FDA believes that these comments require no changes to its proposed regulations.

36. Other comments asserted that adherence to State-enforced GMP's, quality assurance programs (QAP's), or HACCP programs, or any validated HACCP program should be as acceptable as a means of satisfying FDA's proposed pathogen reduction performance standard as would be adherence to the proposed Federal (i.e., FDA) HACCP program.

FDA recognizes that State GMP's, QAP's, and HACCP programs can serve as a useful foundation to assist processors in achieving public health goals and may in fact allow a manufacturer to attain the performance standard required by proposed § 101.17(g)(6). Nonetheless, these programs vary from State to State and may not exist in some States. Therefore, juice that is in interstate commerce may be subject to one or more State requirements or to no State requirements. Accordingly, FDA continues to see a need for a comprehensive Federal regulatory approach for all juice products.

The agency encourages processors to develop and use an appropriate HACCP program in the processing of juice. However, FDA emphasizes that it had tentatively concluded in the HACCP proposal that an appropriate HACCP program must include control measures that will produce, at a minimum, a 5-log reduction in a pertinent microorganism. As noted, the warning statement will not be required on products produced under a HACCP program validated to achieve the pathogen reduction performance standard described in proposed § 101.17(g)(6).

37. Several comments questioned why, as part of its HACCP program, the agency is proposing a pathogen reduction performance standard rather than requiring pasteurization. A few comments contended that to ensure the safety of juices, the agency should require that all juices be pasteurized. Other comments suggested that not all 5-log reduction methods are equally effective and that some could be less effective than pasteurization.

The agency does not believe that mandating pasteurization is necessary. Pasteurization is one method of achieving the pathogen reduction performance standard proposed in the HACCP rule and established in this rule as the basis for exemption from the warning statement requirement. FDA believes that establishing a performance standard rather than mandating the use of a particular process (such as pasteurization) provides flexibility in how the pathogen reduction can occur and will permit the development of new technology. Importantly, however, a performance standard will not preclude the use of pasteurization to achieve the standard. The agency recognizes that some methods may achieve a 5-log reduction in a more direct manner than other methods (i.e., in one step versus in several steps). Nevertheless, by its very definition, a 5-log reduction in the pertinent microorganism is the same reduction—i.e., a reduction by a factor of 100,000—regardless of the method used.

For these reasons, in this final rule, FDA is maintaining its performance standard approach rather than mandating pasteurization.

38. A few comments stated that pasteurization would not solve all the problems with juice and could provide a false sense of security to consumers.

The agency agrees with these comments. Pasteurization does not address all problems that may occur during the manufacture of juice and that have an adverse effect on public health. Recognition of the multiplicity of hazards that are reasonably likely to occur and of the need for their control is the basis for the agency's HACCP proposal.

39. One comment stated that the juice labeling rule was not necessary because the pH in cider is too low for pathogens to grow in it.

The agency agrees that acidic pH is generally considered to be an unfavorable environment for the survival of pathogens. However, as discussed in detail in both the labeling and HACCP proposals, there are documented cases of outbreaks of disease caused by *E. coli* 0157:H7 or other pathogens in apple juice and apple cider. Indeed, these outbreaks are of particular concern because apple cider typically has an acidic pH (i.e., a pH of approximately 3.5 to 4.0), due to the presence of malic and lactic acids in apples. Contrary to longstanding beliefs regarding microbial tolerance of acidic environments, the available evidence shows that *E. coli* 0157:H7 strains are tolerant of acid pH, particularly when held under refrigerated conditions consistent with juice manufacturing (Ref. 13). Therefore, the agency believes

that while acidity may be lethal or inhibitory to some pathogens, it cannot be relied upon as a control measure to reduce the risk of foodborne illness.

40. A few comments asked that FDA provide a grace period on labeling compliance for processors using a validated HACCP program without the pathogen reduction performance standard until the proposed HACCP rule for juices becomes final.

As discussed in the HACCP proposal, the agency has tentatively concluded that an adequate HACCP program for juice must include the pathogen reduction performance standard in proposed § 120.24. Accordingly, the agency incorporated this standard into the juice labeling proposal in proposed § 101.17(g)(6). As discussed above, there are no data or other information in the comments to the juice labeling proposal that demonstrate that the proposed pathogen reduction performance standard is not the appropriate standard.

FDA acknowledges that comments that are submitted to the HACCP proposal may persuade the agency to implement an alternative to the pathogen reduction performance standard set out in the HACCP proposal. However, in the interim between the issuance of this final rule and any final rule based on the HACCP proposal, it is the agency's best judgment, based on the information in the administrative record of this proceeding, that any HACCP program that does not satisfy the proposed pathogen reduction standard—i.e., a 5-log reduction in the pertinent microorganism—cannot be considered adequate for safe juice production, and thus, cannot provide the basis for exempting a product from the warning statement requirement. Accordingly, in this final rule, FDA is retaining (as § 101.17(g)(7)(i)(A)) the provision of proposed § 101.17(g)(6) that the requirement for a warning statement not apply to juice processed in a manner that will produce, at a minimum, a 5-log (i.e., 100,000 fold) reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions.

However, in recognition of the fact that the agency has not completed its rulemaking on the HACCP proposal, in this final rule FDA is broadening the exemption from the warning statement requirement in proposed § 101.17(g)(6) to include (as § 101.17(g)(7)(i)(B)) juice processed in a manner that will achieve or exceed any pathogen reduction performance standard ultimately established in any final regulation requiring the application of HACCP principles to the processing of juice. In the event that the agency's judgment when it completes the HACCP rulemaking is that the interim pathogen reduction performance standard is more strict than necessary, this amendment will automatically ensure that manufacturers would be able to use the final HACCP pathogen reduction performance standard in determining whether their juice products require the warning statement. In the event that the agency's judgment when it completes the HACCP rulemaking is that the interim pathogen reduction performance standard should be altered, FDA will take the appropriate steps to amend this rule.

41. A few comments stated that a HACCP program (without a performance standard) is adequate because there is no evidence of foodborne illness in fresh apple juice or cider from processors using HACCP programs with GMP's, sanitation standard operating procedures (SSOP's), and raw material standard operating procedures (SOP's).

The issues raised in these comments are beyond the scope of this labeling document. The agency notes that it has tentatively concluded in the HACCP proposal that an appropriate HACCP program must include control measures that will produce, at a minimum a 5-log reduction in a pertinent microorganism. The basis for the proposed requirement was discussed in that proposal (63 FR 20450 at 20477). FDA will respond to these comments fully in the HACCP final rule.

42. Several comments requested guidance on how to determine if their process meets the 5-log reduction.

There are essentially two ways for processors to determine if their process accomplishes a 5-log reduction in a pertinent microorganism. Processors or other entities (such as researchers or a State) may test a particular process with a known level of the target pathogen or an appropriate surrogate microorganism that possesses similar properties to the target pathogen and determine whether the process is reducing the microorganism to the appropriate level. Alternatively, manufacturers of processing equipment or sanitizers may test the process that they are recommending for juice processing and supply the applicable information on their product to the juice processor. Consistent with customary scientific practices, the method that produces the 5-log reduction should be validated.

As discussed in the HACCP proposal (63 FR 20450 at 20478), the agency noted that it may be feasible for a processor to achieve a 5-log reduction in a target pathogen in citrus juice using a combination of CGMP's, sanitation SOP's, and the following three measures: (1) Culling and grading, (2) washing, brushing, and sanitizing, and (3) appropriate methods of extraction. If this procedure is validated, it is unlikely that processors of fresh orange juice, and perhaps other fresh citrus fruit juices, will have to implement pasteurization in order to achieve a 5-log reduction in pathogenic bacteria.

In fact, the agency believes that citrus processors should be able to achieve and validate a 5-log reduction without pasteurization. To provide more detail, a system that could achieve a 5-log reduction without pasteurization would likely include, at a minimum: Strict control of incoming material to ensure fruit are intact and clean (including not using dropped fruit); effective employee hygiene and facility sanitation; appropriate chemical sanitizers; juice extraction equipment that minimizes contact of juice with peel; refrigeration immediately after juicing; and bottling in a closed system to minimize environmental contamination. FDA would be willing to meet with manufacturers or groups of manufacturers to discuss and evaluate their proposed processes.

In addition, the agency will make available, in accordance with part 20 of the agency's regulations (21 CFR part 20), information on various processes that it learns have been validated to achieve a 5-log reduction in order to help processors meet the performance standard.

43. One comment requested a definition of ''moderate abuse conditions.''

Moderate abuse conditions, as described in the HACCP proposal (63 FR 20450 at 20478), occur when unusual circumstances arise during regular handling of the product. Unloading a truck on a hot day where the product may sit on a loading dock for a short period of time is one example of moderate abuse. Another example of moderate abuse is illustrated by a consumer who purchases a product on a warm day, places it in a car, and then runs errands before refrigerating the product. In FDA's view, moderate abuse does not include exposure to high temperatures for extended periods of time.

IV. The Warning Statement

A. General Comments

In the juice labeling proposal, FDA tentatively concluded that certain informational elements were essential to the warning statement, i.e., the statement of the hazard, a description of

why the product may have the hazard, and an identification of the consumers at greatest risk. Consequently, FDA proposed to require the following warning statement on covered products:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria which can cause serious illness in children, the elderly, and persons with weakened immune systems.

In this final rule, FDA is replacing the phrase ''which can cause serious illness * * *'' with the phrase ''that can cause serious illness * * *''. This change provides clarity and is not a substantive change.

44. Some comments generally opposed the language in the warning statement on the grounds that it is frightening, confusing or misleading. Some of these comments contended that consumers associate warning statements with products such as pesticides, poisons, or carcinogens.

The agency's intent in requiring a warning statement on untreated juices is to inform consumers that such juices may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems. This statement will ensure that consumers have the information that they need to make informed choices. To achieve this goal, the statement needs to present information about the hazard. By its very nature, any statement that informs consumers about a hazard, particularly a hazard that consumers do not expect, would be, to some extent, ''frightening.''

FDA conducted consumer focus group research to anticipate the likely impact of these statements on the public. This research tested variations in wording to evaluate whether different statements and specific words would produce exaggerated or inappropriate consumer understanding.

Some participants initially considered the warning statement to be alarming because it appeared to contradict their assumption, based on a lifetime of experience consuming these products, that all juices are safe and healthful foods. However, most of the focus group participants who were alarmed by the statements mistakenly assumed that juice products that they routinely consumed were not processed to control pathogenic microorganisms. After receiving information that untreated juice comprises less than 5 percent of all juice consumed, and that most juice products in supermarkets are processed to control pathogenic microorganisms, focus group participants were much less alarmed by the warning statements. Importantly, after receiving this information, many focus group participants appreciated the warning statement because they recognized that it would help them distinguish juice products that were more safe from those that are less safe because the latter products may contain pathogenic microorganisms. Even consumers of untreated juice products such as unpasteurized apple cider were reassured to know that the warning statement would be applied to a narrow and distinctive segment of juice products that had characteristics that specifically warranted the statement because such products had not been processed to control pathogenic microorganisms.

Based on this focus group research, FDA concludes that giving consumers accurate information on untreated juices to better inform their choices is likely to have the desired effect.

45. One comment suggested that the warning statement be changed to reflect that contamination of unpasteurized cider is the cause of a potential hazard. The comment contended that FDA's proposed statement seems to suggest that the presence of harmful bacteria is a matter of a statistical chance and is inherent in the cider, rather than a consequence of contamination of the cider.

FDA disagrees with this comment. While FDA has determined that the fact that bacteria may be present in juice is a material fact within the meaning of section 201(n) of the act, the agency is not persuaded that the process by which the bacteria came to be present is also material information. The comment did not provide a rationale for why the information on what causes bacteria to be present in juice is material with respect to the health hazard. Therefore, the agency is not making this suggested change.

B. Comments on the Term ''Warning''

46. Some comments that supported the use of the word ''WARNING'' in the warning statement asserted that this very explicit term is necessary so that consumers notice and give appropriate attention to the hazard message. Other comments recommended specific alternatives to the term ''WARNING,'' such as ''NOTICE,'' ''CONSUMER ADVISORY,'' ''CONSUMER ALERT,'' ''HAZARD NOTICE,'' ''HAZARD ADVISORY,'' or ''HAZARD ALERT.'' Some of these comments suggested that the term ''WARNING'' be used only for apple juice and that an alternative term, such as ''NOTICE,'' ''ATTENTION,'' or ''CONSUMER ADVISORY'' be used for juice products that pose a lower risk than that posed by apple juice. One comment noted that for oysters a consumer advisory rather than a warning statement is used to inform consumers of the hazard associated with *Vibrio vulnificus* which has a 50 percent mortality rate associated with illness. Comments acknowledged that the use of the same term for all juice products, even those perceived to be of lower risk, may nonetheless be necessary in the interest of uniformity.

FDA disagrees with those comments that suggested that another term be substituted for ''warning'' because the results of the focus group research support the use of the term ''warning.'' Focus group participants examined warning statements that used four signal words, i.e., ''WARNING,'' ''NOTICE,'' ''CAUTION,'' AND ''ATTENTION.'' Participants preferred ''WARNING'' and ''CAUTION'' over ''NOTICE'' and ''ATTENTION'' because these terms were perceived to be stronger and more likely to cause consumers to read the message; participants believed that the word ''WARNING'' was the strongest term. In addition, in identifying their preferred warning statement, most participants preferred the message preceded by the signal word ''WARNING.'' Other terms recommended in the comments, such as ''CONSUMER ADVISORY,'' were not tested in the agency's consumer research. Terms such as ''CONSUMER ADVISORY'' or ''CONSUMER ALERT'' are moderate signal terms, falling between the stronger signal terms tested (''WARNING'' and ''CAUTION'') and the weaker signal terms tested (''NOTICE'' and ''ATTENTION''). Consumers in the focus groups clearly preferred a strong signal to alert them to the warning statement. The term ''WARNING'' was viewed as a simple and unambiguous signal because it is a familiar word that most people readily understand. The comments that suggested alternative terms to ''WARNING'' did not provide consumer data or a compelling rationale to support their recommendations. FDA has conducted several studies of warning messages (in addition to juice) and has concluded that consumer testing of proposed language enhances the likelihood that warning messages will correctly communicate critical information (Ref. 5). Accordingly, because the relevant comments provided no consumer data or compelling rationale to support the use of alternative signal words, FDA has concluded that the warning statement for juice products should utilize the signal word ''warning,'' a signal that is supported by consumer research data. Furthermore, the agency believes that

warning is the more suitable term because it is consistent with past agency regulations (e.g., § 101.17(a), (b), (d)(1), and (e)) that use a term stronger than ''notice.''

The purpose of the warning statement is to inform consumers of the risks presented by certain juice products, thereby allowing them to make better decisions about the purchase and consumption of such products. This goal can only be achieved to the extent that consumers read and process the warning statement. Accordingly, FDA believes that it is appropriate to require the signal term that consumers say would be most likely to cause them to read the statement. Therefore, FDA is retaining ''warning'' as the signal word for the statement required by this rulemaking.

C. Comments on the Phrase ''Has Not Been Pasteurized''

47. Some comments stated that the phrase ''has not been pasteurized'' is inappropriate in the context of the warning statement because it is misleading. A few of these comments asserted that pasteurization provides a safer product than other processes that would satisfy FDA's proposed pathogen reduction performance standard. These respondents contended that the use of ''has not been pasteurized'' is potentially harmful because consumers might believe that all products that did not bear such a warning statement had been pasteurized and were equally safe.

The agency disagrees with these comments. FDA maintains that products processed in a manner to achieve the pathogen reduction performance standard would achieve an appropriate level of safety, whether they had been processed by pasteurization or by some other means. Products that have not been processed to achieve the pathogen reduction performance standard would require the warning statement. Therefore, the agency concludes that the message that the consumers would take from the warning statement is that products bearing the warning may have potential hazards, whereas those not bearing the statement are processed to ensure safe products.

48. Some comments contended that the term ''has not been pasteurized'' is too narrow a term for the warning statement. While the comments did not oppose the term ''pasteurized,'' the comments asserted that consumers should be made aware that pasteurization is not the only means by which juice products can be processed safely. The comments argued that technology can move quickly, and that use of the term ''pasteurized'' would limit the development of new technology for processing juice to destroy pathogenic microorganisms. Therefore, two of the comments suggested the following language: ''this product has not been pasteurized or otherwise treated * * *.''

FDA acknowledges that the term ''has not been pasteurized'' is not technically precise in the context of the warning statement, because products that have not been pasteurized, but have been otherwise processed to meet the pathogen reduction performance standard, do not need to bear the warning statement. In other words, the warning statement will not be required on all juice products that have not been pasteurized because those products subject to a process that achieves the 5-log reduction standard, other than pasteurization, do not need to bear the warning statement. However, as discussed in the juice labeling proposal, FDA proposed the phrase because consumer focus group participants understood the term ''has not been pasteurized'' better than the term ''has not been specifically processed.'' Moreover, as discussed in the juice labeling proposal, the agency believes that the more important message, i.e., that juice products not treated to remove pathogens present some risk, particularly for certain population groups, will be clearly understood by consumers. The comments did not provide information to show that consumers would be confused by the warning statement. Therefore, the agency is not adopting this suggested modification to the warning statement.

D. Comments on the At-Risk Groups

Most comments supporting the proposed labeling requirements generally supported the proposed description of the consumers at risk, although some comments suggested that these groups should be better defined.

49. One comment maintained that the warning statement should be modified unless specific data can be presented on the risks and those at risk. Another comment questioned whether ''children'' meant persons under 18. Another comment suggested that the term ''children'' be replaced with the term ''infants.'' This comment noted that when botulism was a concern in honey, only parents of children under 1 year old had to be concerned. Other comments stated that the term ''children'' was appropriate because there is no scientific basis for excluding older children and because parents will recognize that infants and young children are included in the broad category of ''children.''

Some comments questioned what is meant by the term, ''elderly.'' One comment suggested that the term ''elderly'' be replaced with the term ''senior (50 years or older),'' whereas another comment recommended that ''elderly'' be replaced with ''senior (55 years or older).''

FDA disagrees that the word ''infants,'' which ordinarily refers to children less than 1 year old, should replace ''children'' in the warning statement because some of the foodborne illnesses associated with consumption of juice occurred in children older than 1 year. Therefore, FDA concludes that use of the word ''infants'' in lieu of ''children'' would be misleading.

In the juice labeling proposal, FDA relied on a task force report, from the Council for Agricultural Science and Technology (CAST), that concluded that certain groups (i.e., young children, the elderly, and persons who are immunocompromised) are at greatest risk of serious illness from exposure to foodborne pathogens (63 FR 20486 at 20489). The report did not define a precise age range for either ''children'' or ''the elderly.'' The comment that questioned whether specific data was available to support FDA's description of the at-risk groups did not provide any data on which to refine the descriptive terms used in the report.

FDA recognizes that the terms ''children'' and ''elderly'' are not precise. They are terms chosen by the Council for Agricultural Science and Technology to reflect groups that, in general, have an immune system that is either incompletely developed or beginning to decline. Although the exact age at which a child's immune system is fully developed is not precisely defined and will depend on the individual development of the child, the task force report indicated that the incompletely developed immune system of infants and children younger than 5 makes this age group especially susceptible to foodborne illness. In addition, the report noted that the infective dose may be related to body weight, which would be less for younger children. Nonetheless, the median age of persons who experienced illness in a recent outbreak of *E. Coli* O157:H7 infections associated with juice products was five (Ref. 14); thus, as many individuals older than 5 years experienced illness as did those under 5 years. Therefore, the agency believes that the descriptive term for ''children'' in the warning statement should not be limited, e.g., to ''young children'' or to children 5 years and under.

Likewise, the task force report stated that elderly individuals undergo a decrease in immune function that makes them more susceptible to foodborne illness than the general population. The report both indicated that this decrease in the immune system can occur as early as 50 to 60 years of age and designated the term ''elderly'' to mean an individual over 65. Because the range given by the task force was so wide, the agency tentatively concluded that it had no basis for identifying a specific age for its category of ''elderly'' in the warning statement.

In the juice labeling proposal, FDA asked for comments on whether the age groups for children and the elderly could be better defined. Although some of the comments to the proposal suggested that the warning statement specify particular ages, the comments did not provide a substantive basis for any of these recommended ages. Accordingly, FDA is making no changes to the terms ''children'' or ''the elderly'' in the warning statement.

50. One comment stated that either the risk groups should be better defined or no risk groups should be mentioned at all.

FDA disagrees with this comment. Although the at-risk groups are not described as precisely as some might wish, as noted, there are few available data to identify the ages of children and adults who are at high risk. FDA has concluded that it is preferable to identify the at-risk groups with slightly imprecise terms than not to designate such groups at all. Therefore, FDA rejects this comment.

51. Several comments suggested that pregnant women be included as at-risk consumers. Only one comment provided any rationale for this addition, stating that pregnant women, who during their pregnancies have impaired immune systems, allegedly do not recognize that they are at greater risk of infection. Another comment pointed out that pregnant women are at risk of having miscarriages if they are infected with *Listeria*.

FDA disagrees with the suggestions that pregnant women be included in the at-risk groups. FDA acknowledges that the CAST report noted that the immune system of a pregnant woman is altered to some extent compared to that of a non-pregnant woman. In looking at the populations at greatest risk from foodborne pathogens, CAST identified pregnant women as a group at risk from *L. monocytogenes*, a widely distributed pathogen that has been associated with miscarriages. Nonetheless, there is no evidence that pregnant women or their fetuses are at any greater risk of serious illness from the foodborne pathogens associated with juices than the general population. The agency notes that *Listeria* has not been identified in the documented cases of illnesses associated with consumption of untreated juices. Therefore, FDA has no basis for determining that risk to a pregnancy from *Listeria* is any greater from the consumption of juices than from the consumption of all other foods.

52. Several comments stated that the term ''serious illness'' should be replaced with ''life threatening illness.'' These comments asserted that it is important that high risk consumers are adequately informed of the potential risks and therefore, the language should be explicit enough so that they will avoid the product. According to one comment, the language should be explicit enough so that consumers will overcome the presumption that the warning is meant for someone else.

FDA disagrees with these comments. The term ''serious illness'' is an accurate description of the hazard. Moreover, the FDA focus group research tested a variety of messages that included the phrases ''serious illness'' and ''life-threatening illness.'' The participants preferred a phrase such as ''serious illness'' because it conveyed a significant consequence without being too extreme. In addition, participants viewed ''serious illness'' as a strong statement for persons with weakened immune systems or immature immune systems such as young children. In contrast, participants viewed terms such as ''life-threatening'' or ''death'' as less credible. Thus, in addition to being objectively conceived, FDA focus group research confirmed that the phrase ''serious illness'' is subjectively understood. Accordingly, FDA is making no changes in response to these comments.

E. Comments on the Entire Warning Statement

53. In contrast to the comments that suggested alternatives for specific words or phrases in the proposed warning statement, a few comments suggested alternative wording for the entire warning statement. As examples, comments suggested statements such as the following:

This is a natural product that has not been pasteurized or otherwise treated. There is a slight risk that it may inadvertently contain harmful bacteria that can cause serious illness in children, the elderly and persons with weakened immune systems.

CONSUMER ADVISORY: Unless specifically processed, some juices may contain harmful bacteria known to cause serious illness. This product has not been processed to destroy these bacteria. The risk of life-threatening illness is greatest for children, the elderly, and persons with weakened immune systems.

NOTICE: This product has not been processed to eliminate the possibility of harmful bacteria and, therefore, could cause serious illness to those with weak immune systems, and young children.

Attention: This is a fresh juice. It has not been pasteurized. There is a small possibility it could be harmful to those with weak immune systems.

None of these comments provided a compelling rationale for why the suggested statement was more appropriate than FDA's proposed statement.

FDA's statement was developed and refined based on focus group research that tested multiple warning statements. Because the comments that suggested alternative wording for the entire statement did not provide a sufficient basis to dispute the findings of the focus group studies, FDA is not adopting any of these general suggestions.

F. Comments on Prominence and Placement

54. In the juice labeling proposal, the agency tentatively concluded that the warning statement should appear on the food label in a manner that makes it readily observable and likely to be read. Accordingly, FDA proposed that the statement appear prominently and conspicuously on the information panel or on the principal display panel (PDP) of the product label. Under § 101.2(c) (21 CFR 101.2(c)), information required to appear on the PDP and information panel must appear prominently and conspicuously in a type size no less than one-sixteenth inch. The agency also proposed that the word ''warning'' immediately precede the statement, appear in capital letters and bold type, and that the statement be set off in a box by use of hairlines.

In this final rule, FDA is revising proposed § 101.17(g)(4) (now § 101.17(g)(5)) to remove the provision that the term ''WARNING'' immediately precede the remainder of the warning statement. FDA is making this change, which is not substantive, because it is redundant with the requirements of § 101.17(g)(2), which explicitly places the term ''WARNING'' in front of the remainder of the statement.

55. One comment urged FDA to require that the warning statement appear on the PDP and not the information panel. The comment neither disputed the rationale that FDA presented in the juice labeling proposal in support of its proposal to allow the warning statement to appear on either the information panel or the PDP nor gave a reason for its request. Therefore,

the agency is making no changes in the location of the warning statement in response to this comment.

56. One comment maintained that the statement should not be set off by hairlines and that the agency should follow the same guidelines that it used for other informational statements such as those for saccharin and phenylalanine.

The agency disagrees with this comment. The agency's recent experience with the Nutrition Facts panel has been that the use of hairlines (i.e., enclosing the critical information in a box) greatly increases the prominence of the information. Also, focus group research has shown that such boxes help consumers distinguish the message from other information on the food label. As noted, the warning statement will achieve its purpose only if it is seen and read by consumers. Therefore, the agency is making no changes in response to this comment.

57. A few comments that supported the use of warning statements on juice products stated that a minimum type size of one-sixteenth inch is too small to attract consumer attention. One comment asserted that the proposed type size is too small to be read by many of the elderly, who are one of the at-risk groups targeted by the warning statement. The comment recommended a type size no smaller than 8-point on labels. Another comment suggested a minimum type size of three-sixteenth inch.

The agency does not have data from the comments or elsewhere that indicate that consumers are unable to obtain the information from other warning statements required in § 101.17 and thus, has no reason to believe that consumers would not be able to obtain information from the warning statement in this rule. Accordingly, FDA is making no change to the minimum type size requirements for warning statements for unprocessed juice products.

V. Other Issues

58. A few comments urged FDA to require pasteurized juices to bear a label informing consumers that the product had been pasteurized. These comments contended that juices that have been pasteurized, i.e., heat treated, have lost some of their ''beneficial'' nutrients, e.g., pectin, and certain enzymes and vitamins, and that consumers have a right to this information. The comments further stated that requiring pasteurized juices to bear a label indicating that the product was pasteurized would prohibit manufacturers of pasteurized juice from labeling their products as ''fresh.''

The agency does not object to manufacturers voluntarily labeling their product as ''pasteurized,'' when the product has, in fact, been heat treated in accordance with the practice of the trade. However, to require the term ''pasteurized'' on juice products the agency would have to find that such information was material in light of representations made about the product, or with respect to consequences that may result from use of the product. The comments did not provide the agency with any information on which to make either of these findings. Therefore, the agency is not requiring that the term ''pasteurized'' or any similar term, i.e., heat treated, appear on the label of juice that has been pasteurized. The agency advises that labeling a pasteurized juice product as ''fresh'' is a misbranding violation under section 403 of the act. Such products are subject to regulatory enforcement action.

59. Some comments questioned whether the requirement for a warning statement would apply to products that were manufactured by producers who process their own fruit and sell the resulting fresh juice products directly to consumers at their own retail markets, such as a roadside stand.

Whether the warning statement applies to these products depends on two factors: The ''retail'' status of the producer and the jurisdiction of the FDA.

The source of FDA's authority here is the act. Under the act, FDA's jurisdiction extends to those products, and the manufacturers and distributors of regulated products, that satisfy a necessary connection with interstate commerce. (See 21 U.S.C. 301 and 304.) Juice that is a product of solely intrastate activities (e.g., source of components, location of sales, etc.) is not subject to FDA's jurisdiction and thus, would not be subject to the warning statement requirement.

Nonetheless, in such circumstances, FDA customarily works with State regulatory agencies such as local health departments, who, like FDA, have a mission to protect the public health. Elsewhere in this final rule, FDA has addressed several comments submitted to the juice labeling proposal that described actions already taken by the States to work with producers to ensure the safety of juice products.

60. Several comments asked whether the responsibility for providing a placard or sign, which is an acceptable interim mechanism for manufacturers of packaged juices to comply with the juice labeling rule, lay with a manufacturer who produces the juice and sells it to a wholesaler or retailer or lay with the retailer who actually sells the juice to individual customers.

Under the applicable law, regulations, and agency policy, the firm that is identified as the manufacturer or distributor on the product label bears the principal responsibility to ensure that the product meets all applicable legal requirements, including labeling. However, retailers and wholesalers also have legal responsibility to ensure that products they sell are properly labeled. The legal basis for this shared responsibility is as follows.

Section 301 of the act (21 U.S.C. 331) prohibits the interstate shipment of a misbranded food and also prohibits the misbranding of a food after interstate shipment. In the case of the juice labeling rule, a juice product that is required to, but does not, bear the warning statement is misbranded within the meaning of sections 403(a)(1) and 201(n) of the act. A manufacturer or distributor who ships a misbranded juice product would violate section 301(a) of the act. Likewise, a retailer who fails to provide required labeling containing a warning statement would violate section 301(k). As is FDA's general practice, the agency would evaluate on a case-by-case basis any situation involving a possible misbranding of a covered juice product to determine whether any regulatory action was warranted.

61. Some comments asked whether States would be responsible for enforcing the warning statement requirement for products in intrastate commerce.

State enforcement activities related to this final rule will depend upon the specifics of each State's law (e.g., does that law provide for the automatic adoption of Federal regulations or does that law require a separate State process to establish a State standard?) and the exercise of the State's enforcement discretion.

As a practical matter, the agency is aware that a number of States have already begun to work with producers to improve the safety of juice products. One of FDA's goals in establishing a Federal requirement is to assist States in their efforts and to provide a model to encourage consistency in approach.

62. One comment strongly urged FDA to exempt all growers who process juice and sell directly to consumers at their own retail markets regardless of sales volume. The comment based the request on the belief that the labeling proposal exempted from the warning statement requirement growers who processed their own fruit and sold less than 40,000 gallons of the resulting juice products

directly to consumers and other retailers.

FDA is clarifying that its proposal to require warning statements on untreated juice products did not exempt juices produced by processors that sold less than 40,000 gallons. On the contrary, the agency proposed in the juice labeling proposal that the warning statement appear on the packages of all untreated juice products. Growers, in general, who process their own fruits and sell the resulting juice products commercially are not exempted by FDA from the warning statement requirement based on sales volume. The comment failed to provide the agency with a basis on which to exempt small growers from the labeling requirement, and therefore, the agency declines to do so.

63. Several comments objected to the abbreviated time for comments on the juice labeling proposal. One comment specifically asserted that the shortened comment period resulted in a denial of procedural due process to the industry and the public.

The juice labeling proposal provided interested persons with 30 days to comment on the proposal. In the proposed rule, the agency articulated the basis for its decision under Executive Order 12889 and FDA's regulations, § 10.40(b), for shortening the comment period to 30 days. Subsequently, several interested persons requested an extension of the time for comments. As discussed above, the agency ultimately extended, on June 10, 1998, under the authority of § 10.40(b)(3), the period for comments from all interested persons to June 22, 1998. The agency believes that this comment period is consistent with customary practice and agency regulations. The agency believes that the public health urgency that underlies this rulemaking is sufficient justification under Executive Order 12889 to shorten the comment period from 75 days, a conclusion not challenged in the comments. The agency also believes that the comment schedule of this rulemaking is in compliance with due process. FDA's process here is consistent with the requirements of the Administrative Procedure Act (5 U.S.C. 553). Such requirements are consistent with due process. (See *Bell Lines, Inc.* v. *U.S.*, 263 F. Supp. 40 (D. W. Va. 1967).)

VI. Effective Date

In the juice labeling proposal, FDA proposed that any final rule based on the proposal become effective 60 days after its date of publication in the **Federal Register**.

64. The majority of comments that addressed the proposed effective date supported a 60-day effective date because of the public health concern presented by untreated juices. A few comments asked that the agency change the effective date. One comment suggested that the effective date be changed from 60 to 120 days to allow small processors time to implement HACCP-based programs. Another comment asserted that the 60-day effective date was appropriate if FDA wanted to reach the 1998 apple cider season. That comment suggested, however, that the effective date for other juices be extended to 150 days.

As discussed in the juice labeling proposal, the agency has determined that the urgency of the public health concern with untreated juices requires the mandating of a warning statement as soon as possible, and, in particular, in time for the 1998 ''cider season.'' The comments did not provide any information that contradicted FDA's tentative conclusion that an effective date of 60 days would be needed to coincide with the beginning of the fresh juice season for apple juice and apple cider. Accordingly, the agency is retaining the 60-day effective date for this final rule. Apple juice and apple cider must comply on the effective date of the final rule.

The overarching public health goal of this rulemaking is to provide information about the potential hazards of untreated juice products to consumers at the beginning of the next applicable ''juice season.'' Apple juice and orange juice are the two most consumed juices in the United States, and together account for approximately 80 percent of all juice consumed in the United States (63 FR 24254 at 24365). As discussed in the PRIA (63 FR 24254 at 24273), information available to FDA indicates that the season for apple cider production runs primarily from September through December. Other information available to FDA indicates that the fresh juice season for citrus fruit generally runs from November through June (Ref. 15). Thus, the agency's public health goal can be achieved by establishing a compliance date for citrus juice products that coincides with the start of the fresh citrus juice season. FDA is not aware that the fresh juice season for any juice other than apple juice or apple cider begins as early as the apple juice and apple cider season. Accordingly, in this final rule, FDA is establishing a compliance date for all juices other than apple juice or apple cider at 120 days after the date of publication of the final rule.

As discussed above, in this final rule, § 101.17(g)(4) provides that the required warning statement may be provided in labeling at the point of purchase on a temporary basis until 1 year from the date of compliance with the final rule. In essence, this provision provides manufacturers the alternative of using labeling (e.g., signs or placards) for a single juice season. This flexibility will postpone by a juice season a manufacturer's need to revise and reprint labels that would be affixed to packaged untreated juice products.

VII. Summary of Provisions

In this final rule, FDA is revising its food labeling regulations by requiring 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. FDA is taking this action to inform consumers that such juices may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume untreated juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these products. The requirement that untreated juice products bear a warning statement is part of a comprehensive program, which may include the establishment of HACCP principles proposed for the processing of juice products, to address the incidence of foodborne illness related to consumption of fresh juices and to ultimately address the safety of all juice products.

This juice labeling final rule includes the following revisions to the juice labeling proposal:

(1) Section 101.17(g)(1) has been revised to remove the provision that any juice sold as such or used as an ingredient in beverages is subject to the warning statement requirement. This proposed provision, which specified those products that are subject to the warning statement requirement, became redundant with the final provisions of § 101.17(g)(2) and (g)(3).

(2) Section 101.17(g)(2) has been revised to reflect that, in addition to any juice that has not been processed to satisfy the pathogen reduction performance standard in § 101.17(g)(7), the warning statement requirement applies to any beverage containing juice where neither the juice ingredient nor the beverage has been processed to satisfy that standard. This, together with the exemption in § 101.17(g)(3), clarifies how FDA intended to cover juice used as an ingredient.

(3) New § 101.17(g)(3) establishes an exclusion from the warning statement requirement for certain juice that is not for distribution to retail consumers in the form shipped and that is for use solely in the manufacture of other foods or is to be processed, labeled, or repacked at a site other than originally processed. A warning statement is not required for such juice even if it has not been processed in the manner described in § 101.17(g)(7), so long as the lack of such processing is disclosed in documents accompanying the juice, in accordance with the practice of the trade.

(4) Under § 101.17(g)(4), the compliance date for the rule depends on the nature of the juice. For apple juice and apple cider, the compliance date is 60 days after the date of publication in the **Federal Register**; for all juices other than apple juice and apple cider, the compliance date is 120 days after the date of publication in the **Federal Register**.

(5) Under § 101.17(g)(4), manufacturers of packaged juices may comply with the rule by means of point-of-sale labeling, e.g., through the use of signs or placards, for up to 1 year after the date for compliance with the rule. In essence, this provision provides all manufacturers, regardless of size, the alternative of using labeling for a single juice season.

(6) The provision in proposed § 101.17(g)(4) (now § 101.17(g)(5)) that the term ''WARNING'' immediately precede the remainder of the warning statement has been deleted because it is redundant with the requirements of § 101.17(g)(2).

(7) The provision in proposed § 101.17(g)(6) (now § 101.17(g)(7)) establishing the processing standard for juices to be exempt from the warning statement requirement has been broadened. It now includes juice processed in a manner that will achieve or exceed any pathogen reduction performance standard established in any final regulation requiring the application of HACCP principles to the processing of juice.

VIII. Final Regulatory Impact Analysis

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs or if it raises novel legal or policy issues. FDA finds that this final rule is a significant regulatory action as defined by Executive Order 12866.

In addition, FDA has determined that this rule is not a significant rule under the Unfunded Mandates Reform Act of 1995 (UMRA) requiring benefit-cost and other analyses. Under UMRA significant rule is defined as ''a Federal mandate that may result in the expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any 1 year.''

Finally, in accordance with the Small Business Regulatory Enforcement and Fairness Act, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget (the Administrator) has determined that this final rule is not a major rule for the purpose of congressional review. A major rule for this purpose is defined as one that the Administrator has determined has resulted or is likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In the **Federal Register** of May 1, 1998 (63 FR 24254), FDA published a Proposed Regulatory Impact Analysis (PRIA) analyzing the benefits, costs, and regulatory options of proposed regulations regarding warning statement requirements and HACCP for juice. FDA received several comments on the PRIA from juice processors, trade associations, and consumers. In this document, FDA is finalizing the labeling provisions. FDA intends to publish a final rule on the HACCP requirements at a later date. Thus, FDA is only analyzing the impacts of the warning statement requirement.

A. Regulatory Alternatives

1. Prohibit Display of Warning Statement on Signs

FDA received several comments objecting to the proposed provisions that would temporarily allow the use of signs or other labeling to communicate the warning statement.

65. Several comments stated that FDA did not accurately address the costs or benefits of this proposed provision. For example, some comments asserted that signs with the warning statement will communicate that all of the juice in a refrigerated case is subject to the warning statement and thereby impose costs on processors of pasteurized juice. Some other comments said that signs with the warning statement may not be close enough to the product to be effective in achieving the benefits that the agency seeks. FDA believes that the problems mentioned by these comments will not be significant. Both retailers and sales representatives of products to which the warning statements do not apply have a financial interest in ensuring that the warning statements (particularly in sign or placard form) are not used in a way that would create the appearance that the warning statement applies to a broader set of products than required by this rule. For example, retailers may place signs on individual shelves rather than over entire refrigerated cases. In some stores that do sell untreated juice, the untreated juice products are sold in separate refrigerators in the produce section while pasteurized juice is sold with the other refrigerated products. Thus, products that need to be accompanied by the warning statement may be physically separated from other juices. Also, the sign or placard could specify by name the products covered by the warning statement. For these reasons, the agency disagrees with these comments and declines to adjust estimates of the benefits or costs of the rule based on them.

2. Require a 5-Log Process

66. Some comments said that requiring a process to achieve a 5-log reduction in pathogens as the alternative to the warning statement on untreated juice is too expensive an alternative for small businesses that wish to avoid the warning statement. One comment from a small juice processor said that implementing pasteurization to achieve a 5-log reduction would cost $30,000. Some other comments asserted that all juice should be required to be pasteurized.

In the PRIA, FDA provided an estimate of the cost of pasteurization equipment developed especially for small juice processors ($18,200). The agency does acknowledge that this may be a significant cost for some small businesses. Although the agency is encouraging juice processors to implement pasteurization or other process controls sufficient to achieve a

5-log reduction in pathogens, FDA is not mandating a 5-log reduction at this time. Instead, this final rule permits processors to produce untreated juice and offer it for sale accompanied by the warning statement until a final HACCP regulation (if one is established) is in place. The agency believes that requiring a warning statement on untreated juice is the least stringent regulatory approach acceptable for untreated juice. Processors (especially processors of very small volumes of juice) may find that including the warning statement on untreated juice is a less expensive alternative to implementing a 5-log pathogen reduction process.

However, as noted, FDA believes that requiring pasteurization of all juice would unnecessarily restrict innovation and new product development. Such activities are important to maintain competitiveness in the food industry. Additionally, the agency believes that consumer choice would be unnecessarily restricted by requiring all firms to implement a single type of processing technology. Until the agency has the opportunity to review all comments received in response to the HACCP proposal, the agency is satisfied that the proposed approach is the best balance between achieving the intended benefits and allowing flexibility for production.

3. Require Preventive Controls

67. Some comments suggested that FDA should implement GMP or HACCP (preventive control) requirements immediately rather than require warning statements on untreated juice products. Other comments supported the use of a warning statement on food products only as an interim measure until the agency establishes a more comprehensive solution to the problem of microbial contamination in juice. FDA recognizes the importance of preventive controls and has tentatively concluded that it is essential to implement a HACCP regulation for juice. The agency also believes that it is essential to communicate the risks associated with untreated juice to consumers during the considerable amount of time that will be required for the agency to finalize and implement an inherently more complex HACCP regulation for juice.

4. Require Brochures

68. As described earlier, some comments supported the use of brochures or pamphlets outlining the risks associated with the consumption of untreated juices as an alternative to a label warning statement. FDA declines to require brochures as an alternative in this rule because the focus group research shows that brochures would generate fewer benefits than the approach taken in this rule. FDA further notes that requiring the distribution of a brochure with each package of juice is likely to be at least as costly as placing stickers on each package label.

5. Change Length of Time Signs are Allowed

69. Some comments opposed the length of time that signs with the warning statement would be allowed (until January 1, 2000, the next uniform compliance date for other food labeling changes and until January 1, 2001 for small businesses) under the proposed rule. These comments claimed that signs would be less effective than labels in communicating the warning information.

FDA finds merit in these comments. The agency agrees that placards and signs may be less effective than package labels for the purpose of communicating product-specific information to consumers. However, as a practical matter, producers of untreated juice need time to modify their package labels to include the warning statement. In response to the concerns about the effectiveness of signs and placards, in this final rule, FDA is reducing the length of time that the warning statement may be provided in labeling such as signs or placards. FDA has concluded that a full juice season provides all firms, whether large or small, sufficient time to comply with the label requirement. Accordingly, this final rule provides that the required label statement may be provided in labeling at point of purchase, for a period of 1 year from the date for compliance with the final rule. The interim use of signs, placards, or other labeling for 1 year from the date when compliance is required will, in essence, provide manufacturers the flexibility to use labeling for a single juice season.

B. Benefits

1. Estimates of Juice Consumption

70. One comment stated that FDA had underestimated the amount of untreated juice consumed and, therefore, had underestimated the number of cases of illness that would be addressed by the rule. FDA disagrees that the cases of illness addressed by the rule have been underestimated as a result of the agency's consumption estimates. FDA did not estimate the number of cases of illness based on consumption; instead, the agency estimated the number of cases of illness by multiplying confirmed illnesses associated with juice by factors accounting for the under reporting on foodborne illness. Thus, FDA does not agree with this comment.

2. Recent Activity Not Accounted For

71. Some comments asserted that the agency's estimates of illness are outdated because these estimates do not take into account the recent steps that the industry and State governments have taken to reduce risk associated with juice.

FDA has used the most up-to-date information available on foodborne illness associated with juice. Complete data from the Centers for Disease Control and Prevention for 1997 are not available. The agency acknowledges that industry and State governments have been working to reduce the public health risks associated with consumption of untreated juice, and FDA encourages these efforts and hopes that they continue. However, because FDA has no evidence that the industry and State government efforts have sufficiently minimized the risk associated with juice, the agency believes that the warning statement is needed to inform the choices of consumers. Further, the rule will provide an incentive to continue to improve upon these efforts. Where these efforts of industry achieve a 5-log reduction in pathogens, those processors using such processes are not required to apply the warning statement to their products.

3. Value of Information

72. Some comments said that consumers would value the information in the warning statement because it would increase their ability to make informed choices.

FDA agrees that to the extent that the warning statement lowers the cost to consumers of obtaining information, there is a benefit to consumers in addition to the reduction in illnesses estimated in the PRIA. Although FDA is unable to quantify this benefit, it is appropriately counted as an unquantified benefit of the final rule.

4. Impact of Warning Statement on Lawsuits

73. One comment claimed that the warning statement will protect processors from lawsuits and bad publicity because consumers of the product will be taking responsibility for the risk associated with the product. Another comment said that the warning statement will encourage more lawsuits because the warning statement will suggest to consumers that the juice may be the cause of their symptoms.

State liability laws and their interpretations vary. These conflicting comments provided no specifics on these issues. FDA is not able to evaluate the impact of the warning statement on the filing or adjudication of lawsuits. For this reason, the agency has not made

any changes to the benefits or costs estimated for this rule based on these comments.

5. Benefits Summary

Table 1 shows the quantified benefits estimated for the labeling rule in both the PRIA and Final Regulatory Impact Analysis (FRIA (see section VIII of this document)). No comments persuaded the agency to change the quantified benefits of the rule. There are two additional unquantified benefits that, as a result of comments, the agency acknowledges. The first unquantified benefit is the value of the warning information to consumers regardless of changes in their consumption patterns; the agency is unable to quantify this benefit. Second, the agency believes that there will be some increase in benefits resulting from requiring the warning statement on package labels sooner than originally proposed; the agency is unable to quantify this benefit.

TABLE 1.—QUANTIFIED BENEFITS FOR LABELING RULE AS ESTIMATED IN PRIA AND FRIA

PRIA low estimate	FRIA low estimate	PRIA high estimate	FRIA high estimate
$1 million	$1 million	$6 million	$6 million

C. Costs

1. Effect of Warning Statement on Untreated Juice Sales

FDA received comments regarding the impact of the warning statement on sales of untreated juice. These effects stem from either consumer reaction, retailer response, or both.

74. Some comments said that the warning statement will have a negative effect on sales of untreated juice. FDA acknowledges this possible effect. In fact, the agency intends for the warning statement to reduce the consumption of untreated juice by consumers who are most at risk. The inevitable consequence of this goal is to have a negative effect on the sales of untreated juice.

FDA received one comment demonstrating that a market for unpasteurized juice does exist and may not be significantly harmed by the warning statement requirement of this rule. This comment from a juice processor stated that he produces both pasteurized and unpasteurized cider. The unpasteurized cider is sold accompanied by a leaflet warning consumers of the risk associated with untreated juice. This processor reports that 70 percent of his sales continue to come from unpasteurized cider.

FDA applauds this processor's responsible actions. The agency is not, in this rule, prohibiting the sale of untreated juice, nor does the agency believe that the warning statement will dissuade all consumers from purchasing untreated juice. FDA believes that at-risk consumers should carefully consider the consumption of untreated juice and the availability of the warning statement will allow informed decisionmaking by consumers. It is quite possible that this processor will see no change in the demand for either type of juice as a result of this rule, since the processor was already providing consumers with the warning information and offering them a product that has been subject to a 5-log reduction in pathogens. In fact, the agency believes that the experience of this processor shows that this rule will not have the extreme consequences described by some of the comments.

75. Some comments said that the warning statement will confuse consumers, that at-risk consumers will not be deterred from consuming untreated juice, and that consumers who are not at risk will be deterred from consuming juice.

FDA disagrees with these comments because the agency believes that the warning statement communicates a clear, appropriately targeted message. Importantly, the agency does not claim that all at-risk consumers will stop consuming untreated juice. FDA's estimates of consumption changes range from an expected 5 percent to a maximum of 16 percent. The comments that referred to a larger than 16 percent decline in consumption and sales during the last cider season were based on the effects of adverse publicity surrounding the outbreaks associated with untreated apple juice and cider, not on the effects of labeling. Any costs that resulted from adverse publicity that occurred before the agency first became involved in this issue are not attributable to this rulemaking. FDA believes that the decline in sales experienced by some producers in response to adverse general publicity are not indicative of the potential effects of labeling that provides true and not misleading information. Moreover, these sales declines have already occurred and cannot occur again for the same processors. However, the agency acknowledges that some consumers who are not at high risk may choose not to purchase untreated juice because of the warning statement. The agency believes that consumers are better off whenever they make better informed choices, and that better informed choices demonstrate unambiguously an increase in net societal benefits.

76. Some comments from juice processors said that retailers will refuse to sell products with warning statements. Some comments said that virtually all chain and large grocery stores have stopped selling untreated apple juice because of the publicity of the illnesses associated with untreated apple juice. In addition, some comments from citrus processors said that retailers would refuse to carry citrus juice with the warning statement just as apple juice processors have experienced. These comments stated that they expected a 50 percent reduction in sales because retail stores would not even offer consumers the choice of untreated juice with the warning statement. Some comments said, because of their concern that the warning labels will have a negative impact on citrus juice (including pasteurized as well as citrus fruit sold), that the warning statement would cause catastrophic damage to the Florida citrus industry.

FDA acknowledges that retailers may have this reaction to juice products with the warning statement. Like consumers who may decide not to purchase untreated juice because of the warning statement, retailers may decide not to buy untreated juice from wholesalers or processors for retail sale. The agency believes that the warning statement will have a minor effect on the choice of retailers to carry untreated juice products. For the most part retailers have already made a decision about carrying untreated apple juice based on the publicity of the illnesses associated with untreated apple juice. Also, the agency's estimates of the impact of the juice HACCP and warning statement proposals in the PRIA were based on the agency's conjecture that citrus processors may be able to achieve and validate a 5-log reduction without pasteurization (63 FR 20450 at 20478). If processors of untreated citrus juices are able to accomplish this then the citrus industry will experience little effect of this warning statement rule because citrus juices would then not require the warning statement. The agency does not believe that this rule

will have a significant impact on the citrus industry.

77. Some comments said that retailers will refuse to place signs bearing warning statements so that processors will have to place the warning statements on the juice package. One comment representing retailers indicated that retailers did not want the agency to permit the warning statement to appear on signs.

If the only issue is whether the warning statement appears on signs or on package labels, then retailers could make it a condition of sale that the warning statement be on the product package so that they do not have to deal with signs. The agency believes that these issues are best left to the market to determine. Regardless of how these issues are resolved, they do not result in costs of the rule that should be included in the FRIA.

A reduction in sales of untreated juice as a result of the warning statement is not a social cost of the rule if the effect of the warning statement is to restore consumers to a correct understanding of the actual risk posed by consumption. In fact, all estimated gains to public health reflect the agency's belief that the effect of the warning statement is to enable consumers to more correctly account for this risk. However, if the warning statement results in exaggerated consumer risk perceptions, then the warning statement would result in excess reduction in the demand for untreated juice and new, unintended social costs. These new social costs would include reductions in both consumers' and producers' surplus. Thus, the magnitude of net social benefit depends on the extent to which the warning statement changes consumer risk perceptions so as to result in a new demand that overshoots or undershoots the socially optimal demand.

2. Effect of Warning Statement on Pasteurized Juice Sales

78. Some comments asserted that the warning statement will have a negative effect on the sales of pasteurized juice. One comment stated that the warning label would eliminate the competitive edge that untreated juice has over pasteurized juice. Another comment said that the warning statement will eliminate consumer confusion about the difference in risk between pasteurized and unpasteurized products.

FDA agrees that the warning statement referring specifically to unpasteurized products will provide consumers with more information and increase consumers' ability to make informed choices between the two types of juice. Comments that claimed that the warning statement would negatively affect sales of pasteurized juice provided no information or other justification for such statements. Likewise, the agency is unaware of any research showing that warning statements referring to one type of product have a negative impact on the sale of products to which the warning statement does not apply. FDA agrees with the comment that untreated juice will lose some competitive advantage with pasteurized juice. In fact, FDA believes it likely that the warning statement will have a small but positive effect on sales of pasteurized juice because the most likely alternative for consumers who wish to avoid juices covered by the warning statement (i.e., untreated juice) is the purchase and consumption of pasteurized juice, because the closest substitute for unpasteurized juice is probably pasteurized juice.

3. Effect of Warning Statement on International Trade

79. Some comments said that the warning statement could act as a non-tariff trade barrier both to U.S. processors who are interested in exporting untreated juice and to foreign processors who import untreated juice into the United States.

FDA disagrees with these comments. This rule is not a prohibited trade barrier. U.S. trade obligations permit the agency to establish measures that regulate the safety of imported foods as long as the measures are consistent with the Sanitary and Phytosanitary (SPS) agreement. Trade agreements administered by the World Trade Organization (WTO) require that WTO members not apply measures that are more restrictive to imported goods than to domestic goods, without science-based justification. This is not the case with this rule. Further the trade agreements require that measures be based on risk assessment, appropriate to the circumstances, taking into account available scientific information, relevant processes and production methods; and other relevant factors. The agency believes it carried out a comprehensive and science-based evaluation of the risks in making its decision to require a warning statement. The agency recognizes that its decision can impact trade, but believes that the resulting measure is fully consistent with the rights and obligations of the WTO agreements.

4. Cost of Label Change

80. Some comments stated that the warning statement should appear on product labels within 60 days of publication of the final rule. These comments said that label changes could be made by very small businesses easily, quickly, and at very low cost. Some other comments said that if the warning statement were required to be included on product labels this season, processors would suffer extreme hardship and expense. These comments requested more time before the warning statement is required to be placed on labels.

In the PRIA, FDA estimated the cost of label changes for compliance periods of different lengths. In light of these conflicting comments, the agency has further considered the costs of including the warning statement on package labels. As a result of these investigations, FDA is revising the estimate of the administrative costs of the label change in the case of this rule.

The comments outlined the activities and changes that are specific to the juice warning statement situation and identified the activities involved for this rule that are different from those for most label changes. The estimate for administrative costs in the PRIA was based on a model for calculating costs of labeling changes based on more comprehensive changes in food labels. FDA is convinced that the label change involved in this specific rule is simpler and therefore requires a lesser effort (Ref. 14). Because the agency is prescribing the exact words to be used in the warning statement and because affected processors have been so significantly alerted to FDA's intent to establish the rule, the administrative costs of determining the need to and manner in which to comply should be greatly reduced from other labeling change situations. FDA estimates that the administrative costs of making this label change would require 8 labor hours. At $13 per labor hour, the estimated administrative cost is approximately $100 for a 1-year compliance period. Table 2 shows the label change costs for different compliance periods as estimated in the PRIA and in this FRIA.

TABLE 2.—INTEGRATED LABEL CHANGE COSTS PER SKU FOR DIFFERENT LENGTHS OF THE COMPLIANCE PERIOD

Item	2 Months PRIA	2 Months FRIA	6 Months PRIA	6 Months FRIA	1 Year PRIA	1 Year FRIA
Administrative Costs	$6,000	$700	$1,800	$200	$900	$100
Redesign Costs	$1,500	$1,500	$450	$450	$450	$450
Inventory Loss	$800	$800	$250	$250	$0	$0
Total Integrated Labels	$8,300	$3,000	$2,500	$900	$1,350	$550

81. Some comments suggested that stickers could be used to supplement existing labels within 2 months. The agency has investigated the cost of using stickers to augment the package labels so as to include the warning statement on packages without changing labels existing in inventory. Stickers would result in no redesign or inventory loss. However, there would be administrative costs for designing, ordering and coordinating placement of the stickers. The agency believes that the administrative cost for using stickers is significantly lower than that for integrated label changes in the same period of time. In addition to administrative costs, use of stickers would result in costs for printing the stickers and labor and equipment needed to apply the stickers. Table 3 shows the estimated cost for stickers for a very small juice processor producing approximately 10,000 gallons of juice per season. This size plant is typical of the processors likely to be affected by this rule.

TABLE 3.—LABEL STICKER COSTS

Item	Cost
Administrative Costs	$100
Printing Costs	$250
Application Costs	$600
Total Stickers	$1,000

5. Costs Summary

FDA has relied on the most recent data available to estimate risks of foodborne illness from untreated juice and the costs associated with this rulemaking. Information about baseline risk is somewhat older than information about cost; hence, estimates of baseline risk do not account for changes that may have occurred since public concern about the safety of untreated juice arose. However, cost estimates treat as ''sunk'' those expenditures that firms and consumers have made in recent years in response to concerns about the risks associated with untreated juice.

The quantifiable costs of this final rule include the cost of signs or placards, earlier implementation of pathogen controls to avoid warning statements, and changing container labels to include the warning statement.

In this final rule, FDA is requiring that the warning statement appear on products sooner than the proposed rule would have required. The costs estimated in the PRIA were based on a 2-year compliance period. The costs of label changes estimated in this FRIA are based on a 1-year compliance period (2,980 firms x $550 per firm = $1,639,000).

As discussed earlier, the agency acknowledges one category of unquantified costs that result from responses to the comments, specifically, the transaction cost of the working of the legal system for increased product liability lawsuits. The agency believes this cost will be small.

Table 4 shows the quantified costs estimated for the rule in the PRIA and FRIA.

TABLE 4.—COSTS ESTIMATED FOR RULE IN PRIA AND FRIA

Cost	PRIA Estimate	FRIA Estimate
Signs and Placards	$398,000	$398,000
Earlier Implementation of Pathogen Controls to Avoid Warning Statement	$2,688,000	$2,688,000
Container Labels	$1,301,000	$1,639,000
Total	$4,387,000	$4,725,000

IX. Final Regulatory Flexibility Analysis

FDA has examined the impacts of this final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the Regulatory Flexibility Act (RFA), FDA finds that this final rule will have a significant impact on a substantial number of small entities.

The agency has evaluated comments on the juice labeling proposal and on the Preliminary Regulatory Impact Analysis (PRIA) and Initial Regulatory Flexibility Analysis (IRFA) on matters that bear on small business impacts. The agency's responses to these comments are set out in the next section; that section is followed by a summary of the estimates of costs of this final rule to small businesses.

A. Responses to Comments

1. Warning Statement Effect on Viability of Small Businesses

82. Some comments asserted that the warning statement will harm the viability of small farm businesses. Some of these comments said that the price of purchasing, installing, and operating pathogen controls (so as to avoid application of the warning statement) was too much for small businesses to pay.

FDA acknowledges that the initiation of new pathogen controls may be a significant expenditure for some small businesses. However, the agency believes that the public health risk associated with untreated juice is significant enough to warrant requiring all juice either to be subject to pathogen controls or to bear a statement warning consumers of the health risks associated with untreated juice. These public health risks exist regardless of the size of the producer—small or large. Very few untreated juice processors are stand-alone businesses. Instead, virtually all are side businesses of orchards that use fruit not sent to packing houses for making juice. This primary business—growing fruit for whole packing—should not be adversely affected by this rule.

2. Expense of Label Changes for Small Businesses

83. As noted, some comments stated that the warning statement should be required to appear on product labels within 60 days of publication of the final rule. These comments said that label changes could be made by very small businesses easily, quickly, and at very low cost. Other comments asserted that if the warning statement was required to be included on product labels this season, processors would suffer extreme hardship and expense. These comments requested more time before the warning statement was required to be placed on labels.

As described in the FRIA above, FDA has revised the estimate of the administrative costs of the label change in the case of this rule. The agency has determined that it is appropriate to reduce the length of time that manufacturers will be permitted to provide the required warning statement in labeling, (e.g., on signs and placards) to up to 1 year from the date for compliance with the rule. This will allow the warning statement to appear on signs and placards for one juice season.

3. Coverage of Small Juice Processors

84. One comment requested that processors of less than 40,000 gallons of juice annually be exempt from the rule. The comment stated that small farmers use untreated juice production as an automatic stabilizer to augment their income from the sale of whole fruit, probably when growing conditions are bad. According to the comment, not all fruit grown in an orchard meets the size, shape and other standards necessary for it to be sold as whole fruit. It is not unusual for these culls to amount to 10 percent of the harvest; when crop growing conditions are less favorable (e.g., due to hail damage), the percentage of culls is greater. Farmers may sell culls to large processors for processed juice and other highly processed fruit products, or they may use culls to produce their own untreated juice. The comment asserted that culls used for untreated juice production return 300 percent to 400 percent more than culls sold for highly processed products. Other comments, however, said that small businesses should not be exempt from the rule.

FDA's labeling proposal did not exempt any juice processors. The agency understands that small businesses may lose some income as a result of this rule. The agency believes, however, that it is essential that consumers be informed of the risk associated with the consumption of untreated juice regardless of the size of the processor. The risk faced by the consumer is related only to the product and not to the size of the product's processor. The agency has sought to craft this rule in the most cost-effective manner in order to minimize the rule's burden on processors while still attaining the goals of the rule. Given this fact, the agency is not aware of any rational basis related to the rule's goal that would justify completely excluding small processors from the labeling requirement.

4. Level Playing Field for Business

85. Some comments asserted that the proposed rule gave unfair advantages to large corporations. Other comments claimed that the proposal would give undue consideration to small businesses. Comments on both sides of this issue requested that the agency establish ''a level playing field'' for business. FDA interprets a request for a ''level playing field'' as a request for equitable treatment. The RFA (as amended in 1995) and Executive Order 12866 require that FDA address the issue of equity. The agency has considered these issues, including regulatory alternatives that would reduce the burden on small businesses, and has determined that the risks to public health associated with untreated juice are such that small processors should not be excluded from the labeling requirement.

B. Objectives

The RFA requires a succinct statement of the purpose and objectives of any rule that will have a significant impact on a substantial number of small entities.

This rule responds to the need to alert consumers to the potential risk of foodborne illness from consumption of juice products not pasteurized or otherwise processed to destroy pathogens that may be present; these pathogens pose a risk of serious foodborne illness. FDA is requiring warning statements for such juice products to inform consumers of the potential hazard of pathogens in such products; such labeling is not required for juice that is processed to achieve a 5-log reduction in the pertinent microorganism. If FDA finalizes a rule requiring the application of HACCP principles to the processing of juice, the warning statement will no longer be required for those products that achieve a pathogen reduction that is equal to, or greater than, the standard established in a HACCP final rule.

C. Definition of Small Business and Number of Small Businesses Affected

The RFA requires a statement of the definition of small business used in the analysis and a description of the number of small entities affected.

Table 5 shows the definition of small business for each type of establishment affected by the rule and an estimate of the number of small entities of each type. The agency has applied the Small Business Administration (SBA) definitions of small business for this analysis.

TABLE 5.—APPROXIMATE NUMBER OF SMALL ESTABLISHMENTS COVERED BY THIS RULE

Type of Establishment	Standard Industry Classification Codes	SBA Definition of Small by Category	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by Rule
Juice manufacturers in the OEI	2033, 2037	Less than 500 employees	75%	20
Roadside-type apple juice makers	2033, 2037	Less than 500 employees	100%	1,600
Roadside-type orange juice makers	2033, 2037	Less than 500 employees	100%	300
Grocery stores and supermarkets processing at point of sale	5411	Less than $20 million of annual sales	85%	1,100

TABLE 5.—APPROXIMATE NUMBER OF SMALL ESTABLISHMENTS COVERED BY THIS RULE—Continued

Type of Establishment	Standard Industry Classification Codes	SBA Definition of Small by Category	Percentage of Category Defined as Small by SBA	No. of Small Establishments Covered by Rule
Total				3,020

D. Description of Impact on Small Entities

1. Costs to Small Entities

Table 6 shows the average cost for small entities that can reasonably predict, based on the proposed rule, that they will be required to implement an adequate HACCP program and will therefore implement 5-log pathogen controls (to avoid use of the warning statement) earlier than they would if the warning statement was not required for products without validated 5-log pathogen process controls. Table 6 also shows the average cost for small entities that will not expect to implement 5-log pathogen controls in the future. These entities will be required to adopt the warning statement for their products. The private costs to small businesses of the warning statement also include the lost revenue that results from a reduction in sales. These costs are not societal costs and are therefore not included in the costs estimated in the FRIA.

TABLE 6.—AVERAGE COST OF COMPLIANCE FOR SMALL ENTITIES

Item	Cost for Entities Covered by HACCP Rule	Cost for Entities not Covered by HACCP Rule
Sign or Placard		$100
Container Label Change		$550
Lost Sales Resulting From Warning Statement (for 5-16% loss on average sales of $20,000)		$1,000-$3,200
Early Implementation of 5-Log Pathogen Controls to Avoid Labeling	$16,000	
Total	$16,000	$1,650-$3,850

The impacts that the costs will have on a firm will vary depending on the total revenue derived from juice by a firm and the profit (return on sales) associated with juice production. Data on food manufacturing firms indicates that 75 percent of firms have a return on sales of less than 5 percent.

2. Professional Skills Required for Compliance

The RFA requires a description of the professional skills required for compliance with this rule. Compliance will require managerial skills necessary to design, order, and utilize signs and labels.

3. Recordkeeping Requirements

The RFA requires a description of the recordkeeping requirements of the rule. There are no recordkeeping requirements.

E. Description of Outreach to Small Entities

The RFA requires a description of the outreach activities taken by the agency to inform small entities about the rule and to encourage comments from small businesses.

In addition to publishing the proposed rule in the **Federal Register**, the agency published the rule on the FDA world-wide web site to make the text of the rule more easily and widely accessible. The web site contains instructions about how to submit comments to the agency. FDA officials have on several occasions made speeches and presentations at meetings where small entities have been represented by trade associations, legal counsel, and academic juice specialists who are providing assistance to small entities for commenting and complying. FDA has also made a number of special mailings of the rule to small entities requesting individual paper copies and has fielded a number of phone inquiries about the rule.

F. Minimizing the Burden on Small Entities

The RFA requires an evaluation of any regulatory overlaps and regulatory alternatives that would minimize the costs to small entities.

1. On Requiring a 5-Log Process

86. Some comments said that requiring a process to achieve a 5-log reduction in pathogens as the alternative to the warning statement on untreated juice was too expensive an alternative for small businesses that wish to avoid the warning statement. One comment asserted that implementing pasteurization to achieve a 5-log reduction would cost $30,000. Other comments claimed that all juice should be required to be pasteurized.

In the PRIA, FDA provided an estimate of the cost of pasteurization equipment developed especially for small juice processors ($18,200). The agency understands that this may be a significant cost for some small businesses. Although the agency is encouraging juice processors to implement pasteurization or other process controls sufficient to achieve a 5-log reduction in pathogens, at this time, FDA is not mandating a 5-log reduction. Instead, this final rule permits processors to produce untreated juice and offer it for sale accompanied by the warning statement until a final HACCP regulation (if one is established) requires such processors to implement process controls sufficient to achieve a 5-log reduction in pathogens. The agency believes that requiring a warning statement on untreated juice is the least stringent regulatory approach acceptable for untreated juice. Processors (especially processors of very small volumes of juice) may find that including the warning statement on untreated juice is a less expensive alternative to implementing a 5-log pathogen reduction process.

However, as noted earlier, FDA believes that requiring pasteurization of all juice would unnecessarily restrict innovation and new product and process development. Such activities

are important to maintain competitiveness in the food industry. Additionally, the agency believes that consumer choice would be unnecessarily restricted by requiring all firms to implement a single type of processing technology. At this time, the agency is satisfied that the proposed approach is the best balance between achieving the intended benefits to consumers and allowing flexibility for production.

2. Change Length of Time Signs are Allowed for Small Businesses

The proposed rule would have allowed the use of signs or placards until January 1, 2000, the next uniform compliance date for other food labeling changes, and until January 1, 2001 for small businesses to relieve the burden on such businesses.

87. Some comments opposed the length of time that signs with the warning statement would be permitted. These comments asserted that signs would be less effective than labels in communicating the hazard information. Some of these comments also opposed the additional time allowed for small businesses to comply with the requirement that the warning statement appear on the labels of their products. The comments asserted that the public health concern with untreated juice existed whether the producing firm was large or small. Other comments supported giving small businesses additional time to place warning statements on packages.

The agency agrees that placards and signs may be somewhat less effective than labels for the purpose of communicating product-specific information to consumers. However, as a practical matter, producers of untreated juice need time to modify their labels to include the warning statement. In response to the concerns about the effectiveness of signs and placards, in this final rule, FDA is reducing the length of time that manufacturers will be allowed to provide the warning statement in labeling. The label change is not complex. FDA believes that small businesses will not experience more difficulty than large businesses in making the change. Therefore, FDA is giving small and large businesses the same amount of time to make the change. Accordingly, this final rule provides that the required warning statement may be provided in labeling at point of purchase until 1 year from the date that firms must comply with the requirements of the final rule. The interim use of labeling (e.g., signs or placards) for 1 year will, in essence, provide manufacturers the option of using labeling for a single juice season.

G. Summary of Regulatory Flexibility Analysis

FDA has examined the impact of the rule on small businesses in accordance with the RFA. This analysis, together with the FRIA and remainder of the preamble, constitutes the Final Regulatory Flexibility Analysis. FDA has determined that this rule will have a significant impact on a substantial number of small entities.

X. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (63 FR 20486 at 20491). No new information or comments have been received that would affect the agency's previous determination that this action is of a type that does not individually or cumulatively have a significant impact on the human environment (21 CFR 25.30(k)). Thus, neither an environmental assessment nor an environmental impact statement is required.

XI. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the warning statement is ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

XII. References

1. Williams, R., T. Wilcox, B. Timbo, D. Street, C. Nardinelli, P. McCarthy, G. Jackson, M. T. Hendricks, and E. Elliot, ''Preliminary Investigation Into the Morbidity and Mortality Effects Associated With the Consumption of Fruit and Vegetable Juices,'' October 31, 1997.

2. Miller, A. J., R. C. Whiting, and J. L. Smith, ''Use of Risk Assessment to Reduce Listeriosis Incidence,'' *Food Technology*, 51:100–103, 1997.

3. FDA memorandum, ''Consumer Awareness of Unpasteurized Juice as a Risk,'' Brenda M. Derby to Elizabeth Campbell, June 22, 1998.

4. Stewart, D. W. and I. M. Martin, ''Intended and Unintended Consequences of Warning Messages: A Review and Synthesis of Empirical Research,'' *Journal of Public Policy and Marketing*, 13(1):1–19, 1994.

5. FDA memorandum, Alan S. Levy to Kenneth Falci, June 26, 1997.

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7. Fratamico, P. M., M. Y. Deng, T. P. Strobaugh, S. A. Palumbo, ''Construction and Characterization of *Escherichia coli* 0157:H7 Strains Expressing Firefly Luciferase and Green Fluorescent Protein and Their Use in Survival Studies,'' *Journal of Food Protection*, 60(10):1167–1173, 1997.

8. FDA Memorandum, Robert L. Buchanan to the Record, June 15, 1998.

9. Centers for Disease Control, ''*Salmonella typhimurium* Outbreak Traced to a Commercial Apple Cider—New Jersey,'' *Morbidity and Mortality Weekly Report*, 24:87–88, 1975.

10. Centers for Disease Control and Prevention, ''Outbreaks of *Escherichia coli* O157:H7 Infection and Cryptosporidiosis Associated With Drinking Unpasteurized Apple Cider—Connecticut and New York, October 1996,'' *Morbidity and Mortality Weekly Report*, 46(1):4–8, 1997.

11. Miller, L. G. and C. W. Kaspar, ''*Escherichia coli* 0157:H7 Acid Tolerance and Survival in Apple Cider,'' *Journal of Food Protection*, 57(6):460–464, 1994.

12. Centers for Disease Control and Prevention, ''Outbreak of *Escherichia coli* O157:H7 Infections Associated with Drinking Unpasteurized Commercial Apple Juice—British Columbia, California, Colorado, and Washington, October 1996,'' *Morbidity and Mortality Weekly Report*, 45(44):975, 1996.

13. FDA Memorandum, David Zorn to Elizabeth Campbell, June 18, 1998.

14. FDA Memorandum, David Zorn to The Record, June 19, 1998.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.17 is amended by adding paragraph (g) to read as follows:

§ 101.17 Food labeling warning and notice statements.

* * * * *

(g) *Juices that have not been specifically processed to prevent, reduce, or eliminate the presence of pathogens.* (1) For purposes of this paragraph (g), ''juice'' means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purees of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or puree.

(2) The label of:

(i) Any juice that has not been processed in the manner described in paragraph (g)(7) of this section; or

(ii) Any beverage containing juice where neither the juice ingredient nor the beverage has been processed in the manner described in paragraph (g)(7) of this section, shall bear the following warning statement:

WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems.

(3) The warning statement required by this paragraph (g) shall not apply to juice that is not for distribution to retail consumers in the form shipped and that is for use solely in the manufacture of other foods or that is to be processed, labeled, or repacked at a site other than originally processed, provided that for juice that has not been processed in the manner described in paragraph (g)(7) of this section, the lack of such processing is disclosed in documents accompanying the juice, in accordance with the practice of the trade.

(4) The warning statement required by paragraph (g)(2) of this section shall appear prominently and conspicuously on the information panel or on the principal display panel of the label of the container, except that:

(i) For apple juice or apple cider, the warning statement may appear in labeling, including signs or placards, until September 8, 1999;

(ii) For all juices other than apple juice or apple cider, the warning statement may appear in labeling, including signs or placards, until November 5, 1999.

(5) The word ''WARNING'' shall be capitalized and shall appear in bold type.

(6) The warning statement required by paragraph (g)(2) of this section, when on a label, shall be set off in a box by use of hairlines.

(7)(i) The requirements in this paragraph (g) shall not apply to a juice that has been processed in a manner that will produce, at a minimum, a reduction in the pertinent microorganism for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, of the following magnitude:

(A) A 5-log (i.e., 100,000-fold) reduction; or

(B) A reduction that is equal to, or greater than, the criterion established for process controls by any final regulation requiring the application of Hazard Analysis Critical Control Points (HACCP) principles to the processing of juice.

(ii) For the purposes of this paragraph (g), the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice.

Dated: July 2, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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