this chapter, shall include in their Hazard Analysis and Critical Control Point (HACCP) plans control measures that will produce, at a minimum, a 5 log (i.e., 10^5) reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. For the purposes of this regulation, the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice.

Dated: April 17, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

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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 Statements; Labeling of Juice Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require warning statements on packaged fruit and vegetable juice products that have not been processed to destroy pathogenic microorganisms that may be present. FDA is taking this action because of the recent outbreaks of foodborne illness and deaths caused by consumption of juice products that were not pasteurized or otherwise processed to control pathogenic microorganisms. This requirement for warning labels will serve to reduce the risk of foodborne illness. Elsewhere in this issue of the **Federal Register**, FDA is proposing to require that juice be processed under a Hazard Analysis and Critical Control Point program (HACCP).

DATES: Submit written comments by May 26, 1998. See section V of the **SUPPLEMENTARY INFORMATION** section of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION:

I. Background

There recently have been outbreaks of foodborne illness associated with the consumption of juice and beverages containing juice, i.e., juice products, that have not been pasteurized or otherwise treated to destroy pathogenic microorganisms.[1] On October 30, 1996, the Seattle-King County Department of Public Health and the Washington State Department of Health reported an outbreak of *Escherichia coli* O157:H7 infections epidemiologically associated with consumption of unpasteurized apple juice. The outbreak resulted in at least 66 cases of illness in 3 western States and British Columbia, and the death of 1 child (Refs. 1 and 2).

Pathogens other than *E. coli* O157:H7 may be present in apple and other types of juice products and have been documented as the cause of foodborne illness. In particular, outbreaks caused by *Salmonella typhimurium* and *Cryptosporidium* in apple cider (Refs. 3, 4, and 5) and *Vibrio cholerae* in coconut milk (Ref. 6) have been reported. In addition, outbreaks caused by consumption of unpasteurized orange juice contaminated with *S. hartford* (Ref. 7), orange juice drink contaminated with *S. agona* (Ref. 8), orange juice contaminated with *Bacillus cereus* (Ref. 9), and home-made carrot juice contaminated with *Clostridium botulinum* (Ref. 10) have been reported.

Because of the agency's concern that its regulatory program for fresh juices may not be adequate to ensure the production of safe juice and juice products, and because of the severity of the recent outbreak of *E. coli* O157:H7 associated with apple juice, the agency held a public meeting on December 16 and 17, 1996, to discuss safety issues presented by juice products. At that meeting, FDA met with interested parties to review the current science, including technological and safety factors, relating to fresh juice production and to consider the measures that would be necessary to provide safe fruit and vegetable juices. Experts from industry, academia, and the regulatory and consumer sectors presented information on illnesses and the epidemiology of outbreaks arising from microbially contaminated juices; concerns with emerging pathogens; procedures for processing juices; and new and existing technology to control pathogens in juice products.

In light of the information developed at the public meeting and in comments received by the agency, as well as other information available to the agency, FDA has developed a strategy that it believes will address both the immediate goal of reducing the risk of foodborne illness associated with juice products and the long-term goal of ensuring that juice products are safe. In the **Federal Register** of August 28, 1997 (62 FR 45593), the agency 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 aspects of all juice products. The agency invited comment on the appropriateness of its strategy to: (1) Initiate rulemaking on a mandatory HACCP program for some or all juice products; (2) propose that the labels or labeling of juice products not specifically processed to prevent, reduce, or eliminate the presence of harmful bacteria 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 fresh juice. FDA stated that it would consider comments received within 15 days of publication of the notice of intent as part of any rule proposed by the agency.

This document addresses the warning statements for labels of packaged juice products that have not been specifically processed to prevent, reduce, or eliminate the presence of harmful pathogens. FDA has reviewed all the comments received within 15 days of publication of the notice of intent and has determined that the comments provide no information that would cause the agency to conclude that this proposal is inappropriate. In this document, the agency addresses these comments to the extent that they are relevant to this proposal. Comments in response to the notice of intent received more than 15 days after publication of that notice that address issues in this

[1] In this 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.

proposal will be considered in any final rule published in response to this proposal.

II. The Proposal

A. Rationale for Proposal

As discussed in the notice of intent, implementation of a HACCP program appears to be the best long-term control measure for pathogens and for other safety concerns related to the production and distribution of some or all juice products. Therefore, elsewhere in this issue of the **Federal Register**, the agency is publishing a proposal (''the HACCP proposal'') to require that most juice be processed under a HACCP program. However, the agency recognizes that rulemaking and implementation of a HACCP program are time consuming, and that a HACCP program for some or all juices would likely not be fully implemented for several years. During this period of rulemaking and implementation, the risk of illness caused by pathogens in fresh juice will persist. The agency is concerned that, unless warned, consumers at greatest risk could suffer serious illness and even death from the consumption of juices that have not been treated to prevent, reduce, or eliminate microbial pathogens. Accordingly, FDA has tentatively concluded that there is an immediate need to inform consumers of the public health risks associated with consumption of untreated juice products through the use of a warning on the label of such products.

Implementation of a labeling requirement can be completed more quickly than implementation of a mandatory HACCP program. Consequently, FDA is proposing to require that the labels of packaged juice products not pasteurized or otherwise specifically processed to prevent, reduce, or eliminate the presence of pathogens bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product. As discussed in more detail in section II of this document, the agency is also proposing that this labeling requirement not apply to any juice processed under an adequate HACCP program or otherwise processed in a manner sufficient to destroy pathogens, e.g., pasteurization, or to any unpackaged juice sold for immediate consumption, e.g., products sold by the glass in restaurants, grocery stores, or other food establishments.

B. Legal Authority for FDA to Require Warning Labels

As a general rule, FDA's authority to require warning labels on food products derives from sections 201(n), 403(a)(1), and 701(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n), 343(a)(1), and 371(a)). Under section 403(a)(1) of the act, a food is misbranded if its labeling is false or misleading in any particular.[2] Section 201(n) provides that, in determining whether labeling is misleading, FDA shall take into account not only representations made about the product, but also the extent to which the labeling fails to reveal facts material in light of representations made or suggested in the labeling, or facts material as to consequences that may result from use of the product under conditions of use prescribed in the labeling or under customary or usual conditions of use. Section 701(a) of the act authorizes FDA to issue regulations for the efficient enforcement of the act. FDA has relied on the authority of sections 201(n), 403(a), and 701(a) of the act to require warning labels that alert consumers to the potential hazards of certain ingredients of foods and dietary supplements. (See 49 FR 13679, April 6, 1984 (protein products) and 62 FR 2218, January 15, 1997 (iron-containing dietary supplements).)

As previously discussed, some juice products have been the vehicles of outbreaks of illnesses from foodborne pathogens, including *E. coli* O157:H7 and *Salmonella*. The consequences of consuming juice products that contain pathogenic microorganisms are well documented; such consumption may result in serious, life threatening illnesses or death (Refs. 1 to 7). Therefore, the agency tentatively concludes that there is a risk of serious illness from consuming juice products that have not been processed in a manner designed to destroy these pathogens. Given the possible presence of pathogens in untreated juice, and the potential consequences of consumption of these beverages, the fact that juice may contain harmful pathogens and the fact that a product has not been treated to control such pathogens are material facts regarding the consequences that may result from use of these juice products. Unless these facts are disclosed to consumers at the time that they are deciding whether to purchase and consume the juice, the juice products are misbranded under sections 201(n) and 403(a)(1) of the act. Accordingly, the agency is proposing to require a warning statement on the labels of packaged juice products not processed to destroy pathogens. The agency is not proposing to require warnings for unpackaged juice (e.g., juice sold by the glass in restaurants or other food establishments). The proposed regulation does not draw a distinction between packaged and unpackaged juice products, because, by its terms, the regulation applies only to packaged juice products and not the unpackaged products. This approach is consistent with the agency's food labeling regulations which do not apply to food distrubuted to consumers in unpackaged form unless specifically noted in the regulations.

C. Covered Products

In the HACCP proposal, FDA is proposing to define ''juice'' as the aqueous liquid expressed or extracted from one or more fruits or vegetables, the puree of the edible portion of one or more fruits or vegetables, or any concentrate of such liquid or puree. The agency is proposing that the term ''juice'' have the same definition for purposes of the warning statement. Furthermore, the agency notes that fruit and vegetable juices may be used as ingredients in other beverages (e.g., diluted juice beverages and flavored bottled waters). Because these products often resemble juices, are processed in a manner that is similar to the manner in which juices are processed, are handled by consumers similarly to juices, and would support pathogen outgrowth similarly to juices, these foods are likely to present the same food hazards as juices. Therefore, consistent with its HACCP proposal, the agency is proposing in § 101.17(g)(1) that the requirement for a warning statement cover any packaged juice, as defined in section II.C of this document, sold as such or used as an ingredient in another beverage. The agency notes that juice processed on premises and sold for immediate consumption in establishments such as restaurants, in-store delis, and juice bars are not subject to the requirements of this proposal.

D. Circumstances in Which Warning Statements Required

In comments that it submitted in response to the public meeting held on December 16 and 17, 1996, the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) stated that the history of public health problems with juice necessitates some safety

[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).

interventions by manufacturers. The NACMCF recommended that a tolerable level of risk may be achieved by requiring interventions that have been validated to achieve a cumulative 5-log (i.e., 100,000 fold) reduction in *E. coli* 0157:H7 or *Listeria monocytogenes* or a reduction in the yearly risk of illness to less than 10^{-5}, assuming consumption of 100 milliliters of juice daily. However, the NACMCF did not specify the manner in which this reduction should be accomplished.

As discussed in the HACCP proposal published elsewhere in this issue of the **Federal Register**, FDA has tentatively concluded that a 5-log reduction in the target pathogen is a tolerable level of risk in juice products. Therefore, for purposes of the HACCP proposal, the agency is proposing to require that juice made by processors but not retailers as discussed in that proposal be processed in a manner that will produce, at a minimum, a 5-log reduction, for a period at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, in the pertinent microorganism. (As set out in the HACCP proposal, retail establishments includes establishments that process juice for direct sale to consumers and other retailers, as long as total annual sales do not exceed 40,000 gallons.) For the purposes of this regulation, the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in juice. (In the remainder of this document this level of reduction shall be referred to as ''the 5-log reduction.'') FDA recognizes that pasteurization is a process that can achieve this 5-log reduction. In addition, manufacturers may be able to use other technologies and practices (such as a combination of eliminating use of drops, brushing, washing, and using sanitizers) provided that their process is validated to achieve the 5-log reduction in the target pathogen. Therefore, the agency is proposing in § 101.17(g)(2) to require that all packaged juice that has not been processed in a manner that will produce the 5-log reduction bear a warning statement alerting consumers to the potential presence of harmful bacteria.

E. Label Warning Statements

1. Use of Terms ''Pasteurized'' and ''Unpasteurized''

The agency considered whether the use of the terms ''pasteurized'' and ''unpasteurized'' on the label without additional hazard information, would adequately alert consumers to the microbiological hazards associated with some juice products. FDA received several comments in response to the notice of intent regarding the use of these terms. Some comments suggested that products should be labeled ''unpasteurized'' to distinguish them from pasteurized products. Other comments opposed warning labels for pasteurized products. According to one comment, because there have been no public health problems associated with pasteurized juice, there should be no requirement that these products declare on their label that they are pasteurized. However, the comment further asserted that pasteurized juice products should be permitted to declare that fact voluntarily on their label.

Comments received in response to the notice of intent also addressed the adequacy of labeling using the terms ''pasteurized'' and ''unpasteurized.'' One comment stated that use of the terms ''pasteurized'' and ''unpasteurized'' alone, without hazard information, would be ineffective communication if consumers do not know that pasteurization is a heat treatment designed to kill bacteria and that these microorganisms, if not eliminated and if consumed, could cause life threatening illness for some consumers.

FDA tentatively agrees with this comment. Although label statements indicating whether a product is pasteurized or unpasteurized may be useful to consumers who are seeking to purchase either type product, FDA has tentatively concluded that use of such terms would only inform consumers about the type of treatment, or lack of treatment, that a juice has received and would not properly inform consumers of the risks presented by untreated juices. Also, FDA is not aware of the extent to which consumers understand the terms ''pasteurized'' and ''unpasteurized.'' Thus, the agency is concerned that without effective consumer education, labeling untreated juice products as simply ''unpasteurized'' may not only have relatively little meaning to consumers but could even cause confusion. For example, some consumers may select unpasteurized juice believing that such juice is superior to pasteurized juice in that it is less processed.

In addition, FDA has tentatively concluded that an untreated packaged juice product labeled with the term, ''unpasteurized,'' without an accompanying statement that describes the associated microbiological hazards, or a statement that informs purchasers that children, the elderly, and the immunocompromised are at greatest risk of serious illness from consuming such product, would be misbranded under section 403(a)(1) and 201(n) of the act because such labeling would not reveal material facts about the consequences that may result from use of such juice products.

Finally, FDA is concerned that requiring juice products to be labeled only with the terms ''unpasteurized'' or ''pasteurized'' would not take into account technologies other than pasteurization that may be developed to control pathogens in juice. Thus, requiring use of these terms could be viewed as restricting the development of new technologies. Several comments suggested that there are alternate technologies that could be used to control microorganisms in juice products, e.g., irradiation, high pressure treatment, or pulsed high energy processes. One comment opposed labeling that would preclude alternatives to pasteurization to render juice products safe. The agency agrees with this comment and tentatively concludes that labeling a product as ''unpasteurized'' may be misleading in that the term does not distinguish between a product that may contain harmful pathogens that could result in serious disease and one that is treated using a method (other than pasteurization) that is capable of achieving a 5-log reduction in the target pathogen. A product that is processed by a means other than pasteurization to achieve a 5-log reduction in the target pathogen does not have the potential microbiological hazard, and thus, would not require a warning statement, yet that product could not be labeled ''pasteurized.'' Without additional information, the consumer would not know how to interpret the label with the term ''unpasteurized.''

Therefore, the agency tentatively concludes that labeling juice as either ''pasteurized'' or ''unpasteurized'' without hazard information would not adequately inform consumers about the potential hazard associated with consumption of juices that have not been processed to prevent, reduce, or eliminate the presence of pathogenic microorganisms. Consistent with this tentative judgment, FDA has also tentatively concluded that language that specifically identifies the hazard, in the form of a warning statement, is necessary to inform consumers effectively of the risks associated with the consumption of fruit and vegetable juices that have not been so processed. Manufacturers who wish to label their products voluntarily with the term ''pasteurized'' or with the term ''unpasteurized,'' along with the warning statement, may do so under the

proposed rule, provided that these terms are used in a truthful and nonmisleading manner. The agency requests comments on these tentative conclusions.

2. Essential Elements of Specific Warning Statements

Consumer focus group research available to the agency shows that certain elements are essential if label warning statements are to inform consumers effectively of a hazard (Ref. 11). The agency has previously used this consumer study information to develop effective warning statements. For example, the agency used this information to craft a warning statement for iron-containing dietary supplements (see § 101.17(e) (21 CFR 101.17(e))). As discussed in the final rule that requires that such supplements bear a warning statement (62 FR 2218, January 15, 1997), the elements essential for an effective warning statement are a description of the hazard, handling instructions to avoid the hazard, and an instructional statement that describes conditions under which the hazard occurs and what action to take if the hazard is not avoided.

The consumer research that FDA has reviewed shows that when consumers generally believe that a product is safe, warning messages that note that a hazard exists but that do not provide information about the nature of the hazard, are likely to confuse or frighten them (Ref. 11). Therefore, because juice products have not historically been considered by consumers to be hazardous, and because these products are generally promoted and consumed as an important part of a healthy diet, it is critical that any warning statement for juice clearly describe the potential hazard to consumers. In this case, the hazard to be described is the potential presence of pathogens in the juice that can cause serious illness. Therefore, the agency tentatively concludes that to provide effective information to consumers of the hazard associated with some juice products, a brief description of the particular hazard should be included in the warning statement. These consumer research data also show that the first sentence of a warning statement is likely to influence a consumer's decision as to whether to continue reading the remainder of the statement (Ref 11). Therefore, FDA is proposing that the description of the hazard appear in the warning statement and that such description appear in the first sentence of that statement, i.e., that juice may contain pathogens known to cause serious, life-threatening illness.

The second essential element of an effective warning statement is that it disclose the reason that the labeled product presents the hazard. As discussed previously, consumer research shows that stating that a product presents a hazard without further explanation may be confusing and frightening to consumers. The agency is concerned that consumers may not find credible a warning on a product that they may have consumed safely for years. A warning that juice may be hazardous without an accompanying statement describing why the labeled product has the potential hazard could imply that all juices are potentially hazardous. Therefore, the agency tentatively concludes that it is essential to describe why a particular juice product has the potential hazard, i.e., because it has not been processed in a way that is designed to destroy harmful pathogens that could be present.

The final essential element for a warning statement is an identification of the groups that are at greatest risk of illness. Existing data show that certain subpopulations are more susceptible to foodborne illness than others. Specifically, the evidence suggests that children, the elderly, and persons who are immunocompromised are at greatest risk of serious illness from exposure to foodborne pathogens (Ref. 12). As previously discussed, juice has been a vehicle for foodborne pathogens that have caused serious illness. Therefore, it is essential that the warning statement for untreated juice specifically identify the at-risk groups, so that such individuals may choose to avoid the product.

The agency recognizes that the foregoing elements are somewhat different from those used in warning statements on other products. For example, as previously discussed, the warning label for iron-containing supplements contains handling and instructional statements. Warning statements for self pressurized containers in § 101.17(a), (b), and (c), and for protein products under § 101.17(d) also include handling or instructional statements.

However, the agency tentatively concludes that, for juices, handling and instructional information is not essential for an effective warning statement. Under this proposal, the warning statement will include a description of the hazard, a description of the source of the hazard, and a description of the at-risk groups. The agency believes that it is implicit in this description that the at-risk consumers can avoid the hazard by not consuming the juice product. However, FDA requests comment on whether the agency should require a statement explicitly instructing consumers who are at greatest risk to avoid the product and if so, the basis for such requirement.

Applying the essential elements described above, FDA crafted examples of warning statements. The following examples illustrate some of the variation that could occur in statements by applying the essential elements.

> WARNING: 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.

> 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.

The following is an alternative statement that contains the three essential elements as well as optional instructional and handling statements.

> WARNING: Some juices have been found to contain harmful bacteria known to cause life-threatening illness. This product has not been processed to destroy these bacteria. Children, the elderly, and persons with weakened immune systems should avoid this product. Consumers may protect themselves by boiling this product before serving.

In order to evaluate the examples of warning statements developed through use of the essential elements and to test the effectiveness of such examples in informing consumers of the hazards associated with untreated juice products, FDA conducted focus group research to evaluate consumer understanding of several possible warning statements.

Six focus groups were conducted to test possible warning statements that contained the essential elements as well as the optional handling instructions (Ref 13). All participants examined and discussed seven warning statements, including the three examples presented above. Most participants initially viewed the tested warning statements as very strong messages that indicated that there is greater risk associated with unpasteurized juice than these consumers had previously thought. Because many juice products do not state on the label that the product has been pasteurized, many of the participants assumed that most juices are not pasteurized. Once these

consumers understood that most juices are pasteurized, these consumers no longer believed that the warning statements were extreme.[3]

In comparing and contrasting the various examples of warning statements, there was strong consensus across the groups regarding the preferred warning statement. Specifically, the participants strongly preferred a statement that was short and concise, that clearly stated that the product was not pasteurized, and that clearly identified the consumers at greatest risk of illness. The focus group discussions also provided insight into the clarity of different terminology for conveying the essential elements. Participants were better able to understand the warning statement when the term pasteurization was used rather than a term such as ''specifically processed.'' They also found the term ''harmful bacteria'' easier to understand than ''microorganisms.'' Finally, for the description of risk groups, participants preferred the phrase ''weakened immune systems'' to the alternative ''immune system deficiencies.'' Overall, the participants emphasized the need for simple, straight-forward language that could be comprehended by lay people.

In addition, the focus group research showed that inclusion of handling statements that instructed consumers on how to sterilize unpasteurized juice by heating it was seen as not particularly effective. Overall, participants found the statements somewhat confusing and reacted rather negatively to these instructions. Many participants questioned why they would pasteurize unpasteurized juice when they could simply buy pasteurized juice in the first place.

The focus group research also showed that minor wording differences, such as inclusion of the adjective ''fresh'' in describing the juice product, had a strong impact on the participants' reaction to the statements. Participants stated that warnings that described the product as ''fresh'' were inappropriate because such description invoked a positive characteristic (being fresh) that changed the tone of the warning statement in a way that made the statement inconsistent with a serious warning. The participants believed this inconsistent tone would create confusion and that consumers would not recognize the statement as a warning.

Based on these findings FDA has tentatively concluded that requiring a specific message (i.e., a prescriptive approach) will be the most effective way to ensure that consumers are not misled and correctly understand the warning statement. This approach will ensure that consumers of fresh juice are able to make informed choices about the products they purchase and consume. In addition, use of a prescriptive warning statement for fresh juice is consistent with warning statements for other food products (protein products and iron-containing dietary supplements, § 101.17(d) and (e) respectively).

Although FDA stated in the notice of intent that it would propose essential elements of a warning statement, the agency recognized in the notice that, because the model statements were untested, there could be a more effective way to alert consumers to the potential hazard. The focus group research directed at warning statement examples developed through use of elements demonstrates that allowing variation in the warning statements may lead to a misleading message. Therefore, after having conducted focus group research directed at warning statements for juices that have not been treated to destroy pathogens, and having analyzed the results of the research, FDA has tentatively concluded that a prescriptive approach would be more effective than the ''elements approach'' in informing consumers of the potential hazard.

In addition, FDA believes that a regulation to require a warning statement for untreated juices must be sufficiently clear to allow the regulated industry to determine that its labeling complies with that regulation. In addition, the regulation should establish a so-called ''level playing field'' for all products covered by the regulation by requiring that each product's labeling provide the same information. FDA has tentatively concluded that by prescribing the specific language for a warning statement for untreated juice in a regulation would accomplish these two goals, as well as ensure a message to consumers that is not confusing, misleading or otherwise ineffective. In addition, from the agency's perspective, the enforcement of a labeling rule is more straight forward where the regulation prescribes the contents of the labeling.

Accordingly, FDA is proposing in § 101.17(g)(2) to require that juice products not processed in a manner that will produce, at a minimum, a 5-log reduction in the pertinent microorganism for a period of at least as long as the shelf life of the product when stored under normal and moderate abuse conditions, bear the following 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.

The agency requests comments on the specific language of the warning statement. For example, are the categories of at-risk consumers identified too broadly in the warning statement? Should the at-risk consumers be more narrowly described, and, if so, on what basis? For example, is there any basis for describing certain ages for ''children'' and the ''elderly'' or describing a certain level of ''weakened immune system?'' Should the words that alert consumers to the warning statement be changed from ''WARNING'' to ''ATTENTION,'' ''NOTICE,'' ''CONSUMER ADVISORY,'' ''CONSUMER ALERT,'' or ''HAZARD ADVISORY,'' as suggested by comments to the notice of intent, or to some other term?

FDA is also interested in receiving in comments the results of any other available consumer research. FDA will consider the results of such research in developing any final rule that results from this proposal.

FDA is proposing the use of the term ''pasteurized'' rather than ''specifically processed'' in the warning statement because the term ''pasteurized'' in the context of the entire statement was better understood by the focus group participants to describe a process that makes juice ''safe.'' However, the agency recognizes that the use of this term could imply to consumers that all juices not bearing the warning statement have been pasteurized. While such an implication may not be technically precise for products manufactured under an effective HACCP plan that does not include pasteurization, FDA has tentatively concluded that this imprecision is acceptable because the more important message, i.e., that juice products not bearing the warning statement can be safely consumed by all population groups, will be clearly understood by consumers. Nonetheless, the agency solicits specific comment on whether use of the phrase ''has not been pasteurized'' is appropriate in this context, or whether alternate phrasing not identifying a specific process should be used. Comments that suggest alternate phrasing should include data, information, or a rationale to support the alternative, as well as evidence that consumers would not be confused or misled by the alternate phrasing.

[3] Approximately ninety-eight percent of juice sold in the United States is pasteurized.

3. Placement and Prominence

Section 403(f) of the act requires that mandatory label information be prominently placed on the label with such conspicuousness (compared with other words, statements, designs, or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of use. FDA has generally considered the label information panel to be the appropriate location for warning statements. As discussed in the agency's rulemaking requiring warning statements on iron-containing dietary supplements (62 FR 2218), consumer focus group studies establish that a warning statement need not be placed on the principal display panel (PDP) to be effective in informing consumers of the hazard. Participants in the focus groups reasoned that the front of the product was used for marketing purposes and stated that they were accustomed to looking at the ''back of products'' for nutrition and factual information, including warning statements (Ref. 11). Consequently, in the case of iron-containing dietary supplements, the agency required that the warning statement appear on the information panel.

The agency tentatively concludes that for warning statements on packaged juice products, the requirement for prominence and conspicuousness would similarly be met if the statements appeared on the information panel. However, the agency has tentatively concluded that it would not object to firms placing the warning statement on the PDP, because the PDP would provide even greater prominence. Accordingly, FDA is proposing to require in § 101.17(g)(3) that the warning statement for juices appear either on the product information panel or on the PDP.

The requirement in the act for prominent display means that the warning statement must appear in a manner that makes it readily observable and likely to be read. The agency notes that § 101.2(c) (21 CFR 101.2(c)) requires that mandatory information appearing on the PDP and information panel, including information required by § 101.17, appear prominently and conspicuously in a type size no less than one-sixteenth inch. The agency has tentatively concluded that it is not necessary to repeat type size requirements in the proposed regulation for warning labels on juice products and, therefore, has not done so.

Because of the severity of the hazard, FDA has tentatively concluded that the word ''warning'' in the warning statement should be as prominent and conspicuous as possible. In the past, when the agency has required cautionary information on labels, e.g., on products containing aspartame (39 FR 27317), it utilized bold type to make the information more prominent. In addition, FDA regulations on nutrition labeling, § 101.9(d)(1)(iv) (21 CFR 101.9(d)(1)(iv)), require that certain nutrient information in the nutrition facts panel use bold type. Therefore, consistent with these examples, the agency is proposing in § 101.17(g)(4) to require that the word ''WARNING'' be in bold type to help alert consumers that there is new and critically important information about the juice products.

In addition, current agency regulations that require a ''warning'' statement on the product label or in labeling (e.g., the statement required by § 101.17(e) on iron-containing dietary supplements in solid oral dosage form) or a label ''notice'' statement (e.g., the statement required by § 101.17(d)(3) on protein products that are not covered by the requirements of § 101.17(d)(1) and (2)) require that the identifying term ''WARNING'' or ''NOTICE'' be capitalized and immediately precede the language of the applicable labeling statement. Consistent with these examples, the agency is proposing in § 101.17(g)(4) to require that the capitalized word ''WARNING'' immediately precede the statement.

The agency notes that experience has shown that the prominence of some labeling information may be enhanced by the use of a box around the information. The agency's experience with the nutrition facts panel on food labels has been that the box surrounding the nutrition information greatly increases the prominence of the information. In addition, consumer focus group research has shown that boxes around important messages help consumers to distinguish the message from other information (Ref. 11). The agency tentatively concludes that the use of a box around the warning statement for juice will similarly increase the prominence of the message by setting it off, thereby enhancing the likelihood that consumers will notice and read the message. Accordingly, FDA is including in the proposal a requirement (§ 101.17(g)(5)) that the warning statement be set off in a box by use of hairlines. The agency requests comments on the prominence and placement of the proposed warning statements.

III. Analysis of Impacts

A. Preliminary Regulatory Impact Analysis

In accordance with Executive Order 12866, FDA has developed a single preliminary regulatory impact analysis (PRIA) that estimates benefits and costs associated with both this proposal and the HACCP proposal for juice. The agency will promptly publish the PRIA in the **Federal Register**.

B. Small Entity Analysis

In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), FDA has developed a single small entity analysis that estimates benefits and costs associated with both this proposal and the HACCP proposal for juice. The agency will promptly publish the small entity analysis in the **Federal Register**.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective 60 days after its publication in the **Federal Register**. FDA realizes that it will take time for manufacturers to make label changes and to deplete existing inventories. However, FDA must balance the need for immediate implementation of a warning statement requirement because of the food safety benefits associated with it, with the burden placed on industry to comply with the requirement. The agency, therefore, is considering options in this document that will provide information to consumers while reducing the burden on industry. Accordingly, firms may provide the required warning statement in labeling at point of purchase, e.g., signs or placards, as a temporary alternative to providing the information on the label. When signs or placards are used, the agency is requiring that the type size of the labeling be in accordance with that required in § 101.100(a)(2)(ii) (21 CFR 101.100(a)(2)(ii)), i.e., not less than one-fourth inch in height. The agency is proposing in § 101.17(g)(3)(i) to allow manufacturers until January 1, 2000, to provide the warning message on the label itself. This is the next appropriate uniform compliance date for other food labeling changes. Furthermore, to

relieve the burden on small businesses, the agency is proposing in § 101.17(g)(3)(ii) to allow businesses employing fewer than 500 persons until January 1, 2001 to provide the required warning information on the label. Based on the agency's economic analysis, the agency believes that this date permits small businesses sufficient time to provide information on labels without appreciable economic losses. This definition of a small business is based on that of the Small Business Administration. The agency requests comments on the effective date and the compliance dates for this rule.

Because of the severity of the hazard, the agency urges manufacturers of juice products that have not been processed to prevent, reduce, or eliminate the presence of pathogenic microorganisms to begin immediately to label their products with a warning statement consistent with this proposal. Such labeling can be accomplished by the use of stickers or placards. FDA recognizes that it is possible that the requirements for the warning label statement in the final rule may be different from those in the proposal. However, to encourage manufacturers to use the warning label statement as soon as possible, the agency advises that it intends to allow the continued use of any label or labeling that complies with the proposed regulation and is printed prior to the date of publication in the **Federal Register** of any final rule resulting from this proposal until that inventory is depleted.

VI. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed 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 proposed 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)).

VII. Comments

Interested persons may, on or before May 26, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The agency notes that the comment period in this document is shorter than the 75-day period that is customarily provided by FDA for proposed rules. Likewise, this comment period is less than the 60 days that is the general rule set out in FDA's procedural regulations, § 10.40(b)(2) (21 CFR 10.40(b)(2)). As discussed below, FDA believes that a 30-day comment period is appropriate in these circumstances.

Executive Order 12889 (58 FR 69681, December 30, 1993), which implemented the North American Free Trade Agreement, states that any agency subject to the Administrative Procedure Act, should provide a 75-day comment period for any proposed Federal technical regulation or any Federal sanitary or phytosanitary measure of general application. However, Executive Order 12889 provides an exception to the 75-day period where the United States considers the measure necessary to address an urgent problem related to the protection of human, plant or animal health. Similarly, FDA regulations establish a 60-day comment period as agency practice, but provide that the 60-day period may be shortened if the Commissioner of Food and Drugs finds good cause for doing so.

As discussed in detail in this document, the available evidence demonstrates that some juice and juice products have been the vehicles for outbreaks of serious illness from foodborne pathogens. FDA has tentatively concluded that effective protection of the public health requires that consumers be informed as quickly as possible (i.e., in time for the 1998 ''cider season'') to the hazards associated with these juice products. FDA has concluded that the urgency of this matter is sufficient justification for shortening the comment period for this proposal to 30 days, consistent with Executive Order 12889. Similarly, this urgency constitutes good cause within the meaning of § 10.40(b), which justifies shortening the period to 30 days. In addition, a 30-day comment period is appropriate in these particular circumstances because interested parties have already been provided time to comment on the proposed warning label statements that were published in FDA's August 28, 1997, notice of intent.

VIII. References

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

1. 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.

2. National Advisory Committee on Microbiological Criteria for Foods—Fresh Produce Subcommittee, proceedings, December 16, 1996.

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

4. Millard, P. S., K. F. Gensheimer, D. G. Addiss, D. M. Sosin, G. A. Beckett, A. Houck-Jankoski, and A. Hudson, ''An Outbreak of Cryptosporidiosis from Fresh-pressed Apple Cider,'' *Journal of the American Medical Association*, 272(20):1592–1596, 1994.

5. 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.

6. Centers for Disease Control and Prevention, ''Cholera Associated with Imported Frozen Coconut Milk—Maryland, 1991,'' *Morbidity and Mortality Weekly Report*, 40(49):844–845, 1991.

7. Centers for Disease Control and Prevention, memorandum from Kim A. Cook to Steve Thacker, October 1, 1995.

8. FDA recall data memorandum, Dirk J. Mouw to Raymond P. Mars, June 2, 1992.

9. FDA recall data memorandum, M. Anthony Abel to Ronald E. Joyce, March 21, 1994.

10. Memorandum of telephone conversation between Debra Street, FDA, and P. Walker, Washington State Department of Health, January 15, 1997.

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

12. Council for Agricultural Science and Technology, *Foodborne Pathogens: Risks and Consequences*, Ames, Iowa: Council for Agricultural Science and Technology, Task Force Report No. 122, ch. 3, 1994.

13. Macro International Inc., Focus Group Testing of Warning Statements on Juice Products Not Pasteurized or Otherwise Specifically Treated to Eliminate Harmful Bacteria.

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 the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be 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. Any juice sold as such or used as an ingredient in beverages shall be labeled in accordance with the requirements of this paragraph.

(2) The label of any juice that has not 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 which can cause serious illness in children, the elderly, and persons with weakened immune systems.

(3) 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) The warning statement may appear in labeling, including signs or placards, until January 1, 2000; after this date, the warning statement shall appear on the label of the food.

(ii) For products manufactured by businesses employing fewer than 500 persons, the warning statement may appear in labeling, including signs and placards, until January 1, 2001; after this date, the warning statement shall appear on the label of the food.

(4) The word ''WARNING'' shall immediately precede the statement, shall be capitalized, and shall appear in bold type.

(5) 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.

(6) The requirements in paragraph (g) of this section shall 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. For the purposes of this regulation, the ''pertinent microorganism'' is the most resistant microorganism of public health significance that is likely to occur in the juice.

Dated: April 17, 1998.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

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