JUICE LABELING COMMENTS

May 26, 1998

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

RE: Docket No. 97N-0524

On behalf of the members of S.T.O.P. and the following groups,

- Center for Science in the Public Interest
- Consumer Federation of America
- Government Accountability Project
- Natural Resources Defense Council
- OMB Watch
- Public Citizen
- United Food and Commercial Workers Union

we are providing comments on FDA's Proposed Rule for Juice Labeling.

Safe Tables Our Priority is a nonprofit, grassroots organization consisting of victims of foodborne illness, family, friends and concerned individuals who recognize the threat pathogens pose in the U.S. food supply. We count among our members victims of outbreaks from *E. coli* O157:H7 contaminated juice. S.T.O.P.'s mission is to prevent unnecessary illness and loss of life from pathogenic foodborne illness. We have sent comments for the February 3, 1997 dockets on the topic of juice safety, as well as the September 12, 1997 dockets addressing the FDA's Notice of Intent on juice safety. Today, we are writing in support of FDA's plan to place warning labels on juices that have not been processed to eliminate pathogens (hereafter referred to as "raw juices").

We support the placement of warning labels on raw juices because of the following market characteristics:

1) History of Repeated Juice Outbreaks

To be sure that it is part of the record, we list the following outbreaks, arising from U.S. -sourced raw juices:

- Apple juice - *Salmonella typhimurium*; NJ, 1974
- Apple juice - *E. coli* O157:H7; MA, 1991
- Apple juice - *Cryptosporidium*; ME, 1993
- Apple juice - *Cryptosporidium*; NY, 1996
- Apple juice - *E. coli* O157:H7; WA, CA, CO, 1996
- Apple juice - *E. coli* O157:H7; WA, 1996
- Apple juice - *E. coli* O157:H7; CT, 1996
- Orange juice - *Bacillus cereus*; AL, 1994
- Orange juice - *Salmonella typhi*; NY, 1989

- Orange juice - *Salmonella hartford;* FL, 1995
- Carrot juice - *Clostridium botulinum*; WA, 1993

In the fall of 1997, the state of Michigan recalled several hundred gallons of *E. coli* O157:H7 contaminated cider from Schlubatis Orchards. Exactly whether the contaminated cider caused illnesses and the severity of the illnesses was not determined. We note that these outbreaks are exclusively from U.S. sources. Raw apple juice has also caused outbreaks in Canada.

2) Consumers do not understand the level of harm these pathogens cause

Fortunately, decades of consistent pasteurization of milk have allowed a generation to grow up without direct exposure to life-threatening illnesses in unpasteurized milk products. Unfortunately, consumers assume that all beverages intended for human consumption offer the same level of protection. Consumers are unaware that virulent, pathogenic organisms can exist in raw juice. As FDA knows, some of these organisms have emerged over the last 20 years, and there are no consistent, national awareness or education campaigns about the nature of pathogens in juice.

3) Consumers do not understand the "benefits" of pasteurization

For the labels "pasteurized" and "unpasteurized" to be effective without further wording, the consumer would need to know:

1. pasteurization is a heat treatment to a certain temperature and of a certain duration
2. such heat treatment kills bacterial and viral microorganisms, but not necessarily mold/fungal spores
3. the organisms destroyed by pasteurization could otherwise be life-threatening.

Research conducted by the Processed Apples Institute in 1997 found,

"Although they know that pasteurization does something to apple juice, most consumers are probably not quite sure what that might be. Not many participants could state confidently that apple juice is pasteurized. Some seemed to confuse pasteurization with filtering (no pulp, not cloudy)."

In summary, the consuming public does not fully understand the safety ramifications of pasteurization; therefore, using the term "pasteurized" or "unpasteurized" alone is insufficient.

4) The primary consumers of apple juice are children

Apple juice, the number two juice sold in the United States after orange juice, is primarily consumed by children, and *E. coli* O157:H7 can be deadly to children. Thus, raw apple juice is promoted to a market of people most at-risk to sustain life threatening illness or death, children. Children should not have to suffer because their parents are susceptible to industry marketing.

To these four reasons, we add information gathered since the FDA's announcement of its Notice of Intent, which publicized that FDA planned to require mandatory warning labels by the fall of 1998:

1) Members of the raw juice industry, including juice bars, continue to promote the benefits of raw juice as a "health" related product. Parents, and consumers seeking to improve their health such as people with weakened immune systems, seniors and pregnant women, can thus be led to believe that raw juice is superior to pasteurized juices. In contrast, the American Academy of Pediatrics comments that, with respect to children, "Juice offers little of nutritional value." Raw juices, if contaminated with pathogens, can be life threatening, particularly to the at-risk groups.

2) Some members of industry continue to believe that grounders and unpotable water are the ways in which their product can become contaminated. By eliminating these practices, industry members believe they have done all that is needed to ensure their products are safer.

3) Some members of industry continue to believe that FDA is making a "big deal" out of contamination; and that consumers do not need to be informed of risks. They specifically downplay the risks .

4) Some members of industry do not understand the life threatening nature of pathogenic *E. coli* bacteria, killsteps or the science of the conditions under which bacteria survive.

Lastly, we regret having to point out that two elements of FDA's approach to juice safety in the fall of 1997 were failures. FDA's request for voluntary warning labels was virtually ignored by industry. While some juicers may have distributed leaflets, S.T.O.P. knows of only one producer and one grocery store chain that actually placed a warning label on bottles. Likewise, FDA's consumer education efforts failed to reach at-risk groups in time. For example, a notice from CFSAN Director Shank arrived at one private, California elementary school in January of 1998, long after the conclusion of the apple cider season. We know of no pediatricians' offices that have posted the juice education information, though, for example, they have posters regarding recalls of playpens and other child-related equipment.

In short, S.T.O.P. supports the placement of clear warning labels on juice containers because the combination of industry practices and consumer folk wisdom have led to a situation that specifically endangers the lives of children and at-risk groups. The at-risk groups deserve to have on the product, at the point of purchase, the same information that government and industry already have.

Our comments today address the following components of the FDA's Proposed Rule:

1. Error and Omissions
2. Market Sizing and Segmentation
3. Applicability of Labeling
4. Implementation of Labeling
5. Timing of Labeling
6. Label Size, Shape and Language
7. Addressing the "Pasteurized Juice" Market

Errors and Omissions

In the Background section of the Proposed Rule, FDA states that a juice outbreak announced on October 30, 1996 involved "at least 66 cases of illness." The final total of detected illnesses was 70. Underreporting of foodborne illnesses and outbreaks downplays the severity of the problem. We would ask that, when stating the number of people identified as part of an outbreak, FDA change the final number to 70 and, in the future, verify its numbers with CDC rather than repeat previously published, erroneous information.

We would also note that in the section "Circumstances In Which Warning Statements Required," the FDA states that the NACMCF recommended that a tolerable level of risk may be achieved through certain processes. USDA currently mandates a zero tolerance for the adulterant *E. coli* O157:H7 in raw ground beef. We strongly believe that with respect to this pathogen, which can be deadly in as few as 1 to 10 organisms, zero risk is the only tolerable risk. Further, it would be inconsistent for one federal food regulating agency to declare O157 an adulterant, and another to support a "tolerable level of risk" for the same pathogen.

Market Sizing and Segmentation

We believe that it is quite possible that FDA has substantially underestimated the quantity of raw juice sold in the United States, perhaps by more than 100%. FDA states in both the Proposed Rule and repeated public remarks that "approximately ninety-eight percent of juice sold in the United States is pasteurized." We believe this ignores several critical juice market segments and characteristics that result in the 98% figure downplaying the importance and urgency of the juice safety issue.

Segmentation by Point of Sale

Consumers can buy raw juices in many different styles and sizes at many different types of establishments. Below we attempt to describe as many as possible:

1. Grocery Stores (produce-section-related juice). Juice is squeezed from fruit on the premises and sold in multi-serving-size containers or jugs.
2. Grocery Stores (refrigerated section). Juice is supplied by external raw juice processor in single or multi-serving-size container or jugs.
3. Roadside Stands. Juice is processed by the vendor and sold relatively near the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out in small disposable cups.
4. Farmer's Markets. Juice is processed by the vendor and sold relatively near the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out in small disposable cups.
5. Onsite. Juice is processed by the vendor and sold onsite at the originating orchard direct to the consumer in multi-serving-size containers. Samples are often given out and single servings sold in disposable cups.

6. Storefront Juice Bars. Juice is squeezed from fruit/vegetables on premises OR blended with externally supplied, bulk raw juices OR blended with raw juice concentrate and sold in single serving size, disposable cups; juice is typically not consumed in volume on the premises because the sound of the blenders is unpleasant.
7. In-Store Juice Bars. These bars typically exist inside a facility devoted to another activity, e.g. shopping mall, restaurants, grocery store or fitness facility. They have similar production processes and serving containers to Storefront Juice Bars. Juice is more often consumed on the premises because the loud blenders are used only intermittently.
8. Restaurants. Juice is squeezed from fruit/vegetables on premises OR blended with externally supplied bulk raw juices OR blended with raw juice concentrate and sold in a single serving size in a reusable glass.
9. Amateur Segment. Juice is processed by churches or schools as part of anevent and sold by the disposable cup or a multi-serving-size container.

Thus, a significant percentage of raw juices may, in fact, be sold by the glass. To date, Jamba Juice, a California-based juice bar franchise, has 32 juice bars. In a February, 1997 New York Times article, Jamba Juice officials stated that their businesses grossed between $300,000 and $1,000,000 per storefront. If there were only 200 other juice bars (which is a low estimate) in the U.S., and they and Jamba Juice's stores averaged only $300,000 per store, the Juice Bar market alone would be worth $69,600,000.

Unfortunately, education efforts by the "juice" industry and government have alerted only a percentage of the juice producers closest to growing the fruit and not juice producers across the other segments listed above. S.T.O.P. believes that the farther away the processor gets from the raw fruit industry, the less aware they are likely to be of the potential problems for contamination in juice. As anecdotal information we offer a grocer indicating he would sell raw orange juice into an elementary school lunch program because "we squeeze it ourselves on site." It is quite possible that juicing equipment in stores is cleaned less frequently than the average apple press.

Because it does not address the "immediate consumption" segments, the FDA's Proposed Rule is creating an imbalance in the marketplace by requiring only the "later-consumption" containers bare a label. As a result, we believe that all raw juice suppliers will feel pressured to sell their products into market segments where they are not required to label and where consumers will not receive proper warning. Juice bar suppliers specifically tout their concentrates which have "not been heat treated and therefore have superior flavor." FDA should not underestimate the size of businesses such as JR Woods (Atwater), VacuDry (Sebastapol), MetWest Agribusiness (Del Rey) in California which buy fruit and vegetables and supply juice or concentrates to retail storefronts. These same types of businesses can also be found in Florida and other states.

In Conclusion

An understanding of the total market size shows that the problems that have led FDA to take action are particularly urgent because the market is in all likelihood substantially larger than FDA had originally concluded. Different areas of the country are likely to see raw juices with a higher marketshare percentage than FDA presently suggests with its 98% figure, specifically, the North East, Florida and the West.

Roadside stand sales are more likely to represent significant marketshare in New England, Florida, Washington, Oregon and California. Juice bars have proliferated in California and are likely to flourish in areas where coffee bars have become prevalent, and where weather supports interest in fruit juices and smoothie drinks for at least 2/3 of the year.

Applicability of Labeling to the Market

S.T.O.P. believes that the Juice Bar market is here to stay, or at least until a major foodborne illness outbreak is traced to it. Juice bars consistently advertise the "health" component of their drinks ("One 8 oz. glass of orange juice has the nutritional value of five whole oranges."--Jamba Juice website), thereby contributing to the consumer perception that raw juices are superior to pasteurized beverages. In actuality, juice smoothie recipes can contain fruit or vegetables that are grown on or in the ground, including but not limited to carrots, broccoli and celery, and are therefore more likely to harbor contamination. Juice Bars often sell unregulated additives to these beverages, such as spirulina or wheat grass, which may make them even more risky than straight juice. Lest there be any doubt that juice bars target at-risk groups, the smallest serving size offered by Jamba Juice is called "child" size.

In its Proposed Rule, FDA suggests it will exempt "unpackaged juice sold for immediate consumption, e.g. products sold by the glass in restaurants, grocery stores or other food establishments," and also described as "establishments such as restaurants, in-store delis, and juice bars."

S.T.O.P. maintains that the combination of:

- high employee turnover,
- lack of employee education on juice risks,
- external supplies coming from unpasteurized juices or juice concentrates,
- probability of cross-contamination,
- lack of oversight on equipment sanitation,
- limited inspection,
- lack of regulation of additives, and
- blatant marketing emphasis on health

makes juices and juice smoothies sold through these establishments as great a risk as those at roadside stands, if not greater. We therefore strongly recommend that establishments selling by the disposable cup for immediate consumption off premises be required to label their raw beverages and smoothies as well.

The distinction S.T.O.P. recommends is that, if the juice or smoothie is sold for immediate consumption in a disposable single-serving of multi-serving size, it also must bear a warning label. Under this definition, restaurants that serve their patrons in glasses would not be required to place a label on the glass. We would expect those establishments to bear warning information signs in accordance with similar size and location requirements for posting warnings about the hazards of alcohol and pregnancy.

Implementation of Labeling

S.T.O.P. is surprised and dismayed to see that FDA considered that implementation of the labeling at the point of sale through a placard, in lieu of on-package stickers or labels, would be sufficient. Industry has had 9 months of advance notice that *labeling* was going to be required. FDA cannot ensure that placards will be positioned in a manner such that all consumers will read them. For example, in 1997, FDA gave juice processors the option to produce informational language on slips of paper to be distributed at points of sale. While the U.S. Apple Association incorporated the intent of the language into a slip, it was placed below a paragraph promoting cider as part of a healthy lifestyle. Consumer research indicates that placards and leaflets are less effective means of educating consumers.

S.T.O.P. urges that, as FDA indicated in its August, 1997 Notice of Intent, raw juices be *labeled* with the label language. If a juice producer is unable to integrate the label language into the back or front label on their juice in time, the package should be required to carry a separate sticker that meets all the other requirements defined by FDA, with the exception of the surrounding box graphic, which would be unnecessary on a separate sticker.

Timing/Cost of Labeling

S.T.O.P. considers unacceptable FDA's proposal that industry might need 1.5 to 2.5 years to place stickers or labels on their product. USDA required that the meat industry place safe-handling stickers on packaged raw meats within 60 days of the finalization of the proposed rule. USDA felt the severe threat of *E. coli* O157:H7 warranted immediate action. Again, it would be inconsistent for FDA to move slowly toward labeling a product with the same threat.

S.T.O.P. spoke with five separate companies about the timing and cost of implementing labels. Note that with respect to placing a label on products, the only factor that differs significantly in labeling between the foods industry and other industries is the temperature/humidity conditions of the product, which require different glues and inks. The following examples demonstrate the feasibility of requiring labels in less than 60 days of issuance of the Final Rule.

Zeigler's Apple Cider and Apple Juice Products

Zeigler's considers itself the largest apple cider producer and distributes to 30 states. They recently had a label change when they moved their entire production of cider from unpasteurized to pasteurized. It would take Zeigler's 2-3 weeks to make changes to the black plate on an existing label and get it into production. Working with the label company would take 2 weeks, they would need a night to produce the plate and a 1/2 week to print the labels. According to the company, six weeks would be "extremely doable."

Odwalla

After the outbreak associated with their product, Odwalla needed to reintroduce reformulated products in 6 days with round stickers that said, "contains no apple juice." Odwalla considers 6 weeks to be a reasonable amount of time in which to create and implement a completely new label.

Product Marketing Manager, the Santa Cruz Operation (Software Company)

SCO has recently added a quick label. A "not pretty" label done in-house took them 2 1/2 weeks. A nicer label takes 4 to 6 weeks, with print production taking 2 of those weeks and another 2 weeks to get the label into production. According to SCO, six weeks is realistic.

Product Marketing Manager, Legato Systems (Software Company)

Even under the most relaxed circumstances, Legato Systems need only a few weeks. They have produced labels and put them on product with rush charges in as little as 2 days. More typical would be 1 to a few weeks. Typically, if you want to rush a job, the printer will bump other jobs based on payment of rush charges.

Product Marketing Manager, Netcom, (Internet Services Provider)

Netcom can get stickers printed in about 5 days. Then, they need one day to fulfillment/assembly house for shipping and another day to pull inventory and apply stickers. To achieve this kind of turnaround, the printer needs to be ready to print the stickers as soon as the artwork is finished, the fulfillment house needs to be ready to apply the stickers as soon as they receive the stickers, the stickers are applied by hand, and rush charges are paid at both the printer and the fulfillment house.

Hence larger companies are easily able to produce labels and get them into production within 6 weeks without paying rush charges; and with sufficient warning to work on a label design, they could probably achieve the same in 4 weeks.

S.T.O.P. notes that despite FDA's assumption of hardship, smaller companies have multiple advantages over larger companies when it comes to labeling. Smaller companies can develop and produce labels more quickly. Assuming a juice company designed a label on a computer to a standard format, that company could take advantage laser printable labels. Avery labels now makes a "permanent" adhesive label, so that separate stickers can be produced on a laser printer at 600 dpi and still look professional. Thus, for a small company, production of a separate sticker might take at most 2 days.

We have calculated the additional costs of printing new stickers and modifying labels. FDA's proposed language will fit on a label of standard size, 1 inch by 2 inch. The time and cost required to "design" such a sticker is negligible. For standard papers and standard inks, the cost of printing the label at Shortrun Labels in San Carlos, CA (800-522-3583) would be:

Number of Labels	Total Price	Price Per Label

500	$26.15	$.0523
1000	$27.55	$.02755
2000	$52.10	$.02605
3-4000	$23.45/1000	$.02345
5-9000	$17.50/1000	$.01750
10-14,000	$13.15/1000	$.01315

With a resale certificate, no tax is charged for these labels. S.T.O.P. acknowledges that there would be a slight additional cost for putting a sticker on a bottle. At the high end, one $5.15 per hour laborer applying 6 stickers a minute, or 360 per hour, the cost to sticker 1000 bottles would be $14.31. Based on conversations with industry, many small companies own a piece of equipment called a "Labelaire" which "blows" the sticker onto the bottle with a puff of air. This would represent nearly a zero application cost. If neither of these options were palatable, the juice vendor has the option of having the bottle supplier place the label on it. Costs for this type of application would be as low as 7/10 of a cent per bottle, or $.70 for a 1000 in the North East.

Redesign of the label integrating the warning language should also have negligible cost. Given that all companies should be able to print entirely new labels with the warning integrated into them in 6 weeks without rush charges, the cost associated with integrated labeling would be the loss of previously inventoried labels. To avoid such a loss, the company need merely expend the money for the stickers.

To summarize, with advance warning, companies can put a label on their product in between 1 and 6 weeks, depending on the quality of printing required, the level of integration with an existing label, and the desire to avoid rush charges. The cost of a separate sticker would be approximately $27.55 for 1000 stickers plus $.70 in sticker application charges, e.g. a total of $28.25 or less than 3 cents per bottle. This represents the worst case, with a small vendor who sells *only* 1000 bottles; per sticker prices go down with increasing numbers of containers. S.T.O.P. concludes that there is no hardship, with respect to finances or timing for smaller vendors. Therefore, FDA should require that all stickers or label revisions be completed and on packaging in 6 weeks from the FDA announcement of the Final Rule.

Label Size, Shape and Language

S.T.O.P. supports the graphical requirements developed by FDA for the labeling language. As consumers, we have strong preference for the word "WARNING" in caps. "WARNING" is consistent with cigarette and alcohol public health labels and may be better understood as a precautionary statement by those with limited reading skills. "ATTENTION," "NOTICE," and "CONSUMER ADVISORY" are too weak to attract the appropriate level of attention. "CONSUMER ALERT" is not as strong as "WARNING" and is longer, both disadvantages; and "HAZARD ADVISORY" is more complicated and longer. We might suggest that the font size requirement be increased just slightly; with seniors as a primary at-risk group, weaker eyesight may make it challenging to read any font as small as 1/16th of an inch.

FDA's proposed labeling language is:

"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"

Three elements of the label language should be changed. First, "pregnant women," who are particularly susceptible to miscarriage from *Listeria monocytogenes* should be listed as a separate category of at-risk consumers. Many pregnant women do not fully understand that they fall into the category of a person with a weakened immune system. Second, the word "elderly," should be changed to "seniors (55+)," which more accurately describes the at-risk group. "Elderly" connotes a frail person in a nursing home. We strongly urge a definition of age be added to seniors to ensure that older at-risk consumers are aware that they fall into this category; in our current youth-oriented culture, many people are in denial that they might be considered senior. In contrast, we do not believe the term "children," requires modification by age because most adults are conscious that the age range of childhood ends between 12 and 18, and the devastation of these illnesses is not specific enough to say at which age between 12 and 18 a child would be less affected.

Third, S.T.O.P. strongly urges FDA to use the term "life threatening" in place of the word "serious." The word "serious" is used in medical terminology for a person in stable condition who, barring unforeseen circumstances, is expected to recover through medical care. One pediatrician with whom we spoke said "stable, not dying." It is, in fact, a downgrading from "critical," which means there is a possibility of death. In contrast, the reason FDA is placing warning labels on juice is specifically because at-risk groups can contract a disease from which they will die. Indeed, some of these organisms are antibiotic resistant and others are becoming so; medical treatment does not provide a cure for all of them. To imply that these illnesses might be cured by a trip to a hospital is to encourage consumers to take risks. "Life threatening," more accurately and clearly conveys the nature of the potential illnesses.

Therefore, S.T.O.P. advocates:

"WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause life threatening illness in children, pregnant women, seniors (55+), and persons with weakened immune systems"

If "life threatening" is not used, we believe that FDA should require additional language because "serious" does not convey that the at-risk groups should avoid the product. The at-risk groups should be modified with the word "particularly," and should be followed by the sentence: "Members of these at-risk groups should avoid this product." The alternate label would then say,

"WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness, particularly in children, pregnant women, seniors (55+), and persons with weakened immune systems. Members of these at-risk groups should avoid this product."

Addressing the Pasteurized Juice Market

S.T.O.P. understands that FDA does not currently have the authority to require that pasteurized beverages be labeled to differentiate them from raw beverages. This makes it challenging for consumers to make a truly informed choice. S.T.O.P. has received numerous calls from consumers seeking guidance on differentiating between pasteurized and raw juice products. Clearly, the public wants this information.

S.T.O.P. urges FDA to seek the authority in this matter. In the meantime, we urge you to publicly encourage juice companies that use processes to eliminate pathogens to clearly label their juices with the term describing their killstep and additional phrasing that indicates the process eliminates harmful bacteria. Ideally, FDA would ask that all pasteurized juice manufacturers include appropriate language in their next revision to any labeling or packaging they are doing.

In Conclusion

S.T.O.P. strongly supports FDA efforts to place warning labels on raw juices. We believe that timing is critical and can be completed within 6 weeks of the announcement of the Final Rule. Not only does S.T.O.P. believe small businesses should be treated the same as larger businesses, but we also find no economic or timing hardship differences for small businesses with regards to labeling. Small businesses can create juice that is just as lethal as that of larger businesses. Therefore, small businesses should not be treated differently. We expect FDA to require retail establishments distributing raw juices in disposable cups to label their beverages as well. We ask that FDA encourage pasteurized juice manufacturers to clearly differentiate in packaging their pathogen-eliminated juices from those that are not pathogen-eliminated. FDA should incorporate juice labeling requirements into the Food Code as soon as possible.

Sincerely,

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