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6/26/98

June 24, 1998

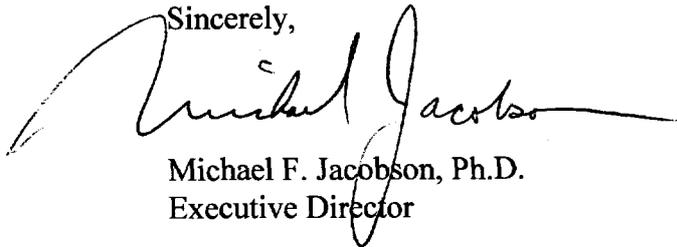
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
Park Building, Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Docket: 98N0339

Dear Sir or Madam:

I am pleased to enclose a copy of a statement that CSPI delivered at the June 24, 1998, public meeting on CFSAN priorities.

Sincerely,



Michael F. Jacobson, Ph.D.  
Executive Director

98N-0339

TSI

Michael F. Jacobson, Ph.D., Executive Director

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CFSAN Priorities

June 24, 1998

Thank you for the opportunity to provide our thoughts on the FDA's priorities. As a general matter, we recommend that CFSAN's priorities be guided primarily by health and economic impacts on consumers. There might be exceptions to that, though, in cases of great public interest in an issue or quick solutions to lower-priority problems.

We endorse the President's Food Safety Initiative as a top CFSAN priority. Inasmuch as this meeting is primarily about other matters, the only thing we want to emphasize is that the FDA needs more authority and more money for more inspectors, and we're working hard to help the FDA get those resources.

**\*\* Improving the nutritional quality of the American diet should be a top priority for CFSAN, even though nutrition is not the agency's primary responsibility. According to a study conducted by the Department of Health and Human Resources, poor nutrition and lack of exercise account for between 310,000 and 580,000 deaths each year. That's about as many deaths as are caused by tobacco. It is important that CFSAN do everything it can to promote a healthier diet. That includes:**

**\* Improving nutrition labeling. The most important change that must be made is to include *trans* fat on the label. There is a consensus in the scientific community that *trans* fat raises cholesterol levels about as much as saturated fat. Nevertheless, CSPI's petition has been languishing for four years. We and many academic experts have urged that *trans* fat either be included as part of saturated fat or as a separate item.**

**\* Health claims is an important area that must be governed carefully. The FDA should promptly approve well-founded health claims that would promote a healthier diet. The claims approved for high-fiber foods, high-calcium foods, low-fat foods, and low-sodium foods do exactly that. But CFSAN should not cave in to every company that wants to make its oatmeal, cranberries, or other product sound like a panacea for heart disease or other ailment.**

The FDA is saddled with a bad amendment to the law concerning health and nutrition claims. But we support the FDA's tentative decision to require that all health claims be supported by significant scientific agreement. That decision should be codified in a regulation. In addition, such regulations should specify that health and nutrition claims based on authoritative statements of other government agencies are limited to statements that were intended to constitute dietary recommendations. Statements made for other reasons could result in misleading label claims.



\* A third labeling issue is that many labels feature claims that can deceive people who are trying to choose more healthful foods. For instance, some foods imply that they are whole-grain foods, whereas in fact they contain mostly refined grains. Other labels imply that foods are made with lots of fruit or made purely with fruit, whereas they contain small amounts of fruit or large amounts of a cheap fruit juice. For decades, the FDA has said that it does not have the resources to police label claims that do not introduce a health threat. But such claims are basically defrauding consumers. It's high time that the FDA made it clear to the food industry that deceptive claims are simply illegal. CSPI filed a petition in 1995 that cited numerous deceptive labels, none of which the FDA has stopped -- though public pressure has caused some companies to remove the claims. If the FDA won't stop deceptive claims, it should tell the public that it is not policing this area, and it should work closely with state officials who, collectively, might have the resources to protect the public.

\* The FDA should also do what it can to stop outright adulterated products, such as juices that contain no juice, or honey that is not 100 percent honey.

\*\* In the area of dietary supplements, the FDA is burdened with a weak law that limits the agency's authority to protect the public from unsafe and misleadingly labeled supplements. The agency should build a record detailing the need for greater authority. In addition, the agency should adopt a containment strategy to ensure that problems with the regulation of dietary supplements do not spread to the regulation of health claims for foods and the safety and efficacy requirements for drugs. CFSAN should start by monitoring carefully the notifications of proposed structure-and-function claims -- and opposing questionable ones.

\*\* Food Additives: We are concerned about the rigor of FDA's food additive approval process. Most additives serve little health purpose and are completely unnecessary. They should be as close to perfectly safe as possible. However, at times, it seems to us that the agency has turned the law on its head. Instead of requiring a company to establish safety ("reasonable certainty of no harm"), it seems that others are required to prove harmfulness. Olestra and acesulfame-K are recent examples, but over the years the FDA has bent over backwards to excuse problems with other additives.

Also with regard to food additives, we hope that CFSAN will defend the Delaney clause. That law is essential to protecting the public health. Without it, industry toxicologists and statisticians will find all sorts of creative ways to prove that cancer-causing chemical are safe.

We also urge the FDA to maintain close scrutiny over GRAS substances. For the FDA to accept pro forma notifications with summaries of scientific studies would not give the public the assurance that the substances were safe.

\*\* The FDA should reconstitute its Food Advisory Committee to increase its credibility: The committee has long been loaded with industry consultants and even industry representatives. It

must include many more bright and independent members whose top priority -- as evidenced by their career records -- is protecting the public's health. The committee must also include consumer activists to balance industry's presence.

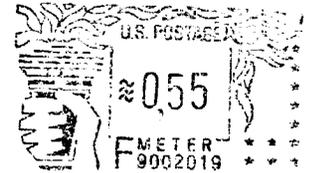
\*\* In the area of international affairs, we are concerned that the FDA is allowing trade concerns to supersede health concerns. CFSAN should be working hard to ensure that the Administration's trade policies are consistent with the Food, Drug, and Cosmetic Act. It should also be seeking to further the objectives of the Act by advocating that standards be harmonized internationally in an "upward" fashion to reflect the best consumer-protection and public-health requirements from around the world.

\*\* One thing that should *not* be a CFSAN priority is eliminating food standards. The public needs those standards, and much of industry supports food standards. The FDA should stop wasting money by reviewing food standards.

\*\* Finally, we recognize CFSAN's financial constraints, and we applaud Mr. Levitt for discussing that earlier today. Over the last 20 years, a period in which CFSAN's responsibilities have increased greatly, the Center has actually experienced a 20 percent decline in staffing. We urge CFSAN to seek additional funding, either through general revenues or by imposing registration fees on food manufacturers. The public cares deeply about food safety and honest labeling and would support a greater budget. But CFSAN, the FDA, and the Administration must make sure the public knows that CFSAN does not have the resources to ensure a safe and honestly labeled food supply.

**SPI** Center for  
Science in the  
Public  
Interest

*Nutrition Action Healthletter*  
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Washington D.C., 20009-5728



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