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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, Maryland 20852

**Re: Docket Number 1998N-0359, CFSAN Program Priorities for FY 2006,
70 Fed. Reg. 29328-29329 (May 20, 2005)**

INTRODUCTION

The Center for Science in the Public Interest (CSPI) appreciates the opportunity to comment on the Food and Drug Administration (FDA) FY 2006 program priorities for the Center for Food Safety and Applied Nutrition (CFSAN).¹

- **Seafood safety**

- 1) *Vibrio vulnificus*

The FDA has established as one of its "Priority Ongoing Activities" for FY 2005 continuing to work with the Interstate Shellfish Sanitation Commission (ISSC) to implement a control strategy for *Vibrio vulnificus* in raw oysters (Part V, number 16). CSPI objects to this classification and believes that it should remain an "A" level priority. While we agree that a control strategy for *Vibrio vulnificus* must be a priority, we disagree that FDA should be looking to the industry-dominated ISSC to resolve this problem. In the Healthy People 2010 Progress

¹ CSPI is a non-profit consumer advocacy and education organization that focuses primarily on food safety and nutrition issues and is supported principally by subscribers to its *Nutrition Action Healthletter*.

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Review, FDA noted that the incidences of some foodborne infections are increasing, and that “[a] major challenge is finding ways to reduce the incidence of infections caused by *Vibrio* species” and other pathogens.² However, in October 2002, FDA denied CSPI’s citizen petition requesting that the Agency establish a performance standard requiring the reduction of *Vibrio vulnificus* to non-detectable levels in raw molluscan shellfish. According to FDA, its best course of action is to continue to work with the ISSC, which adopted a strategy for *Vibrio vulnificus*.³ The ISSC’s plan, however, continues to rely on consumer education as its primary strategy and would not impose any post-harvest controls, if any, until 2007.⁴ The shellfish industry is not meeting the ISSC performance goals for reduction of deaths and illnesses from *Vibrio vulnificus*. Therefore, the FDA should take a more aggressive approach and reconsider CSPI’s citizen petition to establish performance standards.

Consumers continue to become ill and die from *Vibrio vulnificus* related to consumption of raw Gulf oysters. Between 1998 and 2004, 109 illnesses and 71 deaths linked to *Vibrio vulnificus*-contaminated raw shellfish were reported by public health officials.⁵ Since January 2004, there have been at least 36 reported cases of *Vibrio vulnificus* due to consumption of raw shellfish, resulting in 19 deaths.⁶ According to the preliminary FoodNet data for 2004, the

² FDA, FSIS, CDC, *Healthy People 2010 Focus Area Data Progress Review*, Focus Area 10: Food Safety, Challenges, Barriers, Strategies and Opportunities, Section 10-1 (May 11, 2004) [hereafter *Healthy People 2010 Progress Review*].

³ Letter to Michael F. Jacobson, Executive Director, CSPI, from John M. Taylor, III, Senior Associate Commissioner for Regulatory Affairs (Oct. 21, 2002)

⁴ ISSC Final Report, *National Education Program to Influence Consumption Behavior of High-Risk Individuals Regarding Raw Molluscan Shellfish*, Phase III Final Report at 1.

⁵ FDA, Shellfish-Related *Vibrio vulnificus* Case/Deaths, 1998-2004.

⁶ FDA, Shellfish-Related *Vibrio vulnificus* Case/Deaths, 2004.

incidence of *Vibrio* infections, including *Vibrio vulnificus*, has increased 47%.⁷

Because of FDA's failure to exercise leadership in this area, the California Department of Health Services in the summer of 2003 adopted an emergency regulation to restrict the sale of raw oysters harvested from the states bordering the Gulf of Mexico from April through October, unless the oysters are treated with a scientifically validated process to reduce *Vibrio vulnificus* to non-detectable levels. Consumers can no longer afford to have the FDA defer to the ISSC, an industry-dominated organization. The Agency has the authority - and the obligation - under the Public Health Service Act and the Federal Food, Drug and Cosmetic Act to protect consumers from this deadly pathogen.

Although FDA has rejected CSPI's petition to establish a performance standard for *Vibrio vulnificus*, FDA should reconsider that decision and make one of its top priorities establishing a performance standard for *Vibrio vulnificus*.

2) *Vibrio parahaemolyticus*

FDA has classified the publishing of the final *Vibrio parahaemolyticus* risk assessment as an "A" priority level (sub-strategy 1.4.2). While CSPI agrees that this should be a top priority, CSPI believes that developing an enforceable control strategy for both *Vibrio parahaemolyticus* and *Vibrio vulnificus* should also be an "A" level priority. FDA has a responsibility to control *Vibrio parahaemolyticus* and *Vibrio vulnificus* and should therefore develop an enforceable strategy for both.

3) *Establish microbial testing program for hazards in seafood products*

FDA has classified as a "B" priority level review of CSPI's 2002 petition requesting FDA

⁷ CDC, Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 Sites, United States, 2004, 54 *Morbidity and Mortality Weekly Report*, 352-356 (Apr. 15, 2005).

to establish a microbial testing program for hazards in seafood products (sub-strategy 1.4.6).⁸

This petition requests FDA to design a mandatory government program to test not only for the levels of methylmercury in large predatory finfish, but also for *Listeria monocytogenes* in ready-to-eat fish and shellfish, the levels of ciguatera in tropical and sub-tropical reef fish, and the presence of *Vibrio* species in raw shellfish. Review of CSPI's petition should be elevated to an "A" priority because contaminated seafood continues to be a critical public health problem.

CSPI has documented 899 seafood outbreaks with a known etiology that occurred between 1990 and 2003, the largest number of outbreaks from any food source.⁹ FDA's own evaluation of the Seafood HACCP Program for Fiscal Years 2000/2001 has identified continued problem areas, including control of pathogens by processors of cooked, ready-to-eat seafood and smoked seafood, and control of scombrototoxin by processors of scombroid species.¹⁰

- **Fruits and Vegetables**

- 1) *Sprout Safety*

FDA lists as an "A" priority holding a public meeting on sprout safety and initiating an advance notice of proposed rulemaking (ANPRM) for sprouts (sub-strategy 1.5.3). FDA has met this priority by holding such a meeting. However, according to CSPI's database of foodborne illness outbreaks, 5% of all outbreaks associated with produce are caused by sprouts.¹¹ While CSPI agrees that sprout safety should be an "A" priority, we believe that the FDA should draft a

⁸ CSPI, *Petition for Regulatory Action to Establish a Microbial Testing Program for Hazards in Seafood Products* (Oct. 9, 2002).

⁹ See CSPI, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net* (Revised Mar. 2004).

¹⁰ FDA, Center for Food Safety and Applied Nutrition, *FDA's Evaluation of the Seafood HACCP Program for the Years 2000/2001* (Sept. 30, 2002).

¹¹ CSPI, *Outbreak Alert!* (Revised Mar. 2004).

proposed rule now instead of initiating an ANPRM. There is no reason to delay rulemaking on sprout safety any longer. The FDA has held two public meetings and has all the necessary information and knowledge needed to draft a proposed rule rather than an ANPRM. The ANPRM will add at least 12 months to the rulemaking process. Further delay will only increase the already critical public health threat.

2) *Fresh Cut Produce*

FDA lists as an “A” priority the issuance of draft guidance on fresh cut produce (sub-strategy 1.5.2), and lists as a “B” priority the issuance of final guidance on fresh cut produce (sub-strategy 1.5.9). According to CSPI’s database of foodborne illness outbreaks, there have been 554 outbreaks with 28,315 cases linked to produce and produce dishes between 1990 and 2003. In fact, more cases are attributed to produce than any other type of food.¹²

CSPI believes that developing these guidance documents should only be one strategy and should be an “A” priority. There is no need to further delay the process of issuing guidance on fresh cut produce. Because this is only guidance and not formal rulemaking, CSPI believes that the FDA should issue the guidance in final form and avoid further delay and increased threats to public health.

- **Egg safety**

CSPI has long advocated a mandatory national farm-to-table egg safety program to address the public health threat of *Salmonella* Enteritidis (SE) in raw or undercooked eggs. Outbreak data compiled by CSPI show that SE has been implicated in 273 egg outbreaks, which

¹² *Id*

accounted for 83% of all egg outbreaks between 1990 and 2003.¹³

As an “A” priority, FDA lists the development of an egg safety final rule for publication in FY06 (sub-strategy 1.6.3). While CSPI agrees that this should be an “A” priority, we believe that publication of the final rule should not be delayed until 2006. Consumers have waited long enough for FDA to adopt on-farm controls for shell eggs. We encourage FDA to take final action by publishing the egg safety rule immediately, particularly since the rule will implement and enforce proven SE control programs, such as measures that include environmental testing and diversion after an SE-positive result.

- ***Listeria***

Listeria monocytogenes remains one of the most serious foodborne pathogens. It is associated with higher hospitalization rates than any other pathogen and has an estimated 20% case fatality rate.¹⁴ According to the preliminary FoodNet data for 2004, the incidence of *Listeria* did not continue to decline in 2004, as was observed during the preceding 4 years.¹⁵

In September 2003, FDA, with USDA and CDC, published a risk assessment on foodborne *Listeria monocytogenes* in certain categories of ready-to-eat foods. Foods regulated by the FDA, including unpasteurized fluid milk, smoked seafood, and cooked ready-to-eat crustaceans were classed as high-risk foods for listeriosis. Moderate-risk foods include high-fat

¹³ *Id.*

¹⁴ Mead. *et al.* Food-Related Illness and Death in the United States. *Emerging Infectious Diseases* 1999; 5(5): 607-625.

¹⁵ CDC, Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food – 10 Sites, United States, 2004, 54 *Morbidity and Mortality Weekly Report*, 352-356 (Apr. 15, 2005).

and other dairy products, soft unripened cheese, and pasteurized fluid milk.¹⁶

While CSPI believes that FDA has appropriately elevated the issuance of draft guidance advising processors on steps to reduce *Listeria monocytogenes* contamination in ready-to-eat food (sub-strategy 1.7.2) and performing target inspections of dairy products manufacturers with an emphasis on those that produce milk, cream, butter, and other products susceptible to *Listeria* contamination (sub-strategy 1.7.3) to “A” priorities, developing *Listeria* guidance specifically for the dairy industry remains a “B” priority. This should also be elevated to an “A” priority level.

Moreover, FDA needs to go beyond mere guidance and adopt a regulatory response. Over the past 10 years, outbreaks of listeriosis have been documented in FDA-regulated foods, including chocolate milk and queso-fresco cheese. The chocolate-milk outbreak sickened 69 individuals living in three states.¹⁷ In the queso-fresco cheese outbreak, there were 12 reported cases. Ten of these cases were pregnant women, five of whom lost their babies due to stillbirths.¹⁸ Now that FDA has completed the risk assessment, it should make it a priority to require plants producing FDA-regulated foods at risk for *Listeria monocytogenes* (such as soft cheese, pasteurized and unpasteurized milk products, seafood products, and prepared salads) to test their environments and final products for the presence of the pathogen.

- ***Transmissible Spongiform Encephalopathies (TSEs)***

FDA has listed as an “A” priority the finalization of the interim final rule for BSE (sub-

¹⁶ FDA, USDA, CDC, *Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods, Interpretative Summary* (Sept. 2003) at 12.

¹⁷ CDC, *U.S. Foodborne Disease Outbreaks*, available at http://www.cdc.gov/ncidod/dbmd/outbreak/us_outb.htm.

¹⁸ CDC, “Outbreak of Listeriosis Associated with Homemade Mexican-Style Cheese - North Carolina, October 2000-January 2001,” *50 Morbidity and Mortality Weekly Report*, 560-62.

strategy 1.10.2). CSPI agrees that this should be an “A” priority, especially with the recent detection of an infected cow.

FDA has also listed as an “A” priority publishing the final rule on BSE recordkeeping (sub-strategy 1.10.1). Because both of these actions are crucial to FDA’s effort to strengthen safeguards to protect Americans from exposure to the BSE agent, CSPI agrees with the “A” priority listing of both.

- **Acrylamide**

Acrylamide contamination may be causing both thousands of cases of cancer per year in the United States and some less-quantifiable risk of neurologic illnesses. On June 4, 2003, CSPI filed a petition with FDA asking that it immediately establish interim acceptable levels for acrylamide in major food sources (docket number 03P-0276). On June 27, 2003, CSPI filed a comment in a proceeding on infant formula (docket number 95N-0309) asking that FDA immediately test every brand of infant formula to determine whether it contains detectable levels of acrylamide and then convene a workshop to make recommendations to the FDA on how to reduce, if not eliminate, acrylamide in all infant formulas.

In FY 2005 the FDA simply said it would “continue implementation of acrylamide action plan.” This so-called action plan has led to no action, and the FDA should make these two regulatory matters an “A” priority in FY 2006.

- **Qualified Health Claims**

FDA lists as “A” priorities two items related to its qualified health claims policy: (1) publish draft guidance on the evidence-based ranking system for health claims and qualified health claims (sub-strategy 2.1.1) and (2) review comments on the Advance Notice of Proposed Rulemaking (ANPRM) and develop proposed rule to regulate qualified health claims (sub-

strategy 2.1.2). Although FDA announced that it had completed consumer research on the effectiveness of such claims in May 2004, it has yet to issue a report despite requests filed under the Freedom of Information Act and by members of Congress. The most significant results of a study by industry on such claims conducted by the International Food Information Council (IFIC), which parallel the yet-to-be-released FDA study, were as follows:

- Consumers have difficulty distinguishing among four levels of scientific evidence established by FDA under the Qualified Health Claims Initiative, especially with "language only" claims. Seventy-eight percent of consumers incorrectly characterized the level of scientific evidence supporting sample claims.
- Although consumers can distinguish between the levels of scientific evidence if a report card graphic is used specifying the letter grade associated with the level of evidence (e.g., A through D), consumers associate the letter grade with other product attributes such as product safety, quality, and healthfulness.¹⁹

Until such time as FDA can demonstrate that consumers can comprehend the limited nature of the scientific support behind claims on food products that do not meet the "significant scientific agreement standard," it should not spend any additional funds drafting guidance on an evidence-based ranking system, reviewing comments on its ANPRM, or approving pending petitions applicable to food products. Instead, as directed by the Appropriations Committees of both the House and the Senate, FDA should spend such funds to ensure the accuracy of food labels with particular attention to false or misleading claims involving nutrition facts, nutrient content claims, and health claims.

- **Potassium Bromate**

The FDA has known since 1982 that potassium bromate can cause tumors of the kidney, thyroid, and other organs in animals. Subsequent studies on rats and mice confirmed that it can

¹⁹ <http://www.ific.org/research/qualhealthclaimsres.cfm>.

cause such tumors. On July 19, 1999, CSPI petitioned the FDA to ban bromate. FDA listed bromate as a “B” priority in its 2003 Program Priorities, explaining that the Agency would “continue work on developing a strategy for regulating the use of bromates in baked goods and to respond to the pending citizen petition.” In its 2004 priority list, however, FDA stated only that it will “continue to *monitor* the use of bromates in baked goods” (sub-strategy 3.1.2.h) (*emphasis added*), and made no mention of responding to the pending petition. In its 2005 Program Priorities, FDA lists “continue monitoring the use of bromates in baked goods” simply as a priority ongoing activity (Part V, number 60). We urge that this matter be given higher priority.

- **Sorbitol and Mannitol**

In September 1999, CSPI petitioned the FDA to require foods containing one or more grams per serving of sorbitol or other sugar alcohol, such as mannitol, to carry a better warning label that the foods may cause severe diarrhea and are not suitable for consumption by children.²⁰ The use of these sugar alcohols has skyrocketed in the past several years because of the increased sales of low-carbohydrate foods. The FDA should accord this petition priority attention.

- **Salatrim**

As discussed in our 1998 petition to the FDA, salatrim may cause diarrhea in humans and products containing this ingredient may be misbranded.²¹ The FDA has taken no action on this matter. We urge that it be given priority attention.

- **Infant Formula**

On July 9, 1996, FDA issued a proposed rule to establish requirements for current good

²⁰ CSPI, *Petition to Improve the Existing Warning Label on Processed Foods that Contain the Sugar Substitute Sorbitol* (Sept. 27, 1999).

²¹ CSPI, *Petition to FDA on the Generally Recognized as Safe (GRAS) Status of Salatrim* (June 19, 1998).

manufacturing practices and audits, establish requirements for quality factors, and amend its quality control procedures, notification, and records and reports requirements for infant formula.

Nearly seven years later, FDA reopened the comment period to receive new information.²²

While this rulemaking was pending, there was an outbreak of E. Sakazaki among 10 infants in a Tennessee hospital. One of them died.²³ Despite the importance of maintaining the highest quality in infant formula – the sole source of nourishment for many infants – FDA has still not issued a final rule, although it was an “A” priority for 2005 (sub-strategy 2.1.5). This proposed rule has been pending for nine years and should be finalized in FY 2006.

- **Carmine/Cochineal Extract**

CSPI is pleased that the Agency has assigned an “A” priority to the publication of a proposed rule to require the declaration of carmine/cochineal extract, a color additive, on products containing it (sub-strategy 1.12.4). As we stated in our 1998 petition, carmine/cochineal extract may cause severe allergic reactions in humans.

- **Quorn Mycoprotein**

We urge the FDA to give priority attention to revoking the GRAS status and banning the sale of this product for the reasons set forth in our numerous letters to the Agency over the past three and a half years. Although not even mentioned in FDA’s FY 2005 priorities, this product has caused serious health problems, including anaphylaxis, severe vomiting, and diarrhea. We have received about 900 adverse reaction reports, apparently reflecting allergenicity, including about 200 from Americans. It should be removed from the market in FY 2006.

²² 68 Fed. Reg. 22,341 (Apr. 28, 2003).

²³ *Id*

- **Allergens**

In July 2004 Congress passed S. 741, which contains – as Title II – the Food Allergen Labeling and Consumer Protection Act of 2003; the President signed this bill on August 2, 2004 (P.L. 108-282). One part of this law directs the FDA to submit a report to Congress within 18 months analyzing how foods are inadvertently contaminated with major food allergens and how consumers with food allergies would prefer that information about such cross-contact be communicated on food labels. The law also requires the FDA to report on its allergen inspections of food-processing plants, including the number of inspections and the number of violations. The House report on the bill directs the FDA to work with the Alcohol and Tobacco Tax and Trade Bureau of the Department of the Treasury to promulgate allergen labeling regulations for alcoholic beverages.²⁴

In FY 2005 the FDA gave food allergens an “A” priority, and it should continue to be an “A” priority in FY 2006.

- **Preventing Obesity through Better Nutrition**

One of the most important health problems today is the rapid increase in the number of individuals who are overweight and obese. While the FDA has limited authority over restaurant labeling and is, therefore, unable to take all the necessary steps to combat this problem, it should take advantage of whatever leverage it has to support legislation dedicated to reducing the obesity epidemic. The FDA should ask the Department of Health and Human Services (HHS) to support legislation requiring chain restaurants to provide calorie information on menu boards and information about calories, saturated and trans fat, and sodium on printed menus.

²⁴ H.R. Rept. 108-608, 108th Cong., 2d sess. (2004) at 3.

CSPI is pleased that the FDA has established as “A” priorities publishing an ANPRM to solicit comment on establishing proper serving sizes on food packages (sub-strategy 2.1.1.f). This action is urgently needed because many people unwittingly eat several servings at a time and assume they have consumed only the calories in one serving. In order to be effective, the nutrition facts label must include a serving size that accurately reflects the amount of food a typical consumer would consume in a single eating occasion, and this information should be included on the principal display panel (PDP) as well.

CSPI is pleased that the FDA has established as an “A” priority publishing an ANPRM to solicit comment on how to give more prominence to calories on the food label (sub-strategy 2.1.1.e). CSPI believes that calorie content should be listed prominently on the PDP. The FDA should study whether listing the calorie content per serving and per package in larger, bolder type might encourage people to pay more attention to calories.

- **Nutrient Content Claims for Carbohydrates**

In 2004, the Grocery Manufacturers of America, Con Agra and CSPI filed petitions asking the FDA to issue a nutrient content claim regulation defining the term “low carbohydrate.” Spurred by the popularity of the Atkins and South Beach diets and the absence of FDA action, carbohydrate manufacturers have developed a series of synonyms – e.g. carb counting, carb smart, carb aware, carb control, and carb options – to convey the impression that the products are low in carbohydrates. Furthermore, these claims are often based on different methods of calculating carbohydrate content declared as net carbs, impact carbs, or similar terms on the label. These claims are confusing to consumers and thwart the Nutrition Labeling and Education Act’s goal of developing a “limited lexicon” of terms that consumers can rely on to understand the nutrient content of the foods they eat.

Until such time as FDA defines permissible carbohydrate claims and appropriate synonyms, consumers will be misled. Moreover, FDA is sending a message to manufacturers that FDA is not proactive and that they may respond to popular diet trends by making claims consistent with those trends regardless of whether such claims have been approved by the FDA. See the discussion below on the rising number of illegal whole grains claims.

- **Whole Grains**

In its priorities for 2005, FDA listed as a “B” priority the development of a strategy to initiate rulemaking on claims for whole grains (sub-strategy 2.1.2). Since that time, General Mills, Inc. and a number of other manufacturers have begun to make illegal nutrient content claims on their products based on a petition filed by General Mills, Inc. that has not and should not be approved. The inappropriate use of terms such as “good source,” “excellent source,” or “made with whole grains” is confusing to consumers and will not aid them in eating the number of servings of grains recommended by the Dietary Guidelines for Americans 2005. In addition, such claims do not inform consumers of the percent of whole versus refined grains in a product. This information is essential because both the food pyramid and the Dietary Guidelines recommend that consumers take half their grains from whole grain products. FDA should promptly issue a guidance, followed by a rulemaking, to set the parameters for a nutrient content claim for whole grains.

- **Caffeine**

In 1997, both the American Medical Association and CSPI asked the FDA to require that the amount of caffeine in foods be declared on the label. The July 2003 *Consumer Reports* published a story disclosing the hidden amounts of caffeine in various foods and discussing the possible health consequences of caffeine on children – nausea, vomiting, diarrhea, cramps, and

muscle twitching. In addition, both the FDA and physicians advise pregnant women to avoid caffeine or consume only small amounts because of the correlation between the daily consumption of several cups of coffee with low birth weight, miscarriages, and other adverse effects on pregnancy.

In 2003 CFSAN conducted a survey of available databases to determine the prevalence of caffeine in the food supply. At the March 11, 2004 hearing on the FDA's FY 2005 budget, Deputy Commissioner Crawford told Representative Farr that caffeine labeling would be put on the agenda of the FDA's Food Advisory Committee. The FDA subsequently told Representative Farr that it has "decided to conduct a second survey to look at foods that were not represented in the databases. The agency is utilizing a contractor to conduct this survey and will analyze the data when the survey is completed."²⁵ However, caffeine has not yet been put on the agenda of the Food Advisory Committee, and the second survey has apparently not yet been completed.

CFSAN should make it an "A" priority for FY 2006 both to complete this survey and to have the Food Advisory Committee consider the matter so that the FDA can promptly initiate a rulemaking to require that the amount of caffeine in foods be disclosed.

- **Functional Foods**

The FDA should respond to CSPI's petition seeking implementation of the recommendations contained in a report by the General Accounting Office (GAO)²⁶ entitled: "Food Safety: Improvements Needed in Overseeing the Safety of Dietary Supplements and Functional Foods" (July 2000). Among its numerous recommendations, the GAO report

²⁵ *Hearings on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2005*, Part 3 (2004) at 325.

²⁶ CSPI, *Petition for Rulemaking on Functional Foods and Request to Establish an Advisory Committee*, Docket No. 02P-0122/CP1 (Mar. 21, 2002).

concluded that regulations should be adopted on the safety-related information required on labels; the nature and extent of evidence companies need to adequately support structure/function claims;²⁷ a notification procedure prior to the use of novel ingredients; and the use of the same disclaimer as is currently required on dietary supplements. It also called for the establishment of an advisory committee to reevaluate the current labeling approaches for foods with novel ingredients to determine whether the distinctions between structure/function and health claims are understood by consumers and to identify other changes needed to improve consumer understanding of health-related claims.

- **Dietary Supplements**

The FDA should expand the National Academy of Sciences' study of dietary supplement safety. More products should be covered, and the study should be expanded to efficacy as well.

The FDA is burdened with a weak law that limits its authority to protect the public from unsafe and misleadingly labeled supplements. Recently, members of Congress have introduced or called for new legislation. The FDA should, upon request, provide information detailing the need for a new approach to dietary supplement regulation, including the need for explicit statutory authority to impose mandatory adverse event reporting requirements.

- **Impact of the Growth of International Trade on Food Safety**

The FDA should encourage the Administration to set trade policies that further the objectives of the Act. The FDA should ensure that public health takes precedence over trade concerns and should urge that international standards be based on best practices. These factors should assume paramount importance when the Agency takes positions on behalf of the U.S.

²⁷ FDA has issued only a guidance document on substantiating structure/function claims for supplements. 69 Fed. Reg. 64,962 (Nov. 9, 2004).

government at Codex meetings. The FDA should also issue analyses of the food safety implications of proposed free trade agreements.

- **Trans Fatty Acids**

The FDA should make it a top priority to: (1) propose new rules for putting in context the required disclosure of the amount of trans fatty acids on packaged foods and to regulate nutrient content and health claims involving packaged foods that contain trans fatty acids, and/or significant quantities of saturated fat, and/or cholesterol; (2) propose a rule to revoke the GRAS status of partially hydrogenated vegetable oils in packaged and restaurant foods, as requested by CSPI in its May 18, 2004 petition;²⁸ and (3) immediately require restaurants to indicate that the food they serve contains trans fat from partially hydrogenated vegetable oils, as requested by CSPI in its July 22, 2004 petition.²⁹

In FY 2005 the FDA made it an “A” priority to “develop strategy to address claims and disclosure/footnote statements on *trans* fat based on comments of July 11, 2003 Advance Notice of Proposed Rulemaking (ANPRM).” However, the FDA did not issue a proposed rule.

The FDA needs to do more than develop a strategy. Action on all three of these regulatory matters should be made an "A" priority for FY 2006.

- **Sodium**

Cardiovascular-disease experts agree that diets high in sodium increase the risk of heart disease and stroke. In 2002, the American Public Health Association adopted a policy resolution

²⁸ CSPI, *Petition for Rulemaking to Revoke the Authority for Industry to Use Partially Hydrogenated Vegetable Oils in Foods*, Docket No. 2004P-0236/CP1 (May 18, 2004).

²⁹ CSPI, *Petition to Require Restaurants To Indicate That the Food They Serve Contains Trans Fat From Partially Hydrogenated Vegetable Oils*, Docket No. 2004P-0328/CP1 (July 22, 2004).

calling for a 50% reduction in sodium in processed and restaurant foods over the next 10 years.³⁰ In a January 2004 editorial in the *American Journal of Public Health*, Claude Lenfant, then the director of the National Heart, Lung and Blood Institute at the National Institutes of Health and two colleagues estimated that halving sodium intake from those foods would reduce cardiovascular disease deaths by 150,000 per year.³¹

Twenty years ago, the FDA agreed that sodium was a top priority and added sodium to the “voluntary” nutrition label. However, at the same time, the FDA rejected CSPI’s requests to remove sodium chloride from the GRAS list, require sodium labeling of all products, limit sodium levels in key categories of processed foods, and require a warning notice on large packages of salt. The FDA rejected all those measures, but said that if “voluntary” labeling did not deal with the problem adequately, it would consider stronger measures. Ten years later, at Congress’s initiative, the Nutrition Labeling and Education Act was passed (1990) and required sodium labeling on almost all packaged foods (1994). Notwithstanding those labeling measures, along with FDA’s own modest educational program in the early 1980s, sodium consumption has not decreased, but *increased*, over the past 20 years. In other words, the FDA has failed to protect the public from this hidden dietary scourge. Meanwhile, the evidence of sodium’s harmfulness has become ever more solid.

It is urgent that the FDA make sodium-reduction a top priority. We recommend that FDA undertake measures now that it would not take 20 years ago: change salt’s regulatory status from GRAS to “food additive,” limit sodium levels in various categories of processed foods, require a

³⁰ *Reducing the Sodium Content of the American Diet* Washington, DC. American Public Health Association, 2002. Cited in Havas S, Roccella EJ, Lenfant C. Reducing the public health burden from elevated blood pressure levels in the United States by lowering intake of dietary sodium. *Am J Pub Health*. 2004; 94:19-22.

³¹ *Ibid*

warning notice on large packages of salt, and require a special warning notice on processed foods high in sodium (as well as on the menus of chain restaurants).

- **Added Sugars**

The FDA should give priority attention in FY 2006 to proposing a rule that would require the listing of amounts of both total and added-sugars content, along with the percentage of a newly designated Daily Value for added sugars as described in our previous petition to the Agency. The grounds for this request are set out fully in CSPI's August 1999 petition to the Agency.³²

The FDA should also take immediate action to reduce Americans' consumption of soft drinks, especially non-diet drinks containing high-fructose corn syrup and other caloric sweeteners. Soft drink consumption is a major contributor to Americans' calorie intake and likely a significant cause of overweight and obesity. In 2004, the average American consumed 37 gallons – 59,000 calories – of carbonated, non-diet soft drinks. As requested by CSPI in its July 13, 2005 petition,³³ the FDA should revoke the GRAS status of corn sugar, corn syrup, invert sugar, sucrose, and high-fructose corn syrup and require health messages on labels of soft drinks as a condition of use.

- **Food Choking Hazards to Children**

The FDA should give priority attention to protecting young children from choking on foods by requiring companies to label certain products as potential hazards. Every year in the

³² CSPI, *Petition for Proposed Rulemaking to Establish a Daily Value for "Added Sugars," to Require Nutrition Labeling of "Added Sugars," and to Make Corresponding Changes to Nutrient Content and Health Claim Regulations* (Aug. 3, 1999).

³³ CSPI, *Petition to Require Health Messages on Soft Drinks Containing High-fructose Corn Syrup and other Caloric Sweeteners* (July 13, 2005).

U.S., more than 70 children die from choking on food and more than 10,000 children are treated for such problems in emergency rooms. Some companies voluntarily label products (such as hard candies and other foods) as inappropriate for consumption by young children or provide label instructions on how the product should be prepared by parents (chopped, sliced, etc.) in order for it to be consumed safely. The FDA should establish a nationwide surveillance system on childhood food choking, and engage in educational outreach to parents, pediatricians, and hospitals. It should also require all food companies that sell products that constitute choking hazards to provide standardized safety instruction labeling.

- **Percentage Ingredient Labeling**

CSPI has petitioned the Agency to extend percentage-ingredient labeling to all foods. Quantitative Ingredient Declaration (QUID) is necessary for consumers to compare the relative amounts of specific ingredients between seemingly similar products. The FDA should drop its opposition to the work of the Codex Committee on Food Labeling, which is trying to develop an international standard for QUID. We note that the U.S. Department of Agriculture has a rule requiring percentage ingredient labeling of the meat component of frozen pizza and that the FDA requires QUID for fruit juice beverages, seafood cocktails, and other products. Notwithstanding, the FDA has opposed efforts by Codex to establish an international standard, and instead has pursued a position at Codex on this issue that is weaker than U.S. law. The agency should reevaluate its opposition, and adopt a position at Codex that is consistent with its own regulations.

CONCLUSION

CSPI appreciates the opportunity to comment on CFSAN's priorities for FY 2006. The

issues to which the FDA chooses to give priority attention will have a vital impact on the health and well-being of all Americans.

Sincerely,



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