August 12, 2005

Letter to Bill Lockyer, Attorney General of the State of California, RE: a suit filed on June 21, 2004 in San Francisco Superior Court, *The People of the State of California* v. *Tri-Union Seafoods, LLC, et al.*, (Case No.: CGC-04-432394).

Bill Lockyer
Attorney General of the State of California
Office of the Attorney General
1300 "I" Street
P.O. Box 944255
Sacramento, California 94244-2550

Dear Mr. Lockyer:

On June 21, 2004, your office filed suit in San Francisco Superior Court, in *The People of the State of California* v. *Tri-Union Seafoods, LLC, et al.*, (Case No.: CGC -04-432394) seeking an injunction and civil penalties to remedy defendants' alleged failure to warn consumers that canned and packaged tuna products sold by defendants were "exposing consumers to chemicals known to the State of California to cause cancer and reproductive harm." The chemicals described in the complaint are mercury and mercury compounds.

Under the Safe Drinking Water and Toxic Enforcement Act of 1986, Health and Safety Code section 25249.6 ("Proposition 65"), businesses must provide persons with a "clear and reasonable warning" before exposing them to such chemicals. According to the above-cited complaint, on July 1, 1987, methylmercury was added to the list of chemicals known to the State of California to cause reproductive toxicity and, on May 1, 1996, methylmercury compounds were added to the list of chemicals known to the State of California to cause cancer.

The warnings that would be required on the defendants' products if the lawsuit is successful are some derivation of the following: "WARNING: This product contains a chemical known to the State of California to cause cancer," and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."[1]

FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts these Proposition 65 warnings concerning mercury and mercury compounds in tuna. Furthermore, FDA believes that compliance with both the Federal Food, Drug, and Cosmetic Act ("Act") and Proposition 65 is impossible and, as a result, the latter is preempted under federal law.

The Act provides broad authority to the FDA to regulate the labels of food products. However, rather than requiring warnings for every single ingredient or product with possible deleterious effects, FDA has deliberately implemented a more nuanced approach, relying primarily on disclosure of ingredient information and nutrition information, taking action in instances of adulterated and misbranded foods[2] and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels.[3] As part of this deliberate regulatory approach, FDA has required warnings only in those instances where there is clear evidence of a hazard, in order to avoid overexposing consumers to warnings, which could result in them ignoring all such statements, and hence creating a far greater public health problem.[4]

FDA has been studying the issue of methylmercury in fish for several years. In so doing, it has compiled substantial data, and has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter. As a result, the agency believes that it is uniquely qualified to determine how to handle the public health concerns related to methylmercury in fish. After many years of analysis on this issue, FDA has chosen to issue an advisory rather than to require a warning on fish and shellfish (collectively, "seafood") product labels for several reasons. First, consumer advisories are communicated to the target audience directly, rather than to all consumers. Second, FDA believes that the advisory approach is more effective than a product label statement in relaying the complex messages about mercury in seafood.[5] Third, a label statement that reaches the public at large can also have unintended adverse public health consequences. FDA focus group results have suggested that people who are not in the target audience (i.e., women who are not nursing and not likely to become pregnant, and men) might eat less fish or refrain from eating fish altogether when they receive information about the mercury content of fish and possible harmful health effects to the targeted audience (i.e., pregnant women, women who might become pregnant, nursing mothers, and young children).

The agency issued its first methylmercury in fish advisory in the mid 1990s. As more information has come to light regarding the relative benefits and possible risks of eating seafood, FDA has revised the advisory to change its emphasis. For instance, in July 2002, the FDA Food Advisory Committee ("FAC") recommended that FDA clarify the language of the existing advisory, develop a quantitative exposure assessment, and increase monitoring for methylmercury. Recognizing the importance of a coordinated and consistent message on this issue, it also recommended that FDA and EPA combine their two independent advisories. The FAC recommendations were addressed by the two agencies as follows:

- FDA and EPA jointly held four stakeholder meetings between July 29 and July 31, 2003, regarding methylmercury in seafood. The meetings consisted of a series of formal presentations from FDA and EPA, followed by a general discussion in which participants provided comments on the progress toward a joint advisory.

- FDA conducted focus group testing in November 2003 to assess consumers' understanding of the existing advisory.
- The exposure assessment, which had been conducted by FDA, underwent a peer review in August 2003.
- Additional seafood monitoring data were collected during 2002 and 2003.

Revisions to the advisory were made in consideration of these activities in addition to the prior recommendations made by the FAC. This draft advisory ("2003 Draft Advisory") was then presented to the FAC for its review and released to the public on December 10, 2003.

On March 10, 2004, the FAC provided additional recommendations for the FDA and EPA to consider, including providing a list of seafood that have low levels of mercury, a list of common names of seafood, clarifying the portion size to make it easier to understand, making portion size consistent between variety and frequencies of consumption, and including a Web site in the advisory for those who might want further information. The FAC also recommended that FDA and EPA avoid the need to issue multiple advisories by designing the advisory in such a way that it is understood by more than just the original target audience. FDA and EPA considered these recommendations as they refined the 2003 Draft Advisory.

On March 19, 2004, FDA and EPA released the 2004 Advisory, "What You Need to Know About Mercury in Fish and Shellfish." The objective of the 2004 Advisory, as described in the Backgrounder document released simultaneously therewith, is to inform women who may become pregnant, pregnant women, nursing mothers, and parents of young children as to how to get the positive health benefits from eating fish and shellfish, while minimizing their mercury exposure.

The 2004 Advisory provides three principal recommendations for women and young children. These recommendations incorporate the relative mercury levels of "canned light tuna" and "albacore (white) tuna" in relation to each other as well as in relation to other seafood, together with advice as to how frequently these tuna products can be consumed by the targeted audience.

1. Do not eat Shark, Swordfish, King Mackerel, or Tilefish because they contain high levels of mercury.
2. Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury.

- Five of the most commonly eaten fish that are low in mercury are shrimp, canned light tuna, salmon, pollock, and catfish.
- Another commonly eaten fish, albacore ("white") tuna has more mercury than canned light tuna. So, when choosing your two meals of fish and shellfish, you may eat up to six ounces (one average meal) of albacore tuna per week.

3. Check local advisories about the safety of fish caught by family and friends in your local lakes, rivers and coastal areas. If no advice is available, eat up to six ounces (one average meal) per week of fish you catch from local waters, but don't consume any other fish during that week.
   Follow these same recommendations when feeding fish and shellfish to your young child, but serve smaller portions. [Emphasis added]

As subsequent steps, FDA and EPA are engaged in a comprehensive educational campaign to reach the targeted audience. The agencies are working with state, local, and tribal health departments to get information out into their communities. Physicians, other health professionals, and health care associations are being sent information to distribute through their offices. Extensive outreach through the media is also planned. Radio and television stations, health editors at newspapers, magazines, and other popular media will be contacted to encourage them to carry public service messages. The 2004 Advisory will also be an important part of a comprehensive food safety education program to be used by educators of pregnant women.

In addition to issuing these advisories, FDA has used its expertise in this area to advance the public health other ways. For example, FDA employed its expertise on mercury in food and food labeling in resolving the Omega-3 fatty acid health claim petitions: On September 8, 2004, FDA issued its decision to allow qualified health claims involving Omega-3 fatty acids and a reduced risk of coronary heart disease.[6] Omega-3 fatty acids are abundant in a variety of fish. FDA stated in these letters that it would consider exercising enforcement discretion for the following qualified health claim:

> "Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. One serving of [Name of the food] provides [ ] gram of EPA and DHA omega-3 fatty acids. [See nutrition information for total fat, saturated fat, and cholesterol content.]"

FDA also considered, and rejected, the suggestion by petitioner Martek that the presence of mercury in seafood needed to be addressed in the health claim.[7] With regard to the petitioner's argument that when the health claim appeared on a fish product, such as tuna, it should be accompanied by an advisory statement suggesting a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children, our response was as follows:

> "FDA disagrees with the petitioners' contention that the omega-3 fatty acid qualified health claim should be accompanied by a product label statement about mercury content of fish and possible harmful health effects to the vulnerable population of pregnant women, women who might become pregnant, nursing mothers, and young children. For some time, FDA has been addressing the issue of reducing the exposure to the harmful effects of mercury by communicating with this target population (pregnant women, women who might become pregnant, nursing mothers, and parents of young children) through the use of consumer advisories. The latest consumer advisory was issued in March 2004 jointly by FDA and the Environmental Protection Agency. This advisory includes information about mercury and makes recommendations about the kinds and amount of fish to eat and to avoid.

Agencies are granted broad discretion in determining the means by which to pursue policy goals . . . FDA has decided that it is preferable not to use a label statement about mercury and possible harmful effects to pregnant women, women who might become pregnant, nursing mothers and young children as a condition for the agency's enforcement discretion for the omega-3 fatty acid qualified health claims." [Footnotes omitted]

For all of the public health reasons stated above, FDA believes that California should not interfere with FDA's carefully considered approach of advising consumers of both the benefits and possible risks of eating seafood.

Furthermore, the agency believes California cannot legally require the Proposition 65 warnings on tuna products because they are preempted under federal law, for two principal reasons. First, FDA has been given broad authority to regulate the labels of food products, and has deliberately implemented its regulatory authority with a nuanced approach, relying primarily on disclosure of ingredient information and nutrition information and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels. After years of analysis of the methylmercury in tuna issue, the agency remains convinced that the issuance of an advisory remains the preferred route for advising the public. The Proposition 65 warnings frustrate this carefully considered agency approach, causing federal law to preempt California's warnings.

Second, the Proposition 65 warnings purport to convey factual information, namely that methylmercury is known to cause cancer and reproductive harm. However, it is done without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm. Stated differently, these warnings omit facts which are necessary to place the information in its proper context. As a result, FDA believes that the Proposition 65 warnings are misleading under section 403 of the Act, causing tuna products with such warnings to be misbranded under federal law. Tuna manufacturers would not be able to comply both with Proposition 65 and the Act and, hence, the Proposition 65 warnings are conflict preempted under federal law.

For all of the above-stated reasons, the agency believes that Proposition 65 is preempted by federal law with respect to the proposed warnings concerning mercury and mercury compounds in tuna.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Commissioner of Food and Drugs

cc: Robert E. Brackett, Ph.D, Director CFSAN
Joan E. Denton, Director, Office of Environmental Health Hazard Assessment, Proposition 65 Implementation

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[1] Proposition 65 does not specify the form or wording of the warning. Section 12601 of the California Regulations (22 CCR 12601) addresses Clear and Reasonable Warnings, and provides generally that "[t]he message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm." Section 12601(a). The regulations provide a "safe harbor" warning for carcinogens and reproductive toxicants. The safe harbor warning for reproductive toxicants states, "WARNING: This product contains a chemical known to the State of California to

cause birth defects or other reproductive harm." Section 12601(b)(4)(B). While this provision states that persons are not precluded from providing other warnings that satisfy the requirements of the regulation (Section 12601(a)), it does not provide further clarification as to acceptable warnings.

[2] FDA has adulteration and misbranding authority by virtue of sections 402 and 403 of the Act.

[3] For example, 21 C.F.R. 172.804(e)(2) requires that any food containing the sweetener aspartame must bear the following statement: "Phenylketonurics: contains phenylalanine"; 21 C.F.R. 101.17(g) requires juices that have not been specifically processed to prevent, reduce or eliminate the presence of pathogens to 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"; and 21 C.F.R. 101.17(d) requires food products that derive more than 50 percent of its total caloric value from either whole protein, protein hydrolysates, amino acid mixtures, or a combination of these, and that is represented for use in weight reduction to bear the following statement: "WARNING: Very low calorie protein diets (below 400 Calories per day) may cause serious illness or death. Do Not Use for Weight Reduction in Such Diets Without Medical Supervision. Not for use by infants, children, or pregnant or nursing women."

[4] "When confronted with a problem that threatens the general public, FDA has promulgated regulations requiring placement of warning statements on the food label. For example, in 21 C.F.R. 101.17(d), the agency requires a warning on protein products promoted for weight reduction. However, FDA is unwilling to require a warning statement in the absence of clear evidence of a hazard....[as the agency] is concerned that it would overexpose consumers to warnings. As a result, consumers may ignore, and become inattentive to, all such statements." 56 F.R. 28592, 28615; Preamble to the Proposed Rule on Food Labeling; Declaration of Ingredients (1991).

[5] For instance, the 2004 Advisory, as discussed below, provides information on the relative amounts of mercury in different types of seafood, including "canned light tuna", and "albacore (white) tuna", the number of ounces that the targeted population can eat per week of each of the different types of seafood, together with the types of seafood that the targeted population should altogether avoid. This level of detail would be difficult to provide on a product label. Furthermore, this should be contrasted with the substance of the Proposition 65 warnings referenced at the beginning of this letter.

[6] Health Claim Petitions: Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (Docket No. 2003Q-0401) (Letter responding to Wellness petition can be found at http://www.cfsan.fda.gov/~dms/ds-ltr38.html) (Letter responding to Martek petition can be found at http://www.cfsan.fda.gov/~dms/ds-ltr37.html).

[7] Specifically, the Martek petition argued four principal points in this regard: (1) that when the health claim appears on fish (such as tuna), it should be accompanied by an advisory statement suggesting a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children; (2) that certain fish (including shark, swordfish, king mackerel, and tile fish), and other fish that are similarly high in methylmercury, should be ineligible to bear the proposed health claim; (3) that sources of omega-3 fatty acids derived from fish (such as fish oils) should be ineligible for the health claim unless the oil has been tested and found to contain less than 0.025 ppm of mercury; and, (4) that the presence of mercury may offset the cardio-protective effects of omega-3 fatty acids, and therefore, that the claim would be misleading if it appeared on fish that contained elevated levels of mercury. FDA rejected all of these points after extensive review of the applicable science and considerable deliberation.

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