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March 31, 2008

VIA U.S. MAIL AND E-MAIL

Fran Kammerer
Staff Counsel
OFFICE OF ENVIRONMENTAL
HEALTH HAZARD ASSESSMENT
1001 "I" Street
Sacramento, CA 95812

Re: Proposition 65 Regulatory Update Project: Warnings For Exposures To Listed Chemicals In Foods
SDMA-SF FILE NO.: 4589-000001

Dear Ms. Kammerer:

On behalf of our client, Swanson Health Products, Inc. ("Swanson"), a manufacturer and retailer of foods and dietary supplements located in North Dakota, we are providing these comments to the Office of Environmental Health Hazard Assessment ("OEHHA") in response to its request for comments concerning the *Proposition 65 Regulatory Update Project for Warnings for Exposures to Listed Chemicals in Foods.*

I. PRELIMINARY STATEMENT – OEHHA SHOULD MITIGATE PROPOSITION 65'S CONFLICTS WITH STATE AND FEDERAL LAW

Swanson understands that the scope of this Regulatory Update Project is to revise Proposition 65's implementing regulations as they apply to warnings for foods and dietary supplements, which are considered foods under federal law.[1] Although OEHHA has no authority to *change* the statute, OEHHA has considerable authority, as well as, an obligation to issue regulations and interpret the statute to avoid conflicts with federal and other laws. As this Regulatory Update Project moves forward, OEHHA should be mindful of these conflicts and

[1] For purposes of these comments, the term "food" should be understood to include dietary supplements.

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take steps to correct them. Before making specific suggestions about how the regulations should be amended, we make the following background observations.

As OEHHA is aware, Swanson has submitted a Citizen's Petition to the United States Food and Drug Administration ("FDA") among other things requesting that FDA take "all appropriate steps to prevent Proposition 65[2] from being applied to foods and dietary supplements on the ground that Proposition 65 on its face, and as applied, conflicts irreconcilably with the Federal Food Drug and Cosmetic Act ("FFDCA") and FDA's implementing regulations." The Citizen Petition lists several conflicts that are directly linked to issues on which OEHHA has solicited comments - the application of Proposition 65's warnings for listed chemicals present in food.[3] In addition, California courts addressing the issue of preemption with regard to FDA regulated products have found, among other things, that Proposition 65 warnings are misleading, and therefore, misbrand products, as well overwarn consumers. (*Dowhal v. Smithkline Beecham Consumer Healthcare, et. al.*, 32 Cal. 4th 910, (2004); *People ex rel. Lockyer v. Tri-Union Seafoods, LLC* 2006 WL 1544384 (Cal. Superior May 11, 2006); *see also*, *American Meat Institute v. Leeman*, San Diego County Superior Court, Case No GIN044220, (minute order Feb. 14, 2008)(construing USDA regulations).

FDA has advised California on a number of occasions, dating back to 1987, of its concern about the application of Proposition 65 to foods and other FDA-regulated products. In 1987, then FDA Commissioner Frank Young submitted the following statement to the California Scientific Advisory Panel:

> It is my strong belief that FDA regulated products that are lawfully sold in accordance with federal law do not pose a significant risk to human health. It is my further view that ***warnings on products that do not pose such a risk are unnecessary, are likely to be confusing and may be very costly to industry and consumers***.

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[2] California's Safe Drinking Water and Toxic Enforcement Act of 1986, commonly called Proposition 65, is codified at California Heath & Safety Code §25249.5 et. seq. The warning provision is section 25249.6: "Required Warning Before Exposure to Chemicals Known to Cause Cancer or Reproductive Toxicity. No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10."

[3] A complete copy of the Citizen's Petition has been submitted to OEHHA under separate cover, and we ask that it be included in the record here.

Statement of FDA Commissioner Frank E. Young to the California Scientific Advisory Panel (Dec. 11, 1987)(emphasis added). Other letters have followed, consistently expressing the same view. More recently, FDA has recognized that Proposition 65 warnings frustrate FDA's carefully considered federal approach to advising consumers of both the benefits and possible risks associated with foods. Discussing Proposition 65's application to canned tuna, FDA Commissioner Lester Crawford wrote to Bill Lockyer, California Attorney General, advising that the Agency believed that Proposition 65 is preempted under federal law:

> The [FFDCA] provides broad authority for 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***, and, only in exceptional circumstances, requiring manufacturers to place warnings on their products. As part of this deliberate regulatory approach, FDA has required warnings only when there is a 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.

Letter from FDA Commissioner Lester Crawford to California Attorney General Bill Lockyer, dated August 12, 2005 (Swanson Petition, Exhibit 5) In March 2006, FDA wrote a second letter opposing Proposition 65 warnings, restating its concern that:

> the warnings may have the following adverse effects, among others:
>
> - Create unnecessary and unjustified public alarm about the safety of the food supply;
> - Dilute overall messages about healthy eating, and
> - Mislead consumers into thinking that acrylamide is only a hazard in store-bought food.

Letter from Terry C. Troxell, Phd., Director, Office of Plant and Dairy Foods, Center for Food Safety and Applied Nutrition, to Joan Denton, Director, OEHHA, and Deputy Attorney General Ed Weil, dated March 21, 2006. FDA's statement of policy articulated in these recent letters were issued in the context of tuna and acrylamide, applies equally to *all* foods and dietary supplements.

II. COMMENTS ON PROPOSITION 65 REGULATIONS

Although OEHHA's March 14, 2008 workshop focused on California Code of Regulations tit. 22 ("22 CCR") §12601, we urge OEHHA to consider modifications to, or clarifications of, other regulations that apply Proposition 65 to foods. As discussed below, these should include, but are not limited to, 22 CCR §12501 (the naturally occurring allowance), 22 CCR §12900 (no "knowing and intentional" affirmative defense), and 11 CCR § 3002 (Certificate of Merit). In addition, we urge OEHHA to consider adopting regulations that would require all Proposition 65 settlements (private agreements) that contain standards (including exposure levels at which warnings may be required for foods, and/or testing methods and protocols for quantifying exposures) to be submitted to OEHHA, published and issued as a Safe Use Determination ("SUD"). Swanson also encourages OEHHA and the Office of the Attorney General to administer Proposition 65 *consistently* with requirements and policies of the Sherman Food, Drug and Cosmetic Act ("Sherman Act"), and to involve the State Department of Health Services ("DHS") in all Proposition 65 regulatory and policy making activities that apply to food.[4]

A. Proposition 65 Warning Text for Food[5]

Proposition 65 has been construed to mandate the signal word "WARNING." This word, or any other text that implies that the food or dietary supplement may not be safe and healthful, is misleading, as confirmed by the California Supreme Court in *Dowhal*. For foods, we suggest that it be removed entirely, and replaced with a more appropriate signal word, such as "NOTICE."

The current safe harbor warning text (22 CCR 12601(b)) is also misleading, even without the signal word. "This product contains a chemical known to the State of California to cause cancer, and birth defects or other reproductive harm" – is intended to, and does, alarm consumers. Based upon Swanson's experience, consumers are confused when this warning is given with reference to a health food or supplement product – even when the warning is not on the label, but on the packing slip. Our experience also confirms that this stark message is alarmist and conveys the message that if the consumer eats this food they may get cancer or suffer reproductive effects.

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[4] The Sherman Act may also conflict with Proposition 65.

[5] This comment assumes that it is *possible* to give a "warning" for a food that is healthful and nutritious under the FFDCA and Sherman Act.

Not only is this safe harbor message completely unbalanced, but it omits the critical fact that virtually every food contains detectible amounts of one or more listed chemicals. Since 1961, FDA has conducted the Total Diet Study ("TDS") an ongoing program that determines levels of various contaminants and nutrients in foods. From this information, dietary intakes of the analytes by the nation's citizens are estimated.[6] Thus, the TDS has confirmed for decades that many Proposition 65-listed chemicals are present in some detectible amount in nearly *everything in* the nation's food supply – but not at levels that should cause alarm or merit a "warning," or even an "advisory," under the FFDCA or the Sherman Act.

Where a Proposition 65 warning is deemed to apply, the information provided should be accurate and balanced. It is critically important to let the public know that the food at issue *is* healthful and nutritious, meets all state and federal food safety requirements, and that *all* foods have some amount of listed chemicals in them. Thus, statements should be carefully crafted so that they will not deter consumers from eating a balanced diet composed of a variety of foods. In the case of vitamins and supplements, Proposition 65 statements should not deter consumers from supplementing their diet to ensure they are obtaining needed nutrients.

At the March 14th workshop, OEHHA presented slides of the some of the food warnings that have been adopted in settlement agreements negotiated by the Office of the Attorney General. We believe two examples, fish and the restaurant warning for acrylamide, are misleading *per se*, because they include the signal word WARNING as well as the "core and mandatory" safe harbor warning text. The fish warning is especially egregious because "WARNING" is in huge red letters). The restaurant warning does *attempt* to provide additional information, but it comes well after the "core and mandatory" warning provisions.

At the workshop, OEHHA and Office of the Attorney General representatives stated that OEHHA would consider adopting a policy that FDA advisories are deemed Proposition 65 warnings – without the "core and mandatory" language. This is a good policy and should be adopted. However, it has only limited application – in those rare instances when FDA has issued a food advisory.

Even though the vast majority of foods contain detectable levels of listed chemicals – often well above the level of detection – under the FFDCA regulatory scheme and FDA policy, warnings are not appropriate, and neither are advisories. It is the long-standing, well-

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[6] The TDS monitors a wide range for chemicals, including many that are listed under Proposition 65 as well as, nutrients. To conduct the tests, foods are prepared as they would be consumed (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of the dietary intake of these analytes. *See* http://www.cfsan.fda.gov/~comm/tds-toc.html

articulated policy of FDA - and DHS in administering the Sherman Act - not to provide warnings and to issue advisories *only* after considerable research and policy development. Thus, there will not be an advisory to serve as a Proposition 65 compliant warning for every food or dietary supplement.

This is an important point, because where FDA has made a decision *not to permit* warnings, OEHHA should tread lightly. It is well known that a federal agency's decision not to regulate a subject may provide grounds for a kind of "negative" preemption. The United States Supreme Court has held *repeatedly* that where federal agencies have affirmatively refused to exercise their full authority, the ***decision not to regulate takes on the character of a ruling that no regulation is appropriate*** pursuant to the policy of the statute. In these circumstances, "states are not permitted to use their police power to enact such a regulation." *Ray v. Atlantic Richfield*, 435 U.S. 151, 178 (1978). *See* also, *United States v. Locke*, 529 U.S. 89, 110 (2000) (reaffirming *Ray*); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (stating that negative preemption by a federal administrative agency is a "viable preemption theor[y]").

FDA consistently has taken the position that warnings should be used on FDA-regulated products very judiciously, and only in cases that represent a *material* risk. In this regard, FDA has made clear that the FFDCA "authorizes warnings and affirmative disclosures only with respect to ***serious hazards***." 42 Fed. Reg. 22018 (April 29, 1977) (warning for fluorocarbons). This policy is designed ***to ensure the efficacy of warnings and advisories when they <u>are</u> given***. *Id.* Repeatedly, FDA has expressed its strong concern about the proliferation of warnings on foods:

> A requirement for warnings on all foods that may contain an inherent carcinogenic ingredient or a carcinogenic contaminant . . . would apply to many, perhaps most foods in a supermarket. Such warnings would be so numerous they would confuse the public, would not promote informed consumer decision-making, and would not advance the public health.

44 Fed. Reg. 59509, 59513 (Oct. 16, 1979). *See also* 63 Fed. Reg. 37030, 37035 (July 8, 1998)(FDA confirmed that "too many warning labels on foods could result in loss of consumer credibility and effectiveness.").

Fortunately, OEHHA is not left without a remedy. The Proposition 65 statute (Health & Safety Code 25249.10(a)) resolves the conflict, and authorizes OEHHA to determine that for foods, the warning provision does not apply based upon negative preemption:

> Section 25249.6 shall not apply to any of the following: (a) An exposure for which federal law governs warning in a manner that preempts state authority.

California Health & Safety Code 25249.10(a). Thus, where FDA has issued an advisory, that advisory would be deemed a sufficient Proposition 65 warning and where FDA has not issued an advisory or mandated a warning, no Proposition 65 warning would be compelled.

Finally, if California (OEHHA or DHS) determines that specifically targeted advisories or even warnings are needed in a specific situation, these may be adopted as regulations under the Sherman Act. In this circumstance, the text of the warning and the method of providing it to the public may be appropriately crafted to avoid conflicts, and to work in partnership with federal agencies administering food safety.

B. Proposition 65 Cannot Be Applied To Activities Beyond the Borders of the State

Swanson is a family-owned vitamin and health food manufacturer and retailer located in North Dakota. Since 1969, Swanson has formulated its own brand of products and is in compliance with FDA requirements. Swanson does not have a presence in California, but markets its products exclusively via telephone, on-line (www.swansonvitamins.com), and through mail order. For products sold over the internet servers are located in and subject to North Dakota law. Swanson complies with Proposition 65 by providing prophylactic safe harbor warnings on packing slips mailed to California consumers. This practice has been challenged by a private enforcer, who contends that warnings must be provided on the web-page, and on the product labels and given prior to purchase. This demand, however, would compel Swanson to apply this California law to its business (and server) located in North Dakota. In the case of a Proposition 65 warning on foods, complying with Proposition 65 in North Dakota would clearly misbrand all products under North Dakota law, because North Dakota follows federal law and practices with regard to food labeling and standards.

OEHHA should recognize the limits of California's authority, and adopt regulations that clarify that out-of-state manufacturers of foods have no obligation to comply with Proposition 65, unless and until they establish a physical presence in California. The question is larger than whether California courts have jurisdiction to adjudicate a Proposition 65 claim involving out-of-state manufacturers that avail themselves of the California market – they clearly do. The issue is whether California can compel out-of-state food manufacturers to comply with this States' unique law as to their lawful activities elsewhere. In Swanson's case, Proposition 65 compliance would cause the food product to be "misbranded" under the laws that apply in North Dakota, the state in which the food is produced, packaged, sold, and placed into interstate commerce.

There is precedence for this suggestion, and for an OEHHA determination that Proposition 65 may only be applied to food production and distribution activities that physically occur in this state. In 1997, the Occupational Safety and Health Administration ("OSHA") gave conditional approval to Proposition 65's incorporation into its California's Hazard Communication Plan. 62 Fed. Reg. 31159 (1997) OSHA determined that although California is free to require *California* employers and manufacturers of industrial use products to comply with Proposition 65 as to *activity in California*, the State could not compel out-of-state manufacturers to do so. Rather, each manufacturer must comply with the OSH Act as it applies *in the state in which the* **manufacturer labels and places industrial use products in commerce. In firmly rejecting the** State's claims that Proposition 65 applies to every manufacturer whose product is used in California, OSHA said: "***Proposition 65 as incorporated into the State plan may only be enforced against in-State employers.***" *Id.* at 31167.

C. OEHHA Should Provide a Simple and Consistent Mechanism to Ensure that the Naturally Occurring Allowance Is Workable

As it presently exists, 22 CCR §12501, the "Naturally Occurring Allowance" is too undefined and vague to be useful when applying Proposition 65 to exposures in food. As part of the Regulatory Update Project, OEHHA should also revise §12501 to make it more helpful.

There are a number of simple steps that OEHHA should consider, including recognizing the *Codex Alimentarius*[7] as the bases for establishing naturally occurring levels of contaminants, as well as, FDA's TDS database. Significantly, the Office of the Attorney General relied upon the *Codex Alimentarius* in its determination that a Proposition 65 private enforcer's notice concerning lead in chocolate should not proceed. (Letter from Bill Lockyer, California Attorney General, to Rodger Lane Carrick, dated September 28, 2001 (copy attached). Specifically, the Attorney General used the *Codex Alimentarius* to establish that levels of lead and cadmium in chocolate were naturally occurring. Although the private enforcer could show that lead was present at a detectable level, the *Codex Alimentarius* applied

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[7] The *Codex Alimentarius* Commission was created in 1963 by the Food and Agriculture Organization of the United Nations ("FAO") and the World Health Organization ("WHO") to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The primary purposes of this program are protecting health of the consumers and coordinating all food standards work undertaken by international governmental and non-governmental organizations. Federal law recognizes and incorporates the *Codex Alimentarius*.

through 22 CCR §12501 proved that the lead and cadmium levels in chocolate were not actionable under Proposition 65.

In addition, federal law requires food manufacturers to use "good manufacturing practices" ("GMP"), which among other things sets standards and identifies techniques for removing contaminants to the extent feasible. OEHHA should recognize that compliance with applicable GMPs is sufficient to create a presumption that contaminants have been reduced to the maximum extent feasible within the meaning of 22 CCR §12501.

D. OEHHA Should Amend 22 CCR §12900(a) as It Applies to Exposures from Food to Recognize the Naturally Occurring Allowance

Because virtually all foods contain detectable, albeit naturally occurring, levels of listed chemicals, 22 CCR §12900(a) does not make sense, and therefore cannot be reasonably applied to foods. If anything, this regulation discourages food producers from testing products, because such testing may show detectable levels of contaminants, which in a Proposition 65 enforcement action could be used by the private enforcer *against* the defendant. Consistent with the position that the Office of the Attorney General took in the chocolate litigation, OEHHA should amend 22 CCR §12900(a), by adding a provision that:

> in the case of foods and dietary supplements, there is no knowing and intentional violation where testing performed in accordance with this section shows a concentration of the chemical at a level below the naturally occurring level established by the *Codex Alimentarius*, FDA's Total Dietary Study, or other standard recognized under the federal Food, Drug and Cosmetic Act or the Sherman, Food, Drug and Cosmetic Act.

E. OEHHA Must Involve DHS where Proposition 65 Regulations Set Standards and/or Policy with regard to Food

In matters involving Proposition 65's application to food, OEHHA should at least consult with DHS to avoid conflicts with both the Sherman Act and FFDCA. The Sherman Act is consistent with federal laws that apply to foods. In fact, the Sherman Act mirrors the FFDCA in most respects, and subsumes the well-articulated and long-standing policies to avoid warnings for foods, to limit the use of food advisories, and to require all food label statements and standards be accurate, and not misleading "in any particular." In California, DHS *is* the State's repository of medical, technical and scientific expertise as these apply to food standards involving human health and safety. Moreover, both California's Sherman Act and the FFDCA require that standards for food be based on sound science and medical practice. Under California law, DHS is the agency with this expertise.

F. OEHHA and the Office of the Attorney General Should Take Steps to Ensure that Proposition 65 Is Enforced Consistently and that Standards are Never Negotiated in Secret and Established by Private Agreement

As a practical matter, Proposition 65 enforcement, especially enforcement by private enforcers, has been inconsistent. Of grave concern is the indisputable fact that Proposition 65 standards and methodologies have been developed in the context of settlements - "private agreements" – compelled by litigation necessity. As a result, Proposition 65 standards for foods are not only inconsistent, but also are not based on sound science, not adopted in a public process, and may allow private enforcers to usurp FDA and DHS regulatory authority over food. Although settlement agreements are reviewed by the Office of the Attorney General, they are not reviewed by OEHHA or DHS, and are not "published." The Attorney General reviews them in his capacity as an enforcement officer. Clearly, the Attorney General has neither jurisdiction over nor scientific expertise in food safety and health. Worse, in most cases the methodologies used to derive the standards in settlements are never made available to the public at all. This failure to publish and obtain OEHHA approval of the standards and methodologies used to quantify standards in settlements creates the engine for continued prosecution of ever smaller companies within the effected industry. Out-of-state businesses are especially vulnerable, as are retailers who purchase their products.

Moreover, our review of Proposition 65 settlements indicates that the injunctive relief provisions vary, with some companies settling for both lower per unit settlement costs, as well as less stringent injunctive relief provisions, than others. We believe that if the foundational science and test methodology that supports each settlement is disclosed, not only will businesses be able to use the science to make decisions about when to warn and when warnings are be necessary, but the disclosure will also tend to curb private plaintiff abuses and bring consistency to settlements

Although there is much to say on this topic, we offer two simple suggestions. First, OEHHA could require that all standards and methodologies established in private agreements be "conditional." To become binding on the parties, they must be submitted to OEHHA, who, preferably with the assistance and collaboration with DHS, would treat them as a request for a Safe Use Determination. This mechanism will cause their publication and facilitate public comment and industry participation in adopting them. This public process will also ensure that the standards are based on sound science and good medical practice. Finally, this practice should also correct the current problem of conflicting standards applying to the same product, which creates a record-keeping nightmare for manufacturers, distributors, and retailers alike.

Second, to prevent the abuses noted in Attorney General Jerry Brown's letter of May 11, 2007 to Clifford A. Chanler, Hirst & Chanler (discussing abuses in the Glass and Ceramic Opt-in program), the regulated community should be given a reasonable time to come into compliance with the newly issued standards..

G. Certificate of Merit Policy

The Department of Justice has adopted regulations governing Proposition 65 Private Enforcement, 11 CCR §3000 et. seq. Among other things, these regulations clarify and implement the private enforcer provisions of Proposition 65 (Health & Safety Code §25249.7). Proposition 65 requires private enforcers are required to execute a Certificate of Merit (11 CCR §3100). This regulation should be amended to require that where private enforcers target foods, they must take the naturally occurring allowance into consideration, as well as, any applicable safe harbor NSRL or MADL when certifying to a good faith belief that the defendant cannot establish an affirmative defense. At a minimum, the private enforcer should consult the *Codex Alimentarius,* FDA's TDS data base, and the applicable GMP standard for the product at issue. The certification should expressly require that this be done, and proof of this should be made available to the Attorney General upon request.

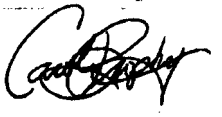
Because Proposition 65 private enforcer lawsuits have the potential to establish inconsistent requirements that also may conflict with the Sherman Act, 11 CCR §3000 should be amended to require that private plaintiffs seeking to enforce Proposition 65 against the food industry must send to DHS a copy of the 60-day notice, the Certificate of Merit, and if requested, the scientific and technical evidence on which it is based. This notification would be similar to the notifications of occupational exposures that are currently required under 11 CCR §3007.

* * *

Swanson thanks OEHHA for the opportunity to comment on the *Proposition 65 Regulatory Update Project For Warnings for Exposures to Listed Chemicals in Foods*. If you have any questions or require additional information about the materials cited or placed in the record, please contact me.

Sincerely,

SEDGWICK, DETERT, MORAN & ARNOLD, LLP



Carol René Brophy
Counsel for Swanson Health Products, Inc.

Enclosures: Swanson Citizen's Petition (submitted under separate cover)
Bill Lockyer letter to Rodger Lane Carrick (September 28, 2001)

cc: Kari Graber, Swanson Health Products, Inc.
Office of the Governor, Hon Arnold Schwarzenegger
Office of the Attorney General, Jerry Brown

CRB/rep

BILL LOCKYER
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September 28, 2001

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RE: Proposition 65 Notices Concerning Hershey and Mars Chocolate

Dear Mr. Carrick and Ms. Corash:

In May of this year, we received sixty-day notices under Proposition 65 from the American Environmental Safety Institute, alleging that certain chocolate products made by Hershey Foods Corporation and Mars, Incorporated, require warnings under Proposition 65 due to the presence of lead and cadmium. Because these products are consumed by millions of Californians, we determined that the matter should be investigated especially carefully. Our investigative efforts have included our own research, consultation with independent experts, analytical testing of numerous products, and the review of substantial information provided by the representatives of both the noticing party and the alleged violators.

As you know, Proposition 65 does not apply to low levels of chemicals in foods that are deemed "naturally occurring" within the meaning of California Code of Regulations, Title 22, section 12501. Under this regulation, the company providing a food product is not responsible for "naturally occurring chemicals" in food if certain criteria are met. This regulation was designed to avoid ubiquitous warnings on many foods due to the existence of small quantities of some chemicals in the air, ground, and water, which results in their being present in food. The validity of the regulation was upheld in *Nicolle-Wagner v. Deukmejian* (1991) 230 Cal.App.3d 652. To fall within the terms of this regulation, however, the chemical cannot be present in the food as the result of any "known human activity," and it must be reduced to the "lowest level currently feasible" through processing, handling, or other techniques.

Based the information obtained in this investigation, we have concluded that the lead present in the products is not present due to known human activity, as that term is used in section 12501. In considering whether lead is present at the "lowest level currently feasible" within the meaning of section 12501, we note the recent lead levels proposed by the Committee on Cocoa Products and Chocolate of the Codex Alimentarius Commission of the World Health Organization. That committee proposed a standard of 1 ppm for cocoa power, 1 ppm for chocolate liquor and 0.1 ppm for cocoa butter. Although that standard was not adopted by the full Codex Commission, we believe that products meeting those strict levels qualify as being within the "lowest level currently feasible" under the regulation. Accordingly, based on the information we have obtained, lead levels falling under those levels would qualify as "naturally occurring" under the regulation.

In addition, the notices we received alleged that the products required warnings based on the presence of cadmium. While cadmium is a listed carcinogen, regulations specifically provide that it poses no significant risk of cancer where the exposure is through ingestion. (22 CCR § 12707(b)(3).) Cadmium also is a listed reproductive toxicant, and the Office of Environmental Health Hazard Assessment has proposed a regulatory safe-harbor level, i.e., the level deemed to be 1-1,000th of the No Observable Effect Level (for reproductive toxicity), of 4.1 micrograms per day. (See June 8, 2001 Notice of Proposed Rulemaking.) Based on the information we have obtained, the products in question fall well below this level, even before determining whether the chemical is "naturally occurring."

It is unusual for the Attorney General to publicly state that he has reviewed a matter under Proposition 65 and determined that it is not appropriate to proceed on the claim. We expect such public statements to continue to be extremely rare. Nonetheless, because these products are consumed by so many Californians, we think it is important for the public to be aware that the Attorney General's decision not to commence a civil action in this matter is based on a conclusion that the action would lack merit, after thorough consideration by this office.

Sincerely,

EDWARD G. WEIL
Deputy Attorney General

For BILL LOCKYER
Attorney General