

November 12, 2015

Ms. Monet Vela
Regulations Coordinator
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812

Via email to monet.vela@oehha.ca.gov

**RE: PRE-REGULATORY PROPOSAL REGARDING NATURALLY OCCURRING
CONCENTRATIONS OF ARSENIC IN RICE AND LEAD IN SOME FOODS**

Dear Ms. Vela:

The California Chamber of Commerce and the below-listed organizations (hereinafter, "Coalition") thank you for the opportunity to submit comments regarding the Office of Environmental Health Hazard Assessment's ("OEHHA") August 28, 2015 Pre-Regulatory Proposal Regarding Naturally Occurring Concentrations of Arsenic in Rice and Lead in Some Foods ("Naturally Occurring Proposal"). Our Coalition consists of dozens of California-based and national organizations and businesses of varying sizes that, collectively, represent nearly every major business sector that would be directly impacted by OEHHA's proposed regulation.

The Coalition supports the concept of adopting naturally occurring levels of chemicals in foods as one of several possible regulatory amendments to make the naturally occurring exemption more workable. Due to the structure of the current naturally occurring regulation, ambiguities in its terms, and associated disparities in proof requirements, the regulation has not achieved its purposes. 27 Cal. Code Regs. § 25501. The Coalition welcomes OEHHA's effort as a first step in the right direction toward furthering the purposes of the exemption and Proposition 65.

1. The Current Naturally Occurring Regulation Has Not Achieved Its Purposes.

The original intent of the current naturally occurring regulation was to differentiate "naturally occurring substances in food and those which are added substances." Final Statement of Reasons, Section 12501. As OEHHA's predecessor agency explained:

Chemicals which are currently subject to the requirement of warning prior to exposure include several chemicals which are naturally occurring constituents of food. The Act does not differentiate between exposure to naturally occurring chemicals and exposures to chemicals added by man. However, due to the abundance of foods which in their natural unprocessed state inherently contain low levels of carcinogens or reproductive toxicants, warning could appear on a large number of food products, and consequently, diminish the overall significance of food warnings.

This regulation provides that human consumption of food containing a listed chemical does not constitute an “exposure” within the meaning of the Act to the extent that it is shown that the chemical is naturally occurring. This exemption is derived from the distinction in state and federal adulteration laws between naturally occurring substances in food and those which are added substances (citation omitted). The laws make it easier to prove adulteration where a deleterious substance was introduced into food by man, than where a substance was naturally occurring in the food. The rationale for this special treatment of food is the historical desire to preserve naturally occurring foods in the American food supply, despite the presence in those foods of small amounts of potentially deleterious substances, as well as a recognition of the general safety of unprocessed foods as a matter of consumer experience (citations omitted). For these same reasons, it is reasonable and appropriate to implement the Act so that warnings are not required for naturally occurring chemicals in food.

The California Court of Appeal in *Nicolle-Wagner v. Deukmejian* recognized that it is appropriate to exempt naturally occurring levels of chemicals in foods. 230 Cal. App. 3d 652 (1991). In upholding the regulation, the court concluded that “the electorate did not intend naturally occurring substances to be controlled by Proposition 65” and that the law’s “use of terms such as ‘knowingly and intentionally’ and ‘putting’ imply that human conduct which results in toxins being added to the environment is the activity to be controlled.”

When the regulation was adopted in 1988, it was expected to reduce the number of lawsuits and the number of warnings posted by food manufacturers and retailers in order to prevent lawsuits, both of which Governor Brown restated in 2013 as goals of his Proposition 65 reform initiative. The current naturally occurring exemption regulation has fallen far short of these goals. Years of experience with the regulation bear this out.

With one exception, the only defendants that have obtained adjudicated naturally occurring allowances have done so through court-approved settlement agreements. The exception was a case involving alleged exposures to mercury in canned tuna. *People v. Tri-Union Seafoods, LLC, et al.*, San Francisco County Superior Court No. 402975 (2006), *aff’d on other grounds*, 471 Cal. App. 4th 1549 (2009). The circumstances of that case made the exemption more effective for the defendants to litigate. First, the product had one ingredient (tuna) that contributed to mercury levels. Second, the case involved the three major companies in the industry, who had the resources and the expertise to establish that the mercury present was naturally occurring. Third, mercury in tuna had already been subject to extensive study and public health review. Fourth, in that case, the Attorney General, which represented the plaintiff in the case, was willing to stipulate that good agricultural and manufacturing practices were not at issue and that there was nothing that could be done to further reduce the levels of mercury in canned tuna. In short, it was an unusual situation. By contrast, for many companies, the naturally occurring regulation is simply not practical, given the burden of proof and complexity of modern supply chains.

The regulation requires businesses to prove a series of negatives: (1) that the chemical did not result from any known human activity; (2) that the chemical was not avoidable by good agricultural or manufacturing practices; and (3) that the chemical is not present above the “lowest level currently feasible,” a term that is not defined in any meaningful way. Moreover, many food products are made of multiple ingredients that may come from different growers, growing regions, and harvests, which compounds the difficulties in proving all three elements.

The result is that the current regulation has not fulfilled the agency's goal in adopting it, nor has it furthered the purposes of Proposition 65.

The Coalition supports OEHHA's efforts to address the practical deficiencies in the naturally occurring exemption. Just as OEHHA adopts presumptively valid safe harbor MADLs and NSRLs to provide guidance, OEHHA has a role to play by providing much-needed guidance on background levels under the naturally occurring exemption. We welcome OEHHA's efforts as the beginning of a process to make the exemption more workable. As a continuation of this process, we hope that OEHHA will consider other structural changes to make the exemption more routine for natural constituents in foods.

2. The Naturally Occurring Proposal.

The Coalition has several suggestions to make the Naturally Occurring Proposal more workable. We also believe it is important for OEHHA—during this pre-regulatory process or in the near future—to consider proposing additional allowances for other foods and consider other regulatory changes to effectuate the purposes of the naturally occurring exemption.

2.1 The Allowances Should Be Increased To Address Variability.

As discussed below, the allowances do not sufficiently account for variability in lead and arsenic levels in foods. OEHHA should consider ways to address variability for all the proposed allowances. One way is to incorporate two standard deviations to the mean results. Another way is to set the naturally occurring allowances using the highest detection levels of the results that OEHHA reviewed because it reflects the full range of inherent variability.

For all foods other than leafy vegetables, OEHHA states that it used the limits of detection in the U.S. Food and Drug Administration's Total Diet Survey ("TDS") as the baseline for the background lead levels. OEHHA then applied a correction of factor of 0.88 to account for anthropogenic sources of lead in soils. OEHHA states that it used the TDS limit of detection because about 95% of the TDS samples had no detectable levels of lead. Using the limit of detection, which is purely a function of analytical technology, understates background levels of lead in food, particularly given the variability of lead levels. Certain plants may take up lead at different rates. Indeed, OEHHA notes this as a reason why the allowance is higher for the category of leafy vegetables. Other factors such as pH, moisture, and soil composition can also affect background levels and the amount of lead or arsenic that a plant takes up from the soil. Thus, one type of vegetable may have a higher lead result than another grown in a different area not because of manmade contamination but rather due to geologic and soil variability. OEHHA should base its allowances on actual detection levels.¹

In addition, we note that all of the proposed allowances are based at least in part on OEHHA's reviews of studies involving California soils. For the proposed arsenic allowances, the allowances are based on the mean levels of rice grown in California. For the proposed lead allowances, OEHHA applied a correction factor of 0.88 based on cropland data in a study of

¹ It is not clear if OEHHA derived the naturally occurring allowance for lead in *leafy vegetables* based on actual detection results or if it was also based on the limits of detection. If the latter, OEHHA should also modify the naturally occurring allowance for lead in leafy vegetables to reflect actual detection levels.

agricultural soil in California.² Background levels of arsenic and lead can vary in different regions of the world. Food products sold and served in California of course include ingredients that originate from all over the world. As discussed above, various factors can affect background levels of arsenic and lead, as well as the amount of uptake by plants. Many commodities are grown in regions other than California and, of course, certain commodities (such as those grown in tropical climates) are not grown in California at all. As OEHHA notes, “[b]oth the USDA data and the USGS data showed that California soils had lower than average lead levels compared to other states.” It follows that it is very likely that background levels of lead and arsenic in other regions are correspondingly higher than in California.

2.2 OEHHA Should Clarify Its Intent in Adopting the Naturally Occurring Proposal.

During the October 14, 2015 workshop, OEHHA clarified that the proposed allowances are levels deemed to be excluded as “exposures” under Proposition 65. In other words, a business does not need to prove the other elements of 27 Cal. Code Regs. § 25501, including showing that the levels are not “avoidable by good agricultural or good manufacturing practices” or that the “producer, manufacturer, distributor, or holder of the food . . . at all times utilize[s] quality control measures that reduce natural chemical contaminants to the ‘lowest level currently feasible.’” 27 Cal. Code Regs. § 25501(a)(4). To make this clear, the proposed prefatory language should be revised as follows:

(a) ~~For purposes of Section 25501(a)(2), the following levels of chemicals in food are deemed to be naturally occurring:~~

The following levels of chemicals in foods are deemed to be naturally occurring and are deemed not to constitute an “exposure” for purposes of Section 25249.6 of the Act:

The Coalition also requests that any Final Statement of Reasons relating to the Naturally Occurring Proposal include a clarifying statement that a business is not required to rely on the proposed allowance and is entitled to prove a higher naturally occurring allowance for the chemicals and foods covered in the Naturally Occurring Proposal.

2.3 OEHHA Should Include Naturally Occurring Allowances for Mineral Compounds and Other Food Ingredients.

As noted above, there have been numerous consent judgments establishing naturally occurring allowances for lead. A partial list of such consent judgments is attached to this letter as **Exhibit A**. In some cases, these levels have been determined following extensive litigation and review, even by the California Attorney General, but they technically apply only to the individual parties to the consent judgments, who represent a subset or in some case a very small subset of the companies who utilize these ingredients in products sold in California. OEHHA should review these past consent judgments and adopt these levels as naturally occurring allowances in regulation so that they will apply uniformly, businesses can rely on them, and private and public enforcers will recognize them.

² Chang AC, et al. (2004). Role of Fertilizer and Micronutrient Applications on Arsenic, Cadmium, and Lead Accumulation on Cropland Soils in California, Final Report to CDFA, University of California at Riverside, Dept. of Envir. Sciences.

As one example, the Coalition believes that, at a minimum, OEHHA should include naturally occurring allowances for lead in certain mineral compounds reached in consent judgments involving the California Attorney General. *People v. Warner-Lambert Co., et al.*, San Francisco Superior Court No. 984503. In June 2011, the court entered a modified consent judgment between the California Attorney General and over a dozen defendants. A copy of that modified consent judgment is attached to this letter as **Exhibit B**. That modified consent judgment reduced naturally occurring allowances for lead that had been established originally in consent judgments in 1998 in the same action. The allowances for lead in the modified consent judgment are as follows:

- 0.8 micrograms per gram (mcg/g) lead in calcium
- 0.4 mcg/g lead in ferrous fumarate
- 8.0 mcg/g lead in zinc oxide
- 0.4 mcg/g lead in magnesium oxide
- 0.332 mcg/g lead in magnesium carbonate
- 0.8 mcg/g lead in zinc gluconate
- 1.1 mcg/g lead in potassium chloride

Since the modified consent judgment was filed in 2011, these same allowances have been incorporated in over two dozen consent judgments in the Attorney General's lawsuit *People v. 21st Century Healthcare, Inc., et al.*, Alameda County Superior Court No. RG08-426937, as well as numerous other consent judgments involving private enforcer actions. Because these allowances have been very widely adopted in settlement agreements, including with major supplement companies, it is appropriate to adopt them into the Naturally Occurring Proposal. Other companies that are not parties to those consent judgments should be allowed to apply those allowances as well.

For the reasons discussed in the comment letter of the National Confectioners Association ("NCA"), it is also appropriate to establish allowances of 1 ppm lead in cocoa powder, 1 ppm lead in chocolate liquor, and 0.1 ppm lead in cocoa butter. These allowances were recognized by the California Attorney General in a 2001 letter after a comprehensive investigation of lead levels in those natural constituents. Since then, consent judgments have included an allowance of 1 ppm lead in cocoa powder, as shown in **Exhibit B**.

2.4 The Term "Unprocessed" in the Title of the Proposed Regulation Should Be Removed.

The Coalition requests that OEHHA remove the term "unprocessed" from the title of the regulation because the term creates unnecessary ambiguity. As OEHHA clarified during the October 14, 2015 public workshop, the allowances for the foods covered in the Naturally Occurring Proposal apply whether the foods are used in processed products or offered for sale to consumers as raw products. This carry-through serves the purpose of the naturally occurring exemption, which is to exempt naturally occurring levels of chemicals in food and food ingredients, not solely foods sold in the produce section of a grocery store, for example. Whether a food product containing naturally occurring lead, for example, is sold raw to a consumer or is sold raw to a food manufacturer who then uses that product to make something else does not change the source of the lead in the food.

Moreover, the term "unprocessed" is unclear. Many foods supplied by agricultural producers go through processes before those foods are shipped for sale to commercial customers such as retailers or food manufacturers. This may include husking, chopping, extracting, pasteurizing,

washing or freezing, for example. The allowances should apply to agricultural products that undergo this type of processing and carry through to the finished products that incorporate them.

* * *

Thank you for considering our comments. We appreciate the opportunity to participate in this very important pre-regulatory process.

Sincerely,



Anthony Samson
Policy Advocate
California Chamber of Commerce

On behalf of the following organizations:

Agricultural Council of California
American Beverage Association
American Herbal Products Association
American Home Furnishings Alliance
Biotechnology Industry Organization
California Business Properties Association
California Citizens Against Lawsuit Abuse
California Citrus Mutual
California Farm Bureau Federation
California Grocers Association
California League of Food Processors
California Manufacturers & Technology Association
California Metals Coalition
California Restaurant Association
California Retailers Association
Consumer Specialty Products Association
Del Monte Foods, Inc.
Grocery Manufacturers Association
International Fragrance Association, North America
Metal Finishing Association of Northern California
Metal Finishing Association of Southern California
National Federation of Independent Business
Nutraceutical Corporation
Pacific Coast Producers
Personal Care Products Council
Plumbing Manufacturers International
Seneca Foods Corporation
USANA
Western Growers Association
Western Plant Health Association
Western States Petroleum Association

cc: Matthew Rodriguez, Secretary, CalEPA
Gina Solomon, Deputy Secretary for Science and Health, CalEPA
Lauren Zeise, Acting Director, OEHHA
Allan Hirsch, Chief Deputy Director, OEHHA
Carol Monahan-Cummings, Chief Counsel, OEHHA
Mario Fernandez, Staff Counsel, OEHHA
Dana Williamson, Cabinet Secretary, Office of the Governor
Ken Alex, Senior Policy Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Policy Advisor, Office of the Governor
Panorea Avdis, Director, Governor's Office of Business and Economic Development
Poonum Patel, Permit Specialist, Governor's Office of Business and Economic
Development
Senator Bob Wieckowski, Chair, Senate Environmental Quality Committee
Assembly Member Luis Alejo, Chair, Assembly Environmental Safety and Toxic
Materials Committee

EXHIBIT A

**SELECTED NATURALLY OCCURRING ALLOWANCES RECOGNIZED IN
COURT-APPROVED CONSENT JUDGMENTS UNDER PROPOSITION 65**

PLAINTIFF	MAXIMUM NATURALLY OCCURRING ALLOWANCES FOR LEAD
Attorney General ⁱ	0.8 micrograms per gram (mcg/g) in calcium 0.4 mcg/g lead in ferrous fumarate 8.0 mcg/g lead in zinc oxide 0.4 mcg/g lead in magnesium oxide 0.332 mcg/g lead in magnesium carbonate 0.8 mcg/g lead in zinc gluconate 1.1 mcg/g lead in potassium chloride
Environmental Research Center ⁱⁱ	Same as allowances above
Environmental Research Center ⁱⁱⁱ	1 mcg/g lead in cocoa powder
Consumer Justice Foundation ^{iv}	1 mcg/g <i>Panax</i> ginseng 5 mcg/g all other ginseng
As You Sow; Stephen Gillett ^v	2.25 mcg/g lead per dietary supplement
As You Sow ^{vi}	3.5 mcg/g lead per dietary supplement
Farbod Nasseri ^{vii}	0.02 mcg/g in amino acids 0.005 mcg/g in maltodextrin 0.4 mcg/g in cocoa powder 0.01 mcg/g in cellulose gum and gel 0.2 mcg/g in carrageenan 0.015 mcg/g in magnesium phosphates 0.05 mcg/g in potassium phosphates 0.05 mcg/g in sodium hexametaphosphates 0.01 mcg/g in potassium bicarbonate 0.025 mcg/g in sodium citrate 0.05 mcg/g in casein caseinate 0.03 mcg/g in milk protein (isolate, concentrate) 0.02 mcg/g in whey protein (concentrate, isolate, hydrolysate) 0.02 mcg/g in flavorings

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- ⁱ *People v. Warner Lambert Co., et al.*, San Francisco Superior Court No. 984503 (1997). The naturally occurring allowances in *Warner Lambert* were modified upon stipulation of the settling parties in 2011 to the levels stated above. Various consent judgments entered in 2012 in *People v. 21st Century Healthcare, Inc., et al.*, Alameda County Superior Court No. RG08-426937, also include these levels.
- ⁱⁱ See, e.g., *Environmental Research Center v. NNC LLC dba Naturade*, Los Angeles Superior Court, BC465087 (Sept. 1, 2011); *Environmental Research Center v. Vitatech International; Bodywise International, LLC*, Los Angeles Superior Court, BC446151 (Sept. 21, 2011), *Environmental Research Center v. S.A.N. Nutrition Corporation*, Los Angeles Superior Court, BC472377 (Oct. 28, 2011); *ERC v. Continental Vitamin Company, Inc.*, Alameda County Superior Court No. RG 12-611776 (March 27, 2012); *Environmental Research Center v. GNLD International, LLC*, San Francisco Superior Court No. 526124 (Feb. 8, 2013).
- ⁱⁱⁱ See, e.g., *Environmental Research Center v. GNLD International, LLC*, San Francisco Superior Court No. 526124 (Feb. 8, 2013); *Environmental Research Center v. Atkins Nutritionals*, San Francisco Superior Court No. CGC-11-513819 (Aug. 31, 2011).
- ^{iv} *Consumer Justice Foundation v. Leiner Health Products, LLC, et al.*, San Francisco Superior Court No. 418038 (Sept. 8, 2003).
- ^v *As You Sow v. IdeaSphere, Inc., et al.*, San Francisco Sup. Ct. No. 07-468381 (June 4, 2008); *As You Sow v. Natural Factors Nutritional Product, Inc.*, San Francisco Sup. Ct. No. 08-477605 (Sept. 10, 2008); *As You Sow v. Wholistic Botanicals, LLC*, San Francisco Sup. Ct. No. 07-468669 (Oct. 7, 2008); *As You Sow v. Vitacost.com, Inc., et al.*, San Francisco Superior Court No. 08-478195 (Jan. 9, 2009); *As You Sow v. Arizona Nutritional Supplements, Inc., et al.*, San Francisco Sup. Ct. No. 08-479178 (March 27, 2009); *As You Sow v. Swanson Health Products, Inc.*, San Francisco Sup. Ct. No. 07-466169 (June 11, 2009); *Gillett v. Madison One Acme*, San Francisco Sup. Ct. No. 07-469239 (Sept. 24, 2008).
- ^{vi} *As You Sow v. Threshold Enterprises, Ltd., et al.*, San Francisco Sup. Ct. No. 422847 (Sept. 8, 2005); *As You Sow v. Irwin Naturals., et al.*, San Francisco Sup. Ct. No. 429279 (June 30, 2005); *As You Sow v. Nature's Way Products, Inc.*, San Francisco Sup. Court No. 422848 (May 24, 2005); *As You Sow v. Nature's Sunshine Products, Inc.*, San Francisco Sup. Court No. 04-437196 (May 24, 2005); *As You Sow v. Botanical Laboratories, Inc., et al.*, San Francisco Sup. Court No. 04-429563 (May 23, 2005).
- ^{vii} *Nasseri v. Cystosport, Inc.*, Los Angeles County Superior Court No. BC439181 (Jan. 15, 2014)

EXHIBIT B

1 KAMALA D. HARRIS
Attorney General of California
2 LAURA J. ZUCKERMAN
Deputy Attorney General
3 State Bar No. 161896
TIMOTHY E. SULLIVAN
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8 *Attorneys for People of the State of California*

FILED
San Francisco County Superior Court

JUL 18 2011

CLERK OF THE COURT

BY: M. Vallejo Deputy Clerk

9 SUPERIOR COURT OF THE STATE OF CALIFORNIA

10 CITY AND COUNTY OF SAN FRANCISCO

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13 **PEOPLE OF THE STATE OF**
CALIFORNIA ex rel. KAMALA D.
14 **HARRIS, Attorney General of the State of**
California,

15 Plaintiff,

16 v.

17 **WARNER-LAMBERT CO.;**
SMITHKLINE BEECHAM CORP.;
18 **AMERICAN HOME PRODUCTION**
CORP.; SOURCE NATURAL, INC.;
19 **SCHERING-PLOUGH HEALTH CARE**
PRODUCTS, INC., PHARMAVITE
20 **CORP.; GENERAL NUTRITION CORP.;**
21 **PERRIGO CO.; TWIN LABORATORIES,**
INC. and DOES 1-200,

22 Defendants.

Case No. 984503
CA

[AMENDED ~~PROPOSED~~] ORDER
MODIFYING CONSENT JUDGMENTS

Date: June 30, 2011
Time: 9:30 a.m.
Dept: 301
Judge: Hon. Peter J. Busch
Trial Date: Vacated
Action Filed: February 6, 1997

1 WHEREAS the Attorney General has provided written notice to the Settling Defendants
2 and other persons that are parties to the February 17, 1998 Consent Judgment, the February 26,
3 1998 Consent Judgment, the June 24, 1998 Consent Judgment, and the November 13, 1998
4 Consent Judgment (together, the "Consent Judgments"), that, pursuant to paragraphs 2.7 and 3.7
5 of the Consent Judgments, as applicable, the Attorney General intends to seek modification of the
6 Consent Judgments; and

7 WHEREAS the Attorney General and the Settling Defendants have conferred for a period
8 of at least ninety (90) days concerning such modification; and

9 WHEREAS the Attorney General and the below-listed Settling Defendants agree,
10 pursuant to paragraphs 2.7 and 3.7 of the Consent Judgments, as applicable, that, as it applies to
11 Access Business Group, LLC (as successor-in-interest to Nutrilite, A Division of Amway Corp.);
12 Bayer HealthCare LLC (as successor-in-interest to Bayer Corporation); Country Life, LLC (as
13 successor-in-interest to Consac Industries); General Nutrition Corp.; GlaxoSmithKline Consumer
14 Healthcare, L.P., GlaxoSmithKline Consumer Healthcare LLC, GlaxoSmithKline LLC and
15 GlaxoSmithKline PLC (as successors-in-interest to SmithKline Beecham Consumer Healthcare);
16 McNEIL-PPC, Inc. (as successor-in-interest to certain rights and obligations of Warner-Lambert
17 Co. regarding Rolaid(s) products); Perrigo Company; Pfizer, Inc. (as successor-in-interest to
18 American Home Products Corp. and Wyeth); and Pharmavite LLC, each of the Consent
19 Judgments should be modified to reflect a new "lowest level currently feasible" for lead in
20 Calcium Supplements and Multiple Vitamin/Minerals;

21 It is hereby ORDERED, that, as it applies to the above-named entities, each of the
22 Consent Judgments, as applicable, is MODIFIED as follows:

23
24 I. All references in each Consent Judgment to "Table 2.3" with respect to Calcium
25 Supplements and Multiple Vitamin/Minerals (but not Antacids) now refer instead to the below
26 Table 2.3A:

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TABLE 2.3A

DATE	NATURALLY OCCURRING AMOUNT OF LEAD PER 1000 MILLIGRAMS OF CALCIUM
July 1, 1997	3.5 micrograms
April 1, 1999	1.0 microgram
November 1, 2011	0.8 micrograms

II. All references in each Consent Judgment to "Table 3.3" with respect to Calcium Supplements and Multiple Vitamin/Minerals (but not Antacids) now refer instead to the below Table 3.3A:

TABLE 3.3A

DATE	INGREDIENT	NATURALLY OCCURRING AMOUNT OF LEAD
November 1, 1998	Ferrous Fumarate	0.456 micrograms/gram (mcg/g)
November 1, 2011	Ferrous Fumarate	0.4 mcg/g
November 1, 1998	Zinc Oxide	10.0 mcg/g
November 1, 2011	Zinc Oxide	8.0 mcg/g
November 1, 1998	Magnesium Oxide	0.5 mcg/g
November 1, 2011	Magnesium Oxide	0.4 mcg/g
November 1, 1998	Magnesium Carbonate	0.415 mcg/g
November 1, 2011	Magnesium Carbonate	0.332 mcg/g
November 1, 1998	Magnesium Hydroxide	0.5 mcg/g
November 1, 2011	Magnesium Hydroxide	0.4 mcg/g
November 1, 1998	Zinc Gluconate	1.0 mcg/g
November 1, 2011	Zinc Gluconate	0.8 mcg/g
November 1, 1998	Potassium Chloride	1.32 mcg/g
November 1, 2011	Potassium Chloride	1.1 mcg/g

1 III. The following paragraph 2.3.1 is added to each Consent Judgment after paragraph 2.3, if
2 the Consent Judgment contains a paragraph 2.3 that contains a Table 2.3:

3 2.3.1. During the time between the entry of the modification to this Consent Judgment
4 and December 31, 2014, a Settling Defendant need not provide a warning that would
5 otherwise be required by paragraph 2.2 for a Calcium Supplement if the Calcium
6 Supplement meets all of the criteria listed below. This provision may be invoked one time
7 only for that Calcium Supplement, for a period covering no more than three months.

8 (a) No warning would have been required for the Calcium Supplement
9 pursuant to section 2.2 if the Settling Defendant were allowed to exclude the
10 amount of lead specified by the Consent Judgment prior to the modification;

11 (b) The calcium in the Calcium Supplement is obtained from a supplier that
12 had previously supplied calcium of the same form, grade, and functionality, with
13 the same specification for lead concentration in the ingredient, to that Settling
14 Defendant for use in that Calcium Supplement;

15 (c) The supplier is unable to provide calcium with the same form, grade, and
16 functionality with lower lead content, and this inability is documented in a writing
17 from the supplier; and

18 (d) The Settling Defendant invokes this exception by sending written notice to
19 the Attorney General prior to shipping the Calcium Supplement and provides
20 evidence showing that criteria (a) through (c), above, have been satisfied.

21
22 IV. The following paragraph 2.7.1 is added to each Consent Judgment after paragraph 2.7, if
23 the Consent Judgment contains a paragraph 2.7:

24 2.7.1 The Attorney General shall not seek to modify the Consent Judgment pursuant to
25 Section 2.7 with respect to the naturally occurring levels set forth in Table 2.3A until three
26 years have elapsed from the date of entry of this modification. This restriction no longer
27 applies, however, if a Settling Defendant seeks to modify the Consent Judgment pursuant
28 to Section 2.8 prior to the expiration of the three-year period.

1 V. The following paragraph 3.7.1 is added to each Consent Judgment after paragraph 3.7, if
2 the Consent Judgment contains a paragraph 3.7:

3 3.7.1. The Attorney General shall not seek to modify the Consent Judgment pursuant to
4 Section 3.7 with respect to the naturally occurring levels set forth in Table 3.3A until three
5 years have elapsed from the date of entry of this modification. This restriction no longer
6 applies, however, if a Settling Defendant seeks to modify the Consent Judgment pursuant
7 to Section 3.8 prior to the expiration of the three-year period.

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9 In addition, it is hereby ORDERED that

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11 VI. Pfizer Inc. is bound by and shall have the benefit of the terms of the November 13, 1998
12 Consent Judgment as modified by this Order. Exhibit B of the November 13, 1998
13 Consent Judgment is hereby amended to include Pfizer Inc.'s Calcium Supplement
14 products and Multi-Vitamin/Minerals products identified in Exhibit 1 hereto.

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16 VII. Bayer HealthCare LLC is bound by and shall have the benefit of the terms of the
17 November 13, 1998 Consent Judgment as modified by this Order. Exhibit B of the
18 November 13, 1998 Consent Judgment is hereby amended to include Bayer HealthCare
19 LLC's Calcium Supplement products and Multi-Vitamin/Minerals products identified in
20 Exhibit 2 hereto.

21

22 VIII. GlaxoSmithKline Consumer Healthcare, L.P., GlaxoSmithKline Consumer Healthcare
23 LLC, GlaxoSmithKline LLC and GlaxoSmithKline PLC ("GSK") are bound by and shall
24 have the benefits of the terms of the November 13, 1998 Consent Judgment as modified
25 by this Order. Exhibit B of the November 13, 1998 Consent Judgment is hereby amended
26 to include GSK's Calcium Products identified in Exhibit 3 hereto.

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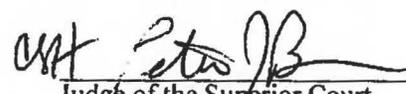
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IX. McNEIL-PPC, Inc. is bound by and shall have the benefits of the terms of the November 13, 1998 Consent Judgment as modified by this Order. Exhibit B of the November 13, 1998 Consent Judgment is hereby amended to include Roloids(r) as Antacid products of McNEIL-PPC, Inc.

In all other respects the Consent Judgments are to remain unchanged.

Dated: JUL 15 2011


Judge of the Superior Court
PETER J. BUSCH

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