

Exhibit A

Prop 65 California Health & Safety Code Sections The Safe Drinking Water and Toxic Enforcement Act of 1986 (added by Initiative Measure, Nov. 4., 1986)

§25249.5 Prohibition on contaminating drinking water with chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly discharge or release a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, notwithstanding any other provision or authorization of law except as provided in Section 25249.9

§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

§25249.7 Enforcement

- (a) Any person violating or threatening to violate Section 25249.5 or Section 25249.6 may be enjoined in any court of competent jurisdiction.
- (b) Any person who has violated Section 25249.5 or Section 25249.6 shall be liable for a civil penalty not to exceed \$2500 per day for each violation in addition to any other penalty established by law. Such civil penalty may be assessed and recovered in a civil action brought in any court of competent jurisdiction.
- (c) Actions pursuant to this section may be brought by the Attorney General in the name of the people of the State of California or by any district attorney or by any city attorney of a city having a population in excess of 750,000 or with the consent of the district attorney by a city prosecutor in any city or city and county having a full-time city prosecutor, or as provided in subdivision (d).
- (d) Actions pursuant to this section may be brought by any person in the public interest if (1) the action is commenced more than sixty days after the person has given notice of the violation which is the subject of the action to the Attorney General and the district attorney and any city attorney in whose jurisdiction the violation is alleged to occur and to the alleged violator, and (2) neither the Attorney General nor any district attorney nor any city attorney or prosecutor has commenced and is diligently prosecuting an action against such violation.

§25249.8 List of chemicals known to cause cancer or reproductive toxicity

- (a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b) and those substances identified additionally by reference in labor Code Section 6382(d).
- (b) A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government has formally required it to be labeled or identified as causing cancer or reproductive toxicity.
- (c) On or before January 1, 1989, and at least once per year thereafter, the Governor shall cause to be published a separate list of those chemicals that at the time of publication are required by state or federal law to have been tested for potential to cause cancer or reproductive toxicity but that the state's qualified experts have not found to have been adequately tested as required.
- (d) The Governor shall identify and consult with the state's qualified experts as necessary to carry out his duties under this section.
- (e) In carrying out the duties of the Governor under this section, the Governor and his designees shall not be considered to be adopting or amending a regulation within the meaning of the Administrative Procedure Act as defined in Government Code Section 11370.

§25249.9 Exemptions from discharge prohibition

- (a) Section 25249.5 shall not apply to any discharge or release that takes place less than twenty months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8
- (b) Section 25249.5 shall not apply to any discharge or release that meets both of the following criteria:
 - (1) The discharge or release will not cause any significant amount of the discharged or released chemical to enter any source of drinking water.
 - (2) The discharge or release is in conformity with all other laws and with every applicable regulation, permit, requirement, and order.

In any action brought to enforce Section 25249.5, the burden of showing that a discharge or release meets the criteria of this subdivision shall be on the defendant.

§25249.10 Exemptions from warning requirement

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.

- (b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in questions on the list required to be published under subdivision (a) of Section 25249.8
- (c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.

§25249.11 Definitions

Definitions.

For purposes of this chapter:

- (a) "Person" means an individual, trust, firm, joint stock company, corporation, company, partnership, limited liability company, and association.
- (b) "Person in the course of doing business" does not include any person employing fewer than 10 employees in his or her business; any city, county, or district or department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof; or any entity in its operation of a public water system as defined in Section 116275.
- (c) "Significant amount" means any detectable amount except an amount which would meet the exemption test in subdivision (c) of Section 25249.10 if an individual were exposed to such an amount in drinking water.
- (d) "Source of drinking water" means either a present source of drinking water or water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses.
- (e) "Threaten to violate" means to create a condition in which there is a substantial probability that a violation will occur.
- (f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

§25192 Civil and criminal penalties; apportionment; disposition; deductions

- (a) All civil and criminal penalties collected pursuant to this chapter or Chapter 6.6 (commencing with Section 25249.5) shall be apportioned in the following manner:

- (1) Fifty percent shall be deposited in the Hazardous Substance Account in the General Fund.
 - (2) Twenty-five percent shall be paid to the office of the city attorney, city prosecutor, district attorney, or Attorney General, whichever office brought the action, or in the case of an action brought by a person under subdivision (d) of Section 25249.7 to such person.
 - (3) Twenty-five percent shall be paid to the department and used to fund the activity of the local health officer to enforce the provisions of this chapter pursuant to Section 25180. If the investigation by the local police department or sheriff's office or California Highway Patrol led to the bringing of the action, the local health officer shall pay a total of forty percent of his portion under this subdivision to said investigating agency or agencies to be used for the same purpose. If more than one agency is eligible for payment under this provisions, division of payment among the eligible agencies shall be in the discretion of the local health officer.
- (b) If a reward is paid to a person pursuant to Section 25191.7, the amount of the reward shall be deducted from the amount of the civil penalty before the amount is apportioned pursuant to subdivision (a).
- (c) Any amounts deposited in the Hazardous Substance Account pursuant to this section shall be included in the computation of the state account rebate specified in Section 25347.2

**§25192 Civil and criminal penalties; apportionment; disposition; deductions
(amended 1997; operative July 1, 1998)**

- (a) All civil and criminal penalties collected pursuant to this chapter or Chapter 6.6 (commencing with Section 25249.5) shall be apportioned in the following manner:
- (1) Fifty percent shall be deposited in the Hazardous Substances Account in the General Fund.
 - (2) Twenty-five percent shall be paid to the office of the city attorney, city prosecutor, district attorney, or Attorney General, whichever office brought the action, or in the case of an action brought by a person under subdivision (d) of Section 25249.7 to that person.
 - (3) Twenty-five percent shall be paid to the department and used to fund the activity of the CUPA, the local health officer, or other local public officer or agency authorized to enforce the provisions of this chapter pursuant to Section 25180, whichever entity investigated the matter that led to the bringing of the action. If investigation by the local police department or sheriff's office or California Highway Patrol led to the bringing of the action, the CUPA, the local health officer, or the authorized officer or agency, shall pay a total of 40 percent of its portion under this subdivision to that investigating agency or agencies to be used for the same purpose. If more than one agency is eligible for payment under this paragraph, division of payment among the eligible agencies shall be made in the discretion of the CUPA, the local health officer, or the authorized officer or agency.
- (b) If a reward is paid to a person pursuant to Section 25191.7, the amount of the reward shall be deducted from the amount of the civil penalty before the amount is apportioned pursuant to subdivision (a).

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**Selected Prop 65 Implementing Regulations
Barclays California Code of Regulations, Title 22, Section 12000 et seq.
Chapter 3 Safe Drinking Water and Toxic Enforcement Act of 1986**

Article 5 Extent of Exposure

§12501 Exposure to a Naturally Occurring Chemical in a Food.

- (a) Human consumption of a food shall not constitute an “exposure” for purposes of Health and Safety Code Section 25249.6 to a listed chemical in the food to the extent that the person responsible for the contact can show that the chemical is naturally occurring in the food.
- (1) For the purposes of this section, a chemical is “naturally occurring” if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.
- (2) The “naturally occurring” level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.
- (3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, “exposure” can only occur as to that portion of the chemical which result from such human activity. For purposes of this section, “human activity” does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.
- (4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the “lowest level currently feasible,” as this term is used in the Code of federal Regulations, Title 21, Section 110.110, subdivision (c) (1988).
- (b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not “expose” an individual within the meaning of Section 25249.6, to the extent that the person can show the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, “exposure” can only occur as to that portion of the chemical from other sources.

Article 8 No Observable Effect Levels

§12805 Specific Regulatory Levels: Reproductive Toxicants.

- (a) Exposure to a chemical at a level which does not exceed the level set forth in subsection (b) for such chemical has no observable effect assuming exposure at one thousand (1,000) times that level.

<i>(b) Chemical Name</i>	<i>Level (Micrograms/day)</i>
Ethylene Oxide	20.0
Lead	0.5
Toluene	7000.0

- (c) Unless a specific level is otherwise provided in this section, an assessment by an agency of the state or federal government that is the substantial equivalent of the assessment described in subdivision (a) of Section 12803, and establishes a maximum allowable daily dose level in the manner provided in paragraph (b) (1) of Section 12801, shall constitute the allowable daily dose level having no observable effect within the meaning of Health and Safety Code Section 25249.10(c).

Exhibit B

Calcium Supplements and Antacids: Chronology of Key Events

1992	Attorney General begins to investigate lead content in calcium supplements and antacids.
1995	NRDC begins its own analyses of lead in calcium supplements and antacids.
12/10/96	NRDC serves 60-day notice letters under Prop 65 on six calcium product companies and the Attorney General.
12/17/96	Association for Responsible Calcium Products (“ARCP”) files action against the Attorney General for declaratory and injunctive relief in Los Angeles Superior Court.
12/24/97	NRDC serves 60-day Notice Letters under Prop 65 on five additional calcium product companies.
01/00/97	NRDC launches public education campaign regarding lead in calcium products.
01/17/97	Attorney General files demurrer and motion to strike ARCP complaint in Los Angeles Superior Court.
01/27/97	NRDC files Citizen’s Petition to Initiate Rulemaking Concerning the Presence of Lead in Certain Dietary Calcium Supplements and Antacids with the U.S. Food and Drug Administration.
01/27/97	NRDC completes settlement with Leiner Nutritional Health Products Group, Inc.
02/03/97	NRDC files complaint against nine calcium product companies under California Business & Professions Code §§17200 et al. (Unfair Competition Act) predicated on noncompliance with Prop 65, and application for TRO, in San Francisco Superior Court.
02/06/97	Attorney General files opposition to NRDC’s request for TRO and files its own complaint against nine calcium product companies alleging violation of Prop 65 and the California Unfair Competition Act.
02/06/97	After hearing, Judge Cahill denies NRDC’s request for TRO and stays the NRDC action for 45 days.
02/08/97	Expiration of the 60-day notice calculated from NRDC’s December 10, 1996 notice letter.
02/22/87	Expiration of the 60-day notice calculated from NRDC’s December 24, 1997 notice letter.
05/13/97	Los Angeles Superior Court sustains Attorney General’s demurrer to ARCP action without leave to amend.
05/19/97	NRDC files motion to intervene in Attorney General’s action against nine companies.
06/20/97	Judge Cahill grants NRDC’s motion to intervene and after hearing enters order approving Attorney General’s settlement with eight companies.

Appendix A

Lead Levels in Calcium Dietary Supplements & Antacid Products in California

**Table 1: Lead Levels In Calcium Dietary Supplements¹
In California**

Product Name	Manufacturer	# of Samples Tested ²	Micrograms Lead per single unit x (SD) ⁴	Milligr. Calcium per single unit	Micrograms Lead per min. dose ³ x (SD) ⁴	Micrograms Lead per max. dose ³ x (SD) ⁴
Source Naturals Calcium Night	Source Naturals, Inc.	7	4.15(1.21)	150 mg	16.60 (4.83)	20.75 (6.04)
GNC Food Source Certified Calcium from Oyster Shell	General Nutrition Corporation	6	1.35 (0.30)	250 mg	5.38 (1.21)	5.38 (1.21)
Country Life Hypo-Allergenic Calcium, Magnesium and Zinc	Country Life	6	2.53 (2.25)	500 mg	2.53 (2.25)	5.06 (4.50)
GNC Dolomite 11 Grain	General Nutrition Corporation	6	1.26 (0.26)	158 mg	1.25 (0.26)	5.02 (1.06)
Rainbow Light Everyday Calcium Systems	Rainbow Light Nutritional	6	1.23 (0.35)	300 mg	4.94 (1.39)	4.94 (1.39)
TwinLab Calcium Rich Prenatal	Twin Laboratories, Inc.	6	1.15 (0.09)	325 mg	4.60 (0.36)	4.60 (0.36)
Longs Calcium and Magnesium	Leiner Health Products, Inc. ⁵	6	1.38 (0.14)	333 mg	1.38 (0.14)	4.13 (0.43)
Sav-On Calcium, Magnesium and Zinc	Distributed by: National Procurement & Logistics Company	6	1.25 (0.76)	333 mg	3.75 (2.27)	3.75 (2.27)
Your Life Natural Calcium and Magnesium USP	Leiner Health Products, Inc. ⁵	6	1.20 (0.25)	333 mg	3.60 (0.74)	3.60 (0.74)
Schiff BoneBuilder with Calcium	Schiff Products, Inc.	6	1.13 (0.82)	333 mg	3.38 (2.46)	3.38 (2.46)

Os-Cal 500 High Potency Chewable Supplements	SmithKline Beecham Consumer Healthcare LP	7	1.13 (0.10)	500 mg	2.25 (0.19)	3.38 (0.29)
Jarrow Formulas Bone-Up Microcrystalline Hydroxyapatite	Jarrow Formulas	6	0.50 (0.22)	167 mg	0.50 (0.22)	2.98 (1.34)
Caltrate 600+D High Potency Calcium Supplement w/Vitamin D	Lederle Consumer Health Division American Cynamid Company	6	1.45 (0.14)	600 mg	1.45 (0.14)	2.91 (0.27)
Walgreens Calcium 600 USP	Leiner Health Products, Inc. ⁵	6	1.44 (0.14)	600 mg	1.44 (0.14)	2.89 (0.27)
Spring Valley High Potency Calcium 600 Supplement w/Vit. D	Perrigo Company	6	1.44 (0.16)	600 mg	1.44 (0.16)	2.88 (0.32)
Solgar Calcium, Magnesium plus Boron	Solgar Laboratories	6	0.858(0.08)	333 mg	2.57 (0.24)	2.57 (0.24)
Your Life Natural Calcium, Magnesium and Zinc USP	Leiner Health Products, Inc. ⁵	6	0.82 (0.22)	333 mg	2.45 (0.66)	2.45 (0.66)
Nature Made 100% Oyster Shell Calcium, 500 mg w/Vitamin D	Nature Made Nutritional Product Pharmavite Corporation	8	0.95 (0.36)	500 mg	1.89 (0.72)	1.89 (0.72)
Target Natural Oyster Shell Calcium	Distributed by: Dayton-Hudson Corporation	6	1.44 (0.41)	500 mg	1.44 (0.41)	1.44 (0.41)
<i>Note: Products listed below meet the requirements of California's Propostion 65</i>						
Posture-D High Potency Calcium with Vitamin D	Whitehall Laboratories, Inc.	6	0.23 (0.05)	600 mg	0.23 (0.02)	0.46 (0.04)
Tums 500 Calcium Supplement, Chewable	SmithKline Beecham Consumer Healthcare LP	7	0.15 (0.15)	500 mg	0.29 (0.31)	0.44 (0.46)

1 Testing was conducted at the University of California-Santa Cruz Department of Environmental Toxicology under the supervision of A. Russell Flegal, Ph.D.

2 Each sample denotes a separate manufacturing lot/batch number, purchased at different retail outlets throughout California.

3 Minimum and maximum recommended doses based on manufacturer's label instructions.

4 x (SD) = mean (standard deviation)

5 ATTENTION: SEE SETTLEMENT AGREEMENT. Under Leiner's settlement agreement with the NRDC, all calcium supplements sold in California are now below 0.5 ug lead per day and meet Prop 65 requirements.

**Table 2: Lead Levels in Antacid Products¹
In California**

Product Name	Manufacturer	# of Samples Tested ²	Micrograms Lead per single unit x (SD) ⁴	Milligr. Calcium per single unit	Micrograms Lead per min. dose ³ x (SD) ⁴	Micrograms Lead per max. dose ^{3,5} x (SD) ⁴
DI-GEL Advanced Formula Antacid	Schering-Plough Healthcare Products, Inc.	6	0.19 (0.03)	280 mg of CaCO ₃	0.38 (0.06)	4.60 (0.75)
Rolaids Antacid Tablets, Calcium Rich	Warner-Lambert Co.	8	0.37 (0.06)	220 mg elemental	0.37 (0.06)	4.48 (0.76)
Mylanta Soothing Lozenges Antacid, Calcium Rich, Cherry Creme	Johnson&Johnson - Merck	6	0.13 (0.07)	240 mg elemental	0.13 (0.07)	1.51 (0.84)
<i>Note: Products listed below meet the requirements of California's Proposition 65</i>						
Children's Mylanta Chewable Antacid, Fruit Punch & Bubble Gum Flavors	Johnson&Johnson - Merck	5	0.04 (0.01)	160 mg elemental	0.11 (0.05)	0.22 (0.09)
Children's Mylanta Liquid Antacid, Fruit Punch & Bubble Gum Flavors	Johnson&Johnson - Merck	8	0.01 (0.00)	160 mg	0.03 (0.01)	0.20 (0.05)

1 Testing was conducted at the University of California-Santa Cruz Department of Environmental Toxicology under the supervision of A. Russell Flegal, Ph.D.

2 Each sample denotes a separate manufacturing lot/batch number, purchased at different retail outlets throughout California.

3 Minimum and maximum recommended doses based on manufacturer's label instructions.

4 x (SD) = mean (standard deviation)

5 **Special note for antacid products:** Dosage information given based on "minimum" and "do not exceed" dosage information, based on manufacturer's label instructions.

SETTLEMENT AGREEMENT AND GENERAL RELEASE

This Settlement Agreement and General Release (the "Settlement Agreement") is entered into effective the 15th day of January, 1997 (the "Effective Date") between the Natural Resources Defense Council ("NRDC") and Leiner Health Products Group Inc. ("LEINER"). The parties hereby agree to settle any and all disputes between them relating to LEINER's manufacture, sale, marketing and/or promotion of dietary calcium supplement products. LEINER denies that it has engaged in any wrongdoing or unlawful activity whatsoever, and specifically contends that its manufacturing processes and products have at all times met or exceeded all relevant industry and governmental regulatory standards and requirements. LEINER enters into this Settlement Agreement solely to accomplish the objective described below in paragraph 1 hereof and to avoid the expense and nuisance of litigating the dispute with NRDC.

RECITALS and DEFINITIONS

1. The central purpose of this Settlement Agreement is to provide California consumers — especially pregnant women, teenage girls, and children — with dietary calcium supplement products that are virtually lead free.

2. As used herein, the term "virtually lead free" product means any product that, at its reasonably anticipated daily dose, produces an exposure to lead of less than 0.5 micrograms/day. The amount of lead permitted in a "virtually lead free" product is sometimes hereinafter referred to as the "Proposition 65 Lead Limit."

As used herein, "Calcium Supplements" means dietary supplement products that contain a compound or compounds of calcium as listed ingredients and were offered by LEINER for sale or consumption in California since December 1992 primarily to provide supplemental dietary calcium.

3. After February 1, 1997, LEINER will only manufacture, distribute, market, advertise, promote and/or sell virtually lead free Calcium Supplements for use in California.

4. LEINER recognizes and agrees that any Calcium Supplement that does not meet the definition of "virtually lead free" set forth in Paragraph 2 after February 1, 1997 shall require a "clear and reasonable" warning in compliance with the Safe Drinking Water & Toxic Enforcement Act of 1986 (hereafter "Proposition 65") that such product contains lead, a known reproductive toxin.

5. NRDC has prepared and will file a Complaint, a copy of which is attached as Exhibit A, in San Francisco Superior Court within 6 days of the Effective Date. All allegations of the Complaint shall be deemed denied by LEINER.

6. Contemporaneous with the filing of the Complaint, the parties will file a proposed Consent Decree, a copy of which is attached as Exhibit B.

7. In recognition of LEINER's agreement to manufacture and sell virtually lead free Calcium Supplements, and to avoid any future, potential claims against LEINER under Proposition 65, Business and Professions Code §§ 17200 *et seq.* and § 17500 (the "Relevant B&P Code Sections"), and any other similar claims, and to avoid the expense of litigation, NRDC and LEINER agree to the terms of settlement as provided below:

TERMS and CONDITIONS

8. NRDC and LEINER agree that the foregoing recitals are true and correct and agree to be bound thereby.

9. NRDC and LEINER agree to be bound by the terms and conditions of the proposed Consent Decree attached for reference as Attachment B, which terms are incorporated herein and made a part hereof by this reference, and which are enforceable under this Settlement Agreement.

10. LEINER shall reimburse NRDC a maximum of \$5,000 for compliance testing during the year ending January 31, 1998. All such tests shall be conducted using a test protocol provided for in the Consent Decree. Copies of all test results shall be provided to LEINER, along with an identification of the product tested.

11. NRDC, in the interest of the general public, agrees that this Settlement Agreement and compliance with the terms and conditions of the Consent Judgment settle and resolve any and all issues, now and in the future, concerning compliance by LEINER, its past, present, and future parents, subsidiaries, affiliates, successors, predecessors, customers, distributors, wholesalers, retailers, and any other person who in the course of doing business has purchased or will purchase Calcium Supplements from LEINER with the requirements of Proposition 65 and the Relevant B&P Code Sections, with respect to the presence of lead in Calcium Supplements manufactured, sold or distributed by LEINER, whether relating to actions by LEINER or by any person or entity within its chain of distribution insofar as such claims relate to the presence of lead in Calcium Supplements attributable to the manufacture, sale or distribution of such products by LEINER.

12. NRDC, on its behalf and in the interest of the general public, hereby releases and forever discharges any and all claims NRDC may have or assert against LEINER, its past, present, and future parents, subsidiaries, affiliates, successors, predecessors, customers, distributors, wholesalers, retailers, and any other person who in the course of doing business has purchased or will purchase Calcium Supplements, from any violation of Proposition 65 and the Relevant B&P Code Sections relating to the presence of lead in Calcium Supplements manufactured, sold or distributed by LEINER, or any other statutory or common law claim that could be or could have been asserted against LEINER relating to the presence of lead in Calcium Supplements attributable to the manufacture, sale or distribution of such products by LEINER, or any other claim similar to those asserted in the proposed Complaint attached as Exhibit A, whether relating to actions by LEINER or by any person or entity within its chain of distribution insofar as such claims relate to the presence of lead in Calcium Supplements manufactured, sold or distributed by LEINER.

13. As set forth in the Consent Judgment, no later than April 1, 1997, LEINER will pay the sum of \$225,000 by delivery to NRDC's counsel Altshuler, Berzon, Nussbaum, Berzon & Rubin (the "Altshuler Firm") of a certified check payable to NRDC. Such funds (the "NRDC Contribution") shall be utilized for public education to inform consumers of the health benefits

that may be derived from calcium and the adverse health effects that may result from exposure to lead, especially during pregnancy and early childhood, for research to better protect the public from listed chemicals subject to Proposition 65, and for recovery of enforcement costs.

14. LEINER and NRDC shall consult in good faith and cooperate with each other in connection with the dissemination of information to the public regarding this settlement, the NRDC Contribution, and the public information campaign referred to in paragraph 13 hereof. Consistent with the spirit and intent of this Settlement Agreement, LEINER and NRDC mutually agree to coordinate and cooperate with each other in the announcement of the settlement. The public education campaign to be conducted by NRDC will point out the health benefits that may be derived from the use of calcium supplement products that meet the requirements of Proposition 65, as well as the adverse effects that may be caused by exposure to lead.

15. In furtherance of the parties' intention that this Settlement Agreement shall be effective as a full and final accord satisfaction and release as to LEINER, and the entities described in paragraphs 11 and 12, from any and all matters released hereunder, NRDC acknowledges familiarity and understanding of section 1542 of the California Civil Code, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM MUST HAVE MATERIALLY AFFECTED HIS SETTLEMENT WITH THE DEBTOR.

To the extent that Section 1542 or any similar law or statute may otherwise apply to this Settlement Agreement, NRDC hereby waives and relinquishes as to all matters released hereunder all rights and benefits that it has, or may have, under Section 1542 of the California Civil Code, or under the laws of any other jurisdiction to the same or similar effect. NRDC further acknowledges that, subsequent to the execution of this Settlement Agreement, it may discover claims that were unsuspected at the time this Settlement Agreement was executed which, if

known on the date this Settlement Agreement was executed, might have materially affected its decision to execute this Settlement Agreement, but nevertheless releases LEINER, and the entities described in paragraphs 11 and 12, from any and all such claims whether known or unknown at the time of the execution of this Settlement Agreement.

16. NRDC has stated its intention to bring litigation against other parties that it contends may be violating Proposition 65, the California Business and Professions Code, and other applicable laws in connection with the presence of lead in their calcium-containing products. If, with respect to any such litigation, NRDC enters into a settlement agreement that provides for a Proposition 65 Lead Limit permitting a greater amount of lead than that provided for under this Settlement Agreement, then the terms of any such settlement will be fully disclosed to LEINER, and this Settlement Agreement shall be deemed modified to permit such higher limit, and NRDC will join with LEINER in seeking a conforming modification of the Consent Decree.

17. The parties acknowledge that the California Attorney General is considering whether his office should take action on behalf of the People of the State of California against LEINER and others regarding the matters that are the subject of this Settlement Agreement. In particular, but without limitation, the Attorney General may adopt a Proposition 65 Lead Limit that permits the presence of a greater amount of lead than that provided for in this Agreement. In such event, LEINER may elect either or both of the following options: (a) nullify its obligations under paragraph 3 hereof, or (b) apply to the Court for a modification of the Consent Decree. Such options are cumulative and not exclusive. If LEINER elects to nullify its obligations under paragraph 3 hereof, NRDC will not be bound by the Attorney General's determination but will be free to assert that a different standard should apply.

18. This Settlement Agreement constitutes the full and complete agreement among the parties. No promises, representations, understandings or warranties other than those contained herein have been made or relied upon by any party as an inducement for executing this Settlement Agreement. This Settlement Agreement may be modified only by the written agreement of the parties hereto.

19. This Settlement Agreement may be signed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, which shall become effective when all parties have executed it as provided herein.

20. This Settlement Agreement shall be governed by and enforced in accordance with the laws of the State of California.

21. Each signatory to this Settlement Agreement certifies that he or she is fully authorized by the party he or she represents to enter into this Settlement Agreement and to enter into and execute this Settlement Agreement on behalf of the party represented and legally to bind that party.

22. In the event of a proceeding to enforce this Settlement Agreement, the prevailing party shall be entitled to recover its reasonable attorneys' fees and costs incurred in that proceeding.

23. Except as provided herein, each party shall bear its own attorneys' fees, costs and expenses.

24. This Settlement Agreement shall be binding upon and for the benefit of the parties, as well as their successors, devisees, executors, heirs, representatives and assigns, and each of them.

NATURAL RESOURCES DEFENSE
COUNCIL

LEINER HEALTH PRODUCTS
GROUP INC.

By: _____

By: _____


Approved as to form:

Altshuler, Berzon, Nussbaum,
Berzon & Rubin

Approved as to form:

Gibson Dunn & Crutcher LLP

By: _____
Attorneys for NRDC

By: 
Charles C. Ivie
Attorneys for Leiner
Health Products Group Inc.

FRED H. ALTSHULER (43878)
ALBERT H. MEYERHOFF (54134)
GRAHAM A. BOYD (167727)
Altshuler, Berzon, Nussbaum, Berzon & Rubin
177 Post Street, Suite 300
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Attorneys for Plaintiff Natural Resources Defense
Council

CHARLES C. IVIE (048049)
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Gibson, Dunn & Crutcher LLP
333 S. Grand Avenue
Los Angeles, CA 90071
Telephone: 229-7000

Attorneys for Defendant Leiner Health Products
Group Inc.

IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA
CITY AND COUNTY OF SAN FRANCISCO

NATURAL RESOURCES DEFENSE
COUNCIL, individually and
on behalf of the general
public,

Plaintiff,

vs.

LEINER HEALTH PRODUCTS GROUP
INC., and DOES 1-500,

Defendants.

Type of Action:
Local rule 2.3(a) - Anti-
Trust/Unfair Competition

NO.
CONSENT JUDGMENT PURSUANT TO
STIPULATION

1. Introduction

1.1 The stipulation for this Consent Judgment is entered effective the 21st day of
January, 1997.

Exhibit B
to Settlement Agreement (Calcium Supplements) dated January 15, 1997

1.2 Contemporaneous with the filing of this Consent Judgment, plaintiff Natural Resources Defense Council ("NRDC") has filed a Complaint for Injunctive Relief ("Complaint") in this Court. Leiner Health Products Group Inc. (hereinafter referred to as "LEINER") is named as the defendant in the Complaint and has accepted service thereof. LEINER manufactures and sells, among other things, dietary calcium supplements ("Calcium Supplements").

1.3. The Complaint alleges that LEINER has sold Calcium Supplements containing lead, and that LEINER has violated Business and Professions Code §§ 17200 *et seq.* & 17500 *et seq.* (the "Unfair Competition Act") by not providing the warning allegedly required by California's Safe Drinking Water & Toxic Enforcement Act of 1986 ("Proposition 65").

1.5. The parties stipulate that this Court has jurisdiction over the allegations of violations contained in the Complaint and personal jurisdiction over LEINER as to the acts alleged in the Complaint, that venue is proper in the City and County of San Francisco, and that this Court has jurisdiction to enter this Consent Judgment as a full settlement and resolution of all claims which were or could have been raised based on the facts alleged therein or arising therefrom.

1.6. The parties have entered into a Settlement Agreement and General Release (the "Settlement Agreement") effective January 15, 1997 relating to the subject matter of this action. The Settlement Agreement, among other things, calls for the stipulation by the parties to this Consent Judgment. By execution of this Consent Judgment, LEINER does not admit any violations of Proposition 65 or the Unfair Competition Act or any other law and specifically denies that it has committed any such violations. Nothing in this Consent Judgment shall be construed as a decision by the Court on any issue of law or fact or as an admission by any party of any fact, issue of law or violation of law, nor shall compliance with the Consent Judgment constitute or be construed as an admission by any party of any fact, issue of law, or violation of law. Nothing in this Consent Judgment shall prejudice, waive or impair any right, remedy or

defense the NRDC and LEINER may have as to each other in any other or future legal proceedings unrelated to (i) these proceedings, (ii) the facts alleged in the Complaint, or (iii) matters covered by the Settlement Agreement or this Consent Judgment. However, this paragraph shall not diminish or otherwise affect the obligations, responsibilities and duties of the parties under the Settlement Agreement or this Consent Judgment.

2. Compliance with Proposition 65

For any Calcium Supplement product that LEINER manufactures for use in California after February 1 1997, unless the reasonably anticipated daily dosage for users contains less than 0.5 micrograms of lead, LEINER shall provide a warning compliant with Proposition 65. Compliance shall be determined in accordance with one of the protocols specified in the following paragraph.

3. Compliance Testing

Leiner shall reimburse NRDC up to a maximum of \$5,000 for testing of Leiner's products for compliance with this Consent Decree during the year ending January 31, 1998. All such tests shall be conducted according to one of the following protocols, or equivalent: The National Food Laboratory, Inc. Protocol (copy attached as Exhibit 1), Antech Protocol (copy attached as Exhibit 2), or Specialty Minerals, Inc. Graphite Furnace Atomic Absorption Spectrometer Analysis Protocol (copy attached as Exhibit 3).

Copies of all test results shall be provided to LEINER, along with an identification of the product tested.

4. Payment to NRDC

No later than April 1, 1997, Leiner shall pay to NRDC the sum of \$225,000. Said payment shall be made by delivery of certified funds payable to NRDC.

5. Costs and Attorneys Fees

Except as specifically provided in this Consent Judgment, each side shall bear its own costs and attorney's fees.

6. Modification of Consent Judgment

The Settlement Agreement provides that this Consent Judgment is subject to modification under certain circumstances. This Consent Judgment may be modified by written agreement of the NRDC and LEINER or after noticed motion by either party, subject in either case to approval by the Court and entry of a modified Consent Judgment by the Court.

7. Retention of Jurisdiction

This Court shall retain jurisdiction of this matter to implement and enforce the Consent Judgment and to consider any modification thereof.

8. Provision of Notice

When any party is entitled to receive any notice under this Consent Judgment, the notice or report shall be sent by overnight courier service and by contemporaneous facsimile transmission to the person and address set forth in this paragraph. Any party may modify the person and address to whom notice is to be sent by sending each other party notice. Any such change shall take effect for any such modification upon receipt. Notices shall be sent to the following:

For the NRDC:

Fred H. Altshuler
Altshuler, Berzon, Nussbaum, Berzon
& Rubin
177 Post Street, Suite 300
San Francisco, CA 94108
Telephone: 415/421-7151
Facsimile: 415/362-8064

For LEINER:

Charles C. Ivie
Gibson, Dunn & Crutcher
333 South Grand Avenue
Los Angeles, CA 90071
Telephone: 213/229-7412
Facsimile: 213/229-7083

9. Court Approval

If this Consent Judgment is not approved by the Court, it shall be of no force or effect and cannot be used in any proceeding for any purpose.

FRED H. ALTSHULER
GRAHAM A. BOYD
ALBERT H. MEYERHOFF
ALTSHULER, BERZON, NUSSBAUM,
BERZON & RUBIN

CHARLES C. IVIE
KAY E. KOCHENDERFER
GIBSON, DUNN & CRUTCHER LLP

By: _____
Fred H. Altshuler

By: _____
Charles C. Ivie

Attorneys for Plaintiff Natural Resources Defense
Council

Attorneys for Defendant
Leiner Health Products Group Inc.

ORDER

On basis of the foregoing stipulation, IT IS SO ORDERED.

Dated: _____

Judge of the Superior Court

Exhibit E

Tuesday, January 28, 1997

The Detroit News**National news**

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Clash develops over calcium supplements

Associated Press

WASHINGTON -- Contending that the amount of lead in many antacids and calcium supplements reaches dangerous levels, a consumer group petitioned the Food and Drug Administration on Monday to develop guidelines for lead content.

Several health advocates decried the petition filed by the Natural Resources Defense Council, saying it was based on shaky science and threatened to discourage women who can benefit from calcium supplements.

"We in no way want to turn people away from calcium supplements," said Dr. Gina Solomon, the group's senior scientist. "Just pick them carefully; you can't get the calcium without the lead."

The council's petition coincided with its announcement that the Leiner Health Products Group, the nation's largest manufacturer of calcium supplements, had agreed to comply with a California law that sets strict lead limits.

Leiner said its products would contain less than five-tenths of a gram of lead per recommended daily dosage.

The Natural Resources Defense Council said its own studies indicated some supplements could more than triple an individual's daily lead intake.

But the National Osteoporosis Foundation took issue with what it called the council's "scare tactics of using a scientifically inappropriate measure" by calculating the lead in products, not their effects in the body.

"Studies that correlate blood lead levels to the amount of lead in tablets must be conducted before conclusions about toxicity can be made," the foundation said. "It is crucial that consumers understand that calcium supplements which meet federal standards are safe."

The Council for Responsible Nutrition, an industry group, said getting enough calcium is essential to fighting osteoporosis, a disease that affects 28 million Americans.

"There is no cause for concern about the safety of calcium supplements and products," said the nutrition council's Dr. Annette Dickinson. "Consumers should take the recommended amount of calcium daily; they should not be discouraged from taking them or think they have to change products for any reason."

An FDA spokesman said the petition would be considered, but he said he couldn't comment until it was reviewed by agency officials.

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The Detroit News[Comments?](#)

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Exhibit F

ALTSHULER, BERZON, NUSSBAUM, BERZON & RUBIN

ATTORNEYS AT LAW

177 POST STREET, SUITE 300

SAN FRANCISCO, CALIFORNIA 94108

(415) 421-7151

FAX (415) 362-8064

ALBERT H. MEYERHOFF
OF COUNSEL
RAÏSSA S. LERNER
FELLOW

FRED H. ALTSHULER
MARSHA S. BERZON
STEPHEN P. BERZON
PETER D. NUSSBAUM
MICHAEL RUBIN
LOWELL FINLEY
JEFFREY B. DEMAIN
INDIRA TALWANI
DANIEL T. PURTELL
SCOTT A. KRONLAND
MARY LYNNE WERLWAS
GRAHAM A. BOYO
JONATHAN WEISSGLASS

April 16, 1997

VIA FACSIMILE -- (510) 286-4020

Susan S. Fiering, Esq.
Office of the Attorney General
2101 Webster Street, 12th Floor
Oakland, CA 94612-3065

Re: People v. Warner-Lambert Co. and
NRDC v. General Nutrition Corp.

Dear Sue:

For the past several weeks, in accordance with the Court's decision at the February 6, 1997 hearing, we have been discussing with your office the proposed settlements you have reached with certain of the defendants in the above lawsuits. In the course of those discussions, you have reviewed with us some of the legal and factual bases that underlie the proposed settlement. Although we have still not arrived at a final position regarding the settlements, we have identified some issues that we believe are particularly important in evaluating them. We are setting forth these issues in this letter with the request that you address them either in your submission to the Court, or separately to us.

Our first question is why the settlements allow other antacid manufacturers at least two years to reach the lead levels set forth in Table 2.3 of the proposed decree, while Tums and Leiner Nutritional Products currently market antacids at even lower lead levels. You have explained that this delay is based in part on the need for FDA approval for the reformulation of the products. We would appreciate your explaining what in the FDA process requires a delay of this length of time.

You have explained that your decision to set the reasonable consumption level for calcium supplements at 2/3 the maximum recommended daily dose is based on a summary of a survey furnished you by the Council for Responsible Nutrition. We have been given this summary by the Council's attorney, and it states

Susan S. Fiering, Esq.
April 16, 1997
Page 2

it was based on one survey of a very small number of persons. Given our mutual concern about the use of these products by pregnant women, we would appreciate knowing whether there are any other surveys or data that underlie the 2/3 figure used in your formula.

Although we have been informed by Specialty Minerals that it can supply the entire California market with low-lead precipitated calcium carbonate virtually immediately, you have indicated that you did not believe that Specialty could do so. At the meeting with Specialty that we attended with you on April 9, 1997, Specialty reiterated this commitment and promised that it could expand to meet the national market in six months time. We would appreciate your clarifying whether you still doubt Specialty's ability to supply the California market with low-lead calcium, or whether you believe there are other factors involving Specialty's sales or marketing that make it unfeasible for Specialty to supply all or most of the market with low-lead calcium.

You have explained that in adopting the lead reduction levels specified in your proposed settlement, you decided to set the same lead levels for calcium products made from calcium carbonate as those made from oyster shells. We would appreciate your explaining why you did not differentiate between the two products, since such a distinction would result in a much lower lead level in calcium carbonate products.

Moreover, we understand that at least one major manufacturer is presently producing an oyster-shell calcium supplement with lead levels in the range of 1 to 2 micrograms/1000 milligrams, and that it has achieved this range not only by using a low-lead source, but also by its processes for cleaning the raw material. How did you arrive at the conclusion that a two-year delay was necessary to accommodate the calcium manufacturers who use oyster shells? Have you determined that the procedures used by the producer of a low-lead oyster shell product are not available to other producers of oyster shell products?

The proposed settlement allows manufacturers to seek modification of its terms so as to allow greater lead exposures based upon a showing that the levels set out in Table 2.3 are lower than "the lowest level currently feasible." We have two questions regarding this escape clause: Given that there are now sources of calcium carbonate and oyster shell calcium well below the initial Table 2.3 levels, why was this clause included; and, further, what is the legal basis for allowing an increase in lead

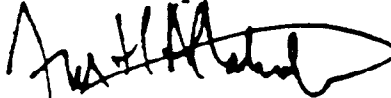
Susan S. Fiering, Esq.
April 16, 1997
Page 3

based on the "cost of low-lead calcium and resulting increase in manufacturers' prices resulting from the use of the low-lead calcium. . . ."

In setting forth the permissible lead levels in your proposed settlement, you excluded specified amounts of lead from the Proposition 65 limit for both calcium supplements and antacids as being deemed "naturally occurring." You have stated that the basis for this exclusion is the fact that 22 Cal. Code Regs. section 12501 provides that "naturally occurring" chemicals in food products do not constitute an exposure under Proposition 65, and you consider any products that contain calcium to be a "food product" under this regulation. Do you have any additional legal authority that supports the appropriateness of applying a "naturally occurring" exclusion to antacids.

We would appreciate your providing the requested explanations and clarifications as soon as possible, as they will greatly assist NRDC in arriving at a definitive position regarding the proposed settlements.

Sincerely,



Fred H. Altshuler

cc: Edward G. Weil, Esq.
FHA:jc

DANIEL E. LUNGREN
Attorney General

State of California
DEPARTMENT OF JUSTICE



2101 WEBSTER STREET, 12th FLOOR
OAKLAND, CA 94612
(510) 286-4200

FACSIMILE: (510) 286-4020
(510) 286-3892

April 21, 1997

Fred Altshuler; Esq.
Altshuler, Berzon, Nussbaum, Berzon & Rubin
177 Post Street, Suite 300
San Francisco, CA 94108

RE: People v. Warner Lambert

Dear Mr. Altshuler:

I am responding to your letter of April 16, 1997. I believe that we have provided answers to most, if not all, of the questions posed, but will be glad to provide you with those answers again and to correct certain misunderstandings that you appear to have.

First, at no time have we stated that we did not believe that Specialty Minerals could supply the California market with Cal-Essence. We have understood from Specialty Minerals that they can currently supply a large portion of the market and, if they make a capital outlay, could supply the entire market within six months. While we, of course, have no way of confirming this information, we have no reason at this time to disbelieve it.

Second, you state that it is our position that any product that contains calcium is a food product. This is inaccurate as well. We have simply followed the regulation contained in 22 CCR section 12501 which states that:

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

Fred Altshuler, Esq.
April 21, 1997
Page 2

Third, you state in your letter and in your press release that we will permit an increase in lead based on the "cost of low-lead calcium and resulting increase in manufacturers' prices resulting from the use of the low-lead calcium. . . ." This is a distortion of our settlement. The settlement permits the issue of feasibility to be determined on the basis of a number of factors including availability of low lead calcium, whether the calcium complies with all regulatory requirements, etc. One of the factors to be considered is the cost of producing the low-lead supplements. It is our position that if the materials and processes required to lower lead levels became so expensive that it priced the product out of the market, (hypothetically, consider what would happen if calcium tablets cost \$50.00 a bottle and working class and poor pregnant women could no longer afford the calcium) that would be a factor to consider in whether it was "feasible" to lower lead levels.

Fourth, you ask why we permitted the manufacturers an opportunity to show that the levels set in Table 2.3 are lower than the lowest levels currently feasible. As a critical part of this settlement, we demanded and received a reopener clause for our office -- i.e., to permit us to argue that the levels could feasibly be lowered from the levels set in the Table based on developments in the industry. The manufacturers obtained a reciprocal clause to account for various contingencies such as low-lead sources of calcium being depleted; suppliers going out of business; changes in federal or state laws that made the low-lead calcium no longer viable, etc. Please note, that in either case, the manufacturers retain the burden of showing that the lower level is not feasible.

Fifth, in regard to the time frame permitted for companies to reach the lower levels, it is our understanding that certain companies must meet FDA requirements (I understand that there is not a formal approval process) as well as their own internal manufacturing and quality control requirements and that this will take some time to achieve. As you know from our discussion with Specialty Minerals, companies that are switching from mined calcium carbonate to precipitated calcium carbonate will require some time to work out tablet formulation and other issues as well. Specialty acknowledged that it was not sure precisely how long this whole process would take. The fact that Leiner and Tums started this process several years ago and have already reached low-lead levels does not contradict the fact that other companies will need some time to reach the lower levels as well.

Sixth, in assuming that the average daily antacid consumption is two-thirds of the stated maximum daily dosage, we relied on the survey to which you refer, as well as on our own understanding of the statute and regulations. As you know, the regulations state that "[f]or exposures to consumer products, the

Fred Altskuler, Esq.
April 21, 1997
Page 3

level of exposure shall be calculated using the reasonably anticipated rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population." (22 CCR § 12821(c)(2)). In order to assume that the average consumer takes the maximum daily dose of an antacid, we would have to assume that there are a substantial number of people who are taking far above the maximum daily dose. We have no reason to believe this. If you are aware of any information indicating that the average consumer or the average pregnant woman takes the maximum dose of antacids, I would appreciate receiving that information.

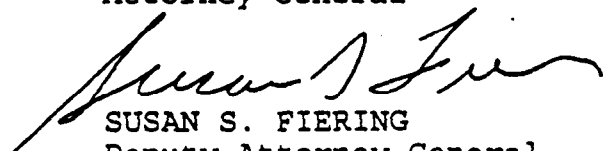
Seventh, you stated that you understand that at least one major manufacturer is presently producing an oyster shell calcium supplement with lead levels in the range of 1 to 2 micrograms per thousand milligrams. As you know, this is above our final level of 1.5 micrograms per thousand milligrams. You asked why a two year delay was necessary to reach the lower level. The two year time period was set for the industry as a whole, not just for oystershell. Furthermore, it is our understanding that the manufacturers of oystershell do not, at this time, even know how they will consistently reach the level we have set and will need some period of time in order to look for even cleaner sources of oystershell or to develop new processes for cleaning the existing sources of oystershell.

Finally, we decided to set the same lead levels for calcium products made from calcium carbonate as from oyster shells for several reasons. First, we believe that the final level that we set can be met by both products and we do not have to set a higher level for oystershell. Second, we believe that it is best from a policy standpoint to treat the industry in a uniform manner. This avoids the argument that there should be a separate level for each type of calcium (such as bonemeal, for example, which traditionally has much higher lead levels). It also avoids the anomaly of having a lower lead supplement on the market with a warning and a higher lead supplement on the market without a warning.

I hope that I have answered all of your questions.

Sincerely,

DANIEL E. LUNGREN
Attorney General



SUSAN S. FIERING
Deputy Attorney General

Exhibit G

1 DANIEL E. LUNGREN, Attorney General
of the State of California
2 RODERICK E. WALSTON
Chief Assistant Attorney General
3 THEODORA BERGER.
Assistant Attorney General
4 CRAIG C. THOMPSON
Supervising Deputy Attorney General
5 EDWARD G. WEIL
SUSAN S. FIERING (State Bar No. 121621)
6 Deputy Attorneys General
2101 Webster Street, 12th Floor
7 Oakland, CA 94612-3049
Telephone: (510) 286-3892
8
9 Attorneys for the People

ENDORSED
FILED
San Francisco County Superior Court

JUN 20 1997

ALAN CARLSON, Clerk

BY: GAIL PEERLESS

Deputy Clerk

ORIGINAL

10 SUPERIOR COURT OF THE STATE OF CALIFORNIA
11 FOR THE CITY AND COUNTY OF SAN FRANCISCO

14 PEOPLE OF THE STATE OF CALIFORNIA)
ex rel. DANIEL E. LUNGREN, Attorney)
15 General of the State of California,)
16 Plaintiffs,)
v.)
17)
18 WARNER-LAMBERT CO.; SMITHKLINE)
BEECHAM CORP.; AMERICAN HOME)
19 PRODUCTS CORP.; SOURCE NATURAL,)
INC.; SCHERING-PLOUGH HEALTH CARE)
20 PRODUCTS, INC.; PHARMAVITE CORP.;)
GENERAL NUTRITION CORP.; PERRIGO)
21 CO.; TWIN LABORATORIES, INC. and)
DOES 1-200)

No. 984503

STIPULATION FOR ENTRY OF
PERMANENT INJUNCTION AND
FOR PAYMENT OF SETTLEMENT
AMOUNT AND ORDER THEREON

22
23 Defendants.
24
25
26
27

STIPULATION FOR ENTRY
OF PERMANENT INJUNCTION
AND PAYMENT OF SETTLEMENT
AMOUNT

1 Plaintiff, the People of the State of California ("People")
2 and defendants Warner-Lambert Co., American Home Products Corp.,
3 Pharmavite Corp., General Nutrition Corp., Perrigo Co., and Twin
4 Laboratories (hereinafter collectively "Settling Defendants")
5 herein enter into this Stipulation for Entry of Permanent
6 Injunction and for Payment of Settlement Amount (hereinafter
7 "Permanent Injunction") as follows:

8 1. Introduction

9 1.1 On February 6, 1997 the People of the State of
10 California, ex rel. Daniel E. Lungren, ("People") filed a
11 Complaint for Civil Penalties and Injunctive Relief ("Complaint")
12 in the Superior Court of the State of California, City and County
13 of San Francisco, against the Settling Defendants and other
14 defendants. On February 3, 1997, the Natural Resources Defense
15 Council filed a Complaint for Injunction and Other Relief in the
16 same court in Natural Resources Defense Council v. General
17 Nutrition Corp. et al., No. 984421 against the Settling
18 Defendants and other defendants.

19 1.2 Settling Defendants are companies that employ more
20 than ten persons and offer for sale within the State of
21 California one or more of the following calcium-containing
22 products (hereinafter "Calcium Products") which are intended to
23 be ingested by human beings: (a) products containing primarily
24 calcium that are intended to provide all or a major portion of
25 the recommended daily allowance of calcium (hereinafter "Calcium
26 Supplements"), (b) antacid products containing calcium
27 (hereinafter "Antacids"), and (c) dietary supplements as defined

1 in the federal Dietary Supplements Health and Education Act,
2 Public Law no. 103-417, 108 Stat. 4325 (1994), 21 U.S.C. §
3 321(ff), containing calcium, other than Calcium Supplements or
4 Antacids. (hereinafter "Multiple Vitamins/Minerals").
5 Notwithstanding any form of packaging of two or more different
6 Calcium Products together, the requirements of this Permanent
7 Injunction shall apply separately to each such different Calcium
8 Product. The term "calcium" as used in this Permanent Injunction
9 means elemental calcium when referring to an amount of calcium
10 and means any form or salt of calcium when referring to calcium
11 as an ingredient (active or inactive) in a Calcium Product. For
12 purposes of this Permanent Injunction, the "date of shipment"
13 shall be the date on which the Calcium Product first enters the
14 stream of commerce; except that, where a Settling Defendant is
15 both a manufacturer and a retailer of the Calcium Product, "date
16 of shipment" shall mean the date on which a Calcium Product is
17 transferred from the manufacturing segment of the Settling
18 Defendant's business.

19 1.3 The People's Complaint alleges that Settling
20 Defendants, through the sale of Calcium Products to consumers in
21 California, violated provisions of the Safe Drinking Water and
22 Toxic Enforcement Act of 1986, Health and Safety Code
23 sections 25249.5 et seq. ("Proposition 65"), and Business and
24 Professions Code sections 17200 et seq. ("Unfair Competition
25 Act"), by knowingly exposing persons to lead, a chemical known to
26 the State of California to cause reproductive toxicity, without
27 first providing a clear and reasonable warning to such

1 individuals.

2 1.4 For purposes of this Permanent Injunction only, the
3 parties stipulate that this Court has jurisdiction over the
4 allegations of violations contained in the Complaint and personal
5 jurisdiction over the Settling Defendants as to the acts alleged
6 in the Complaint, that venue is proper in the City and County of
7 San Francisco and that this Court has jurisdiction to enter this
8 Permanent Injunction.

9 1.5 The parties enter into this Permanent Injunction
10 pursuant to a settlement of certain disputed claims between the
11 parties as alleged in the Complaint for the purpose of avoiding
12 prolonged and costly litigation between the parties hereto. By
13 execution of this Permanent Injunction, Settling Defendants,
14 individually and collectively, do not admit any facts or
15 conclusions of law suggesting or demonstrating any violations of
16 Proposition 65, the Unfair Competition Act or any other
17 statutory, common law or equitable requirements relating to
18 Calcium Products. Nothing in this Permanent Injunction shall be
19 construed as an admission by Settling Defendants of any fact,
20 issue of law or violation of law, nor shall compliance with the
21 Permanent Injunction constitute or be construed as an admission
22 by such Settling Defendants of any fact, issue of law, or
23 violation of law. Nothing in this Permanent Injunction shall
24 prejudice, waive or impair any right, remedy or defense such
25 Settling Defendants may have in this or any other or future legal
26 proceedings. However, this paragraph shall not diminish or
27 otherwise affect the obligations, responsibilities and duties of

1 such Settling Defendants, individually or collectively, under
2 this Permanent Injunction.

3 2. Injunctive Relief - Warning Program

4 2.1 Where required herein, clear and reasonable warning
5 that use of Calcium Products exposes persons to lead, a chemical
6 known to the State of California to cause birth defects or other
7 reproductive harm, shall be provided by a Settling Defendant in
8 the manner provided in this Permanent Injunction.

9 2.2 A Settling Defendant shall provide a warning, pursuant
10 to paragraph 2.5, for each Calcium Product whose date of shipment
11 is on or after July 1, 1997, unless the Settling Defendant can
12 show, pursuant to paragraph 2.10 and the testing protocol set
13 forth in Exhibit A attached to this Permanent Injunction, that
14 the Calcium Product causes a total daily exposure to lead of 0.5
15 micrograms or less, based on the amount of the Calcium Product
16 supplying a thousand (1,000) milligrams of elemental calcium,
17 excluding any naturally occurring lead in the Calcium Product as
18 set forth in paragraph 2.3 below. For those Calcium Products
19 where the recommended or maximum daily dose supplies more than
20 1500 milligrams of calcium, a Settling Defendant shall provide a
21 warning unless the Settling Defendant can show, pursuant to
22 paragraph 2.10 and the testing protocol set forth in attached
23 Exhibit A, that the recommended daily dose of the Calcium Product
24 causes a total daily exposure to lead equal to or less than that
25 set forth in paragraph 2.4 below.

26 2.3 A Settling Defendant shall be entitled to exclude from
27 the calculation of the daily lead exposure caused by a Calcium

1 Product the amount of lead per 1000 milligrams of calcium as set
2 forth in Table 2.3 of this paragraph 2.3. Compliance with this
3 Permanent Injunction is established and no warning is required
4 under Proposition 65 where the lead exposure caused by an amount
5 of the Calcium Product supplying 1000 milligrams of calcium does
6 not exceed the sum of: (a) 0.5 micrograms of lead per thousand
7 milligrams of elemental calcium and (b) the amount of lead
8 excluded on the date of shipment as "naturally occurring"
9 pursuant to Table 2.3 of this paragraph 2.3. For purposes of
10 this Permanent Injunction, Table 2.3 of this paragraph 2.3 sets
11 forth the amount of lead per 1000 milligrams of elemental calcium
12 which shall be deemed to be "naturally occurring" at the "lowest
13 level currently feasible" pursuant to Section 12501 of Title 22
14 of the California Code of Regulations ("CCR"). The amounts of
15 lead and dates set forth in Table 2.3 shall apply as of the date
16 of shipment of the Calcium Product.

17 **TABLE 2.3**

18 DATE	NATURALLY OCCURRING AMOUNT OF LEAD PER 1000 MILLIGRAMS OF CALCIUM
19 July 1, 1997	3.5 micrograms
20 April 1, 1999	1.0 microgram

21 2.4 Even if no warning is required by paragraphs 2.2 and
22 2.3 above, in the event that the recommended daily dose of any
23 Calcium Product, as specified on the label or in any other
24 package material, exceeds 1500 milligrams, a Settling Defendant
25 shall provide a warning pursuant to Proposition 65 if the total
26 daily lead exposure from the Calcium Product, based on the
27

1 recommended daily dose, exceeds 150% of the level that would
2 require a warning pursuant to paragraphs 2.2 and 2.3 (based on a
3 an amount of the Calcium Product supplying 1000 milligrams of
4 calcium) above as of the date of shipment of the Calcium Product.
5 For antacids that do not have a recommended daily dose, for
6 purposes of this Permanent Injunction, the term "recommended
7 daily dose" shall mean two-thirds of the maximum daily dose as
8 set forth on the label or in any other package material.

9 2.5 For a Calcium Product that does not meet the standards
10 set forth in paragraphs 2.2 through 2.4 above, a Settling
11 Defendant shall, at the point of manufacture, prior to shipment
12 to California or prior to distribution within California, (1)
13 affix to or print on the Calcium Product container, cap, label or
14 unit package or (2) display at the point of sale of the Calcium
15 Product the following warning (the language in brackets in the
16 warning below is optional):

17 **WARNING:** This product contains [lead] a chemical
18 known [to the State of California] to
19 cause birth defects or other
20 reproductive harm

21 2.6 The warning required by paragraph 2.5 above shall be
22 prominently affixed to, printed on or displayed proximately to
23 the point-of-sale of each Calcium Product with such
24 conspicuousness, as compared with other words, statements,
25 designs, or devices on the labeling as to render it likely to be
26 read and understood by an ordinary individual under customary
27 conditions of purchase or use. If the warning is displayed on
the product container or labeling, the warning shall be at least

1 the same size as the largest of any other health or safety
2 warnings on the product container or labeling and the word
3 "warning" shall be in all capital letters and in bold print. If
4 printed on the labeling itself the warning shall be contained in
5 the same section of the labeling that states other safety
6 warnings concerning the use of the product. The Attorney General
7 agrees to review any labeling or point of sale signs proposed to
8 be used under this section and advise the Settling Defendant as
9 to whether he believes such labeling or point of sale signs
10 comply with this section. The requirement for product labeling,
11 set forth herein is imposed pursuant to the terms of this
12 Permanent Injunction and is recognized by the parties as not
13 being the exclusive method of providing a warning under
14 Proposition 65 and its implementing regulations for the Calcium
15 Products.

16 2.7 In the event that the Attorney General determines that
17 the naturally occurring levels set forth in Table 2.3 of
18 paragraph 2.3 above are higher than the "lowest level currently
19 feasible" as stated in 22 CCR section 12501(a)(4), he shall have
20 the right to seek a modification of the Permanent Injunction to
21 reflect the alleged "lowest level currently feasible" of
22 naturally occurring lead in the Calcium Products. Prior to
23 seeking such modification, the Attorney General shall provide
24 written notice to the Settling Defendants that he intends to seek
25 the modification. The parties shall have ninety (90) days in
26 which to confer with the Attorney General concerning the
27 modification. If one or more of the Settling Defendants and the

1 Attorney General are unable to agree on a modification to the
2 Permanent Injunction the Attorney General may file a motion with
3 the Court, seeking a modification of the Permanent Injunction.
4 In any motion by the Attorney General seeking such a
5 modification, the burden of producing evidence shall be initially
6 upon the Attorney General to demonstrate a prima facie case that
7 the modification sought by the Attorney General is the "lowest
8 level currently feasible." The Settling Defendants who do not
9 agree to such modification retain the ultimate burden of proving
10 that the modification sought by the Attorney General is lower
11 than the "lowest level currently feasible." The parties hereby
12 agree that the Permanent Injunction should be modified to reflect
13 any agreement of the parties or any determination by the Court
14 concerning what is the "lowest level currently feasible" for lead
15 in Calcium Products.

16 2.8 In the event that Settling Defendants, individually or
17 collectively, determine that the naturally occurring levels set
18 forth in Table 2.3 of paragraph 2.3 above are lower than the
19 "lowest level currently feasible," as stated in 22 CCR section
20 12501(a)(4), such Settling Defendants shall have the right to
21 seek modification of the Permanent Injunction to reflect the
22 alleged "lowest level currently feasible." Prior to seeking such
23 modification, such Settling Defendants shall provide written
24 notice to the Attorney General that they intend to seek the
25 modification. The parties shall have ninety (90) days in which
26 to confer concerning the modification. If the parties are unable
27 to agree on a modification to the Permanent Injunction such

1 Settling Defendants may file a motion with the Court, seeking a
2 modification of the Permanent Injunction. In any motion by
3 Settling Defendants seeking such modification, the burden of
4 producing evidence and of proof shall be on such Settling
5 Defendants to prove that the modification sought by the Settling
6 Defendants is the "lowest level currently feasible." The parties
7 hereby agree that the Permanent Injunction should be modified to
8 reflect any agreement of the parties or any determination by the
9 Court concerning what is the "lowest level currently feasible"
10 for lead in Calcium Products.

11 2.9 The term "feasible" as used in paragraphs 2.7 and 2.8
12 above includes, but is not limited to, a consideration of the
13 following factors: availability and reliability of a supply of
14 low-lead calcium that meets the requirements set forth in
15 paragraphs 2.2, 2.3 and 2.4 above; cost of low-lead calcium and
16 resulting increase in manufacturers' prices resulting from the
17 use of the low-lead calcium; performance characteristics of low-
18 lead calcium and of the resulting Calcium Product, including, but
19 not limited to formulation, performance, safety, efficacy and
20 stability. Nothing in this Permanent Injunction shall be
21 interpreted to require the Settling Defendants to use any calcium
22 material as an ingredient in a Calcium Product that would render
23 their Calcium Product unlawful under state or federal law as
24 measured by existing and/or future applicable California and
25 federal food and drug laws and regulations. Nothing in this
26 Permanent Injunction shall be interpreted to preclude a Settling
27 Defendant from advocating, for purposes of paragraphs 2.7 and/or

1 2.8 that any proposed modification requiring a change in the type
2 of raw calcium source material as an ingredient in a Calcium
3 Product is not feasible as defined herein. Nothing in this
4 Permanent Injunction shall be interpreted to preclude the People
5 from advocating, for purposes of paragraphs 2.7 and/or 2.8 that
6 any proposed modification requiring a change in the type of raw
7 calcium source material as an ingredient in a calcium product is
8 feasible as defined herein.

9 2.10 Each Settling Defendant shall maintain records
10 sufficient to establish its compliance with this Permanent
11 Injunction for a period of four years following the date of
12 shipment of any Calcium Product into California. Such documents
13 shall be sufficient in detail to establish compliance with the
14 Protocol set forth in the attached Exhibit A. Upon reasonable
15 written notice from the Attorney General's Office, a Settling
16 Defendant must produce to the Attorney General within ten (10)
17 business days of the receipt of the Attorney General's notice,
18 the documents required to be maintained according to this
19 paragraph. To the extent that such documents contain information
20 which the Settling Defendant maintains is confidential,
21 proprietary, and/or in the nature of a trade secret (or in fact a
22 trade secret), and upon written notice as to the asserted
23 confidential nature of this information by the Settling
24 Defendant, the Attorney General agrees not to disclose this
25 information to third parties (though the Attorney General may
26 disclose this information to its attorneys and employees,
27 including professional consultants, provided that these persons

1 also agree to maintain the confidentiality of the information in
2 these documents). In addition, any Settling Defendant may
3 designate as confidential "trade secret" information as that term
4 is defined in California Government Code section 6254.7 any data
5 provided to the Attorney General's Office pursuant to this
6 paragraph or any other provision of this Permanent Injunction or
7 relating to the subject matter hereof and such information shall
8 not be released to any member of the public. Provided, however,
9 that nothing in this provision shall prohibit the Attorney
10 General from disclosing information and/or data designated as
11 confidential, proprietary and/or trade secret to other government
12 agencies as is necessary in pursuit of his enforcement authority.
13 Furthermore, nothing in this provision shall prohibit the
14 Attorney General from applying to the Court for a ruling
15 determining that the information and/or data designated by a
16 Settling Defendant as confidential, proprietary and/or trade
17 secret should not be so designated and may be freely disclosed.

18 3. Settlement Payments

19 3.1 Within thirty (30) days of execution of this Permanent
20 Injunction, as full, final and complete satisfaction of all
21 claims for civil penalties or restitution for the alleged
22 violations up to and including July 1, 1997 as set forth in
23 paragraph 10.1, for Calcium Supplements and Antacids, Settling
24 Defendants shall pay the sum of \$264,500 to the Public Health
25 Trust, a program of the California Public Health Foundation to be
26 used for research, investigation and public education projects
27 approved by the Attorney General and relating to exposure to lead

1 in pregnancy and/or nutritional factors related to lead exposure
2 among children. Payment shall be made by delivery of certified
3 funds payable to the Public Health Trust. Making these payments
4 shall not be construed as an admission by Settling Defendants of
5 any fact, issue of law or violation of law, nor shall compliance
6 with the Permanent Injunction constitute or be construed as an
7 admission by such Settling Defendants of any fact, issue of law,
8 or violation of law.

9 4. Payment of Costs and Fees

10 4.1 Within thirty (30) days of execution of this Permanent
11 Injunction, Settling Defendants shall pay \$36,000 as
12 reimbursement for the Attorney General's costs of investigating
13 and prosecuting this action. Payment shall be made by delivery
14 of certified funds in the amount of \$26,000 payable to the
15 Attorney General of the State of California at 2101 Webster
16 Street, 12th Floor, Oakland, California 94612-3049 (Attn: Susan
17 S. Fiering, Deputy Attorney General) and by the delivery of
18 certified funds in the amount of \$10,000 payable to the
19 Environmental Health Account, Public Health Trust, at 2001
20 Addison Street, Ste. 210, Berkeley, CA 94704 (with a copy to
21 Susan S. Fiering, Deputy Attorney General, 2101 Webster Street,
22 12th Floor, Oakland, California 94612-3049).

23 5. Additional Enforcement Actions; Continuing Obligations

24 5.1. By entering into this Permanent Injunction, the People
25 do not waive any right to take further enforcement actions on any
26 violations not covered by the Complaint. Nothing in this
27 Permanent Injunction shall be construed as diminishing each

1 Settling Defendant's continuing obligation to comply with
2 Proposition 65 or the Unfair Competition Act in its future
3 activities.

4 6. Enforcement of Permanent Injunction

5 6.1. The People may, by motion or order to show cause before
6 the Superior Court of San Francisco, enforce the terms and
7 conditions contained in this Permanent Injunction. In any action
8 brought by the People to enforce this Permanent Injunction, the
9 People may seek whatever fines, costs, penalties or remedies as
10 provided by law for failure to comply with the Permanent
11 Injunction. Where said failure to comply constitutes future
12 violations of Proposition 65 or other laws, independent of the
13 Permanent Injunction and/or those alleged in the Complaint, the
14 People are not limited to enforcement of this Permanent
15 Injunction but may seek in another action whatever fines, costs,
16 penalties or remedies are provided by law for failure to comply
17 with Proposition 65 or other laws. In any such future action,
18 the standards and protocol set forth in Section 2 above, as they
19 may be modified from time to time pursuant to paragraphs 2.7 or
20 2.8 shall apply. However, the rights of the Settling Defendants
21 to defend themselves and their actions in law or equity shall not
22 be abrogated or reduced in any fashion by the terms of this
23 paragraph.

24 7. Application of Permanent Injunction

25 7.1 The Permanent Injunction shall apply to, be binding
26 upon and inure to the benefit of, the parties, their divisions,
27 subdivisions, subsidiaries, and affiliates and the successors or

1 assigns of each of them.

2 8.0 Application of Testing Standard and Protocol

3 8.1 The testing standard and protocol set forth in Exhibit
4 A attached to this Permanent Injunction are based on
5 determinations concerning the nature of the laboratory test used
6 and its relationship to actual and specific conditions of Calcium
7 Product use. This Permanent Injunction, including, but not
8 limited to, this standard and protocol, is the product of
9 negotiation and compromise and is accepted by the parties, for
10 purposes of settling, compromising and resolving issues disputed
11 in this action, including future compliance by the Settling
12 Defendants with Section 2 of this Permanent Injunction and shall
13 not be used for any other purpose, or in any other matter and,
14 except for the purpose of determining future compliance with this
15 Permanent Injunction, shall not constitute an adoption or
16 employment of a method of analysis for a listed chemical in a
17 specific medium as set forth in 22 CCR section 12901(b).

18 9. Authority to Stipulate to Permanent Injunction

19 9.1 Each signatory to this Permanent Injunction certifies
20 that he or she is fully authorized by the party he or she
21 represents to enter into this Permanent Injunction on behalf of
22 the party represented and legally to bind that party.

23 10. Claims Covered

24 10.1 This Permanent Injunction is a final and binding
25 resolution between the People and each Settling Defendant of any
26 and all alleged violations of Proposition 65, the Business and
27 Professions Code Sections 17200 et seq. and/or the Consumers

1 Legal Remedies Act, Civil Code section 1750 et seq. up through
2 July 1, 1997 arising from failure to warn of exposure to lead
3 from consumption of any Settling Defendant's Calcium Supplements
4 and/or Antacids or those of any corporate affiliate, that was
5 committed by the named Settling Defendant or by any entity within
6 its respective chain of distribution, including, but not limited
7 to, distributors, wholesalers and retailers of any of the
8 Settling Defendant's Calcium Supplements and/or Antacids. This
9 Permanent Injunction does not resolve any issues concerning
10 Settling Defendants' Multiple Vitamins/Minerals as defined in
11 paragraph 1.2(c) above. The list of past and current Calcium
12 Supplements and Antacids to be governed by this Permanent
13 Injunction is set forth as Exhibit B attached to this Permanent
14 Injunction. All new Calcium Supplements and Antacids hereafter
15 introduced into the stream of commerce for distribution or sale
16 in California shall be governed by this Permanent Injunction.
17 Nothing in this Permanent Injunction shall preclude one or more
18 Settling Defendants from establishing that any non-calcium
19 ingredient in a Calcium Product, other than Calcium Supplements
20 and Antacids, contains naturally occurring lead at the "lowest
21 level currently feasible" pursuant to 22 CCR section 12501.

22 11. Modification

23 11.1 This Permanent Injunction may be modified from time to
24 time by express written agreement of all Settling Defendants and
25 the Attorney General with the approval of the Court or by an
26 order of this Court.

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12. Execution in Counterparts

12.1 This Permanent Injunction may be executed in counterparts, which taken together shall be deemed to constitute one and the same document.

13. Entry of Stipulation for Entry of Permanent Injunction Required

13.1 This Stipulation for Entry of Permanent Injunction shall be null and void, and be without any force or effect, unless entered by the Court in this matter. If the Stipulation for Entry of Permanent Injunction is not entered by the Court, the execution of this Stipulation for Entry of Permanent Injunction by any Settling Defendant shall not be construed as an admission by a Settling Defendant of any fact, issue of law or violation of law.

IT IS SO STIPULATED:

Dated: April 18, 1997

DANIEL E. LUNGREN, Attorney
General of the State of
California
RODERICK E. WALSTON
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING
Deputy Attorneys General

By: Susan S. Fiering
SUSAN S. FIERING
Deputy Attorney General
Attorneys for the People of the
State of California

HEALTH

Lead Levels in Calcium Supplements

Despite earlier precedent, California gives in to higher lead levels without warning.

Over the last decade many Americans -- pregnant women especially -- have been augmenting their calcium intake with dietary supplements in hopes of keeping their bones strong and preventing the development of osteoporosis. Yet recent studies have found that many well known brands of calcium supplements and antacids contain potentially dangerous levels of lead, a toxin which has been linked to health problems including hypertension, decreased cognitive ability, kidney malfunction, and even cancer. Lead presents especially high risks to pregnant and nursing women, their unborn fetuses, and young children.

There are no national standards regulating lead in calcium products. But in California, a tough anti-toxics law (Proposition 65) requires that manufacturers and retailers provide warnings for all products that expose consumers to lead in excess of 0.5 micrograms per day. Recent laboratory testing done at the University of California, however, showed that more than twenty major brands of calcium supplements and antacid tablets contained lead well in excess of that level -- some brands tested were found to triple, or even quadruple, consumers' dietary lead exposure.

The Natural Resources Defense Council took action under California's law, and in January 1997 reached an agreement under which Leiner Health Products Group, the nation's largest manufacturer of dietary calcium supplements, will manufacture virtually lead-free calcium products. Leiner uses a process called chelation to remove lead - a feat that other manufacturers have claimed isn't feasible.

Environmentalists and public health advocates hoped that the Leiner settlement would set a precedent, and that soon other manufacturers would also "get the lead out." But in April 1997 the California Attorney General reached a settlement with several manufacturers allowing them to sell calcium products for the next two years, without warning labels, with exposures of up to 6 micrograms for supplements and up to 9 micrograms for antacids. The settlement proposes lead reductions after two years, but even then these manufacturers can avoid compliance if they can show that it would cause an increase in prices.

For consumers concerned about lead levels, Leiner products appear under the name "Your Life" and as the house brands in such stores as CVS, Rite Aid, Walgreen's, and Walmart. Other products currently on the market that meet the California standards for lead are TUMS 500, Mylanta Chewables for Children, and Posture D High Potency Calcium.

NRDC and other public health and consumer organizations have petitioned the Food and Drug Administration (FDA) to establish a national standard limiting lead in calcium supplements and antacids to the level of 0.5 micrograms daily deemed safe by California. Until such a standard is put into place, consumers may unknowingly be exposed to dangerous lead levels. Even Californians.