

LAW OFFICES OF  
**ANDREW L. PACKARD**

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August 29, 2007

**VIA CERTIFIED MAIL**

Betty Schreck Agent for Service  
SHEN HERB, INC.  
2322 5<sup>th</sup> Street  
Berkeley, CA 94710

Re: Notice of Violations of California Health & Safety Code §25249.5 *et seq.*

Dear Ms. Schreck,

This letter represents Stephen D. Gillett in connection with this notice of violations of California Safe Drinking Water & Toxic Enforcement Act of 1986, codified at Health & Safety Code §25249.5 *et seq.* (also referred to as "Proposition 65"). This letter serves to provide notification of these violations to you and to the public enforcement agencies. Pursuant to §25249.7(d) of the statute, Mr. Gillett will have the right to bring an enforcement action sixty (60) days after effective service of this notice unless the public enforcement agencies have commenced and are diligently prosecuting an action to rectify these violations. A summary of the statute and its implementing regulations, which was prepared by the lead agency designated under the statute, is enclosed with the copy of this notice served upon the violator. The specific details of the violations that are the subject of this notice are provided below.

**Violations: Chemicals and Products At Issue.** The name of the violator covered by this notice is SHEN HERB, INC. (hereafter, the "Violator"). The violator markets and sells in California dietary supplements and herbal products. These ongoing violations arise out of exposures to lead and lead compounds from the consumer products described below. On February 27, 1987, the State of California officially listed lead as a chemical known to cause reproductive toxicity. On October 1, 1992, the State of California officially listed lead and lead compounds as chemicals known to cause cancer. The products subject to this notice are set forth on Exhibit A hereto.

**Routes of exposure.** The consumer exposures that are the subject of this notice result from the purchase, acquisition, handling and/or use of these products by consumers as recommended on the product label. Accordingly, consumer exposures have occurred and continue to occur primarily through the ingestion route, but also may occur through the inhalation and/or and dermal contact routes of exposure.

**Duration of violations.** Each of these ongoing violations has occurred on every day since at least December 23, 2005, as well as every day since the products were

introduced into the California marketplace, and will continue every day until clear and reasonable warnings are provided to product purchasers and users.

In keeping with the public interest goals of the statute and my client's objectives in issuing this notice, Mr. Gillett is interested in seeking a constructive resolution of this matter to avoid further unwarned exposures to lead in these products without protracted litigation. Mr. Gillett's address is Post Office Box 170142, San Francisco, California 94117. Tel. (415) 850-5233. Please direct all communications regarding this notice to Andrew L. Packard at the above-listed firm address and telephone number.

Very Truly Yours,



Andrew L. Packard

Attachments:  
Exhibit A, Products At Issue  
OEHHA Summary  
Certificate of Merit (w/o AG attachments)  
Certificate of Service



P.O. Box 8343 Berkeley CA, 94707  
 Phone (510) 548-2181 ~ Fax (510) 548-2183  
[www.DrShen.com](http://www.DrShen.com)

**EXHIBIT A**

**DR. SHEN LINE**

<u>NAME</u>	<u>SIZE</u>	<u>UPC #</u>
1) Dr. Shen's Yin Chia	90 Tab 750mg	789741000011
2) Dr. Shen's Zong Ga	90 Tab 750mg	789741000028
3) Dr. Shen's Allergy	90 Tab 750mg	789741000035
4) Dr. Shen's Sinus Fc	90 Tab 700mg	789741000042
5) Dr. Shen's Stomach	80 Tab 750mg	789741000059
6) Dr. Shen's Rhubarb	90 Tab 700mg	789741000080
7) Dr. Shen's Shou W	200 Tab 700mg	789741000134
8) Dr. Shen's Women's	200 Tab 750mg	789741000141
9) Dr. Shen's Yin Chia	200 Tab 750mg	789741000158
10) Dr. Shen's Zong C	200 Tab 750mg	789741000165
11) Dr. Shen's Free &	200 Tab 750mg	789741000172
12) Dr. Shen's Two In	200 Tab 750mg	789741000189
13) Dr. Shen's Jade S	150 Tab 650mg	789741000196
14) Dr. Shen's ColdSt	15 Tab 750mg	789741000202
15) Dr. Shen's Gan M	60 Tab 700mg	789741000219
16) Dr. Shen's Good S	150 Tab 700mg	789741000226

IMPORTED CHINESE PATENT MEDICINES

Abundant Yin	Jiao Gu Lan	Tian Wang Bu Xin Dan Wan
An Shui	Jin Gu Die Shang Wan	Tong Jing Wan
Aucklandia and Coptis	Jin Gui Shen Qi Wan	Tong Qiao Huo Xue Wan
Bai Hu Tang Wan	Jing Fang Bai Du Wan	Tong Xie Yao Fang Wan
Bai Xing Shi Gan Wan	Juan Bi Wan	Wen Dan Tang Wan
Ba Jin Yin Yang Wan	Liang Ge Wan	Wen Jing Tang Wan
Ban Xia Huo Po Wan	Liu Jun Zi Wan	Wu Ling San Wan
Ba Zheng San Wan	Liu Wei Di Huang Wan	Wu Pi Yin
Bi Yan Pian	Long Dan Xie Gan Wan	Wu Ren Wan
Bi Xie Sheng Shi Wan	Ma Huang Tang Wan	Wu Wei Xiao Du Wan
Bi Xie Fen Qing Wan	Mai Wei Di Huang Wan	Wu Zi Yan Zong Wan
Bu Fei Wan	Margarite Acne Pills	Xiang Sha Liu Jun Zi Wan
Bu Nao Wan	Ma Zi Ren Wan	Xiao Huo Luo Dan Wan
Bu Yang Huang Wu Wan	Ming Mu Di Huang Wan	Xiao Jian Zhong Wan
Bu Zhing Yi Qi Wan	Nei Xiao Luo Li Wan	Xiao Qing Long Wan
Cang Er Zi Wan	Ning Sou Wan	Xiao Yao Wan
Chai Hu Long Gu Mu Wan	Nu Ke Ba Zhen Wan	Xin Yi Wan
Chai Hu Shu Gan Wan	Ping Wei San	Xuan Bi Wan
Curing Pills	Pu Ji Xiao Du Yin Wan	Xue Fu Zhu Yu Tang Wan
Da Chai Hu Wan	Qi Bao Mei Ran Dan	Yan Hu Suo Zhi Tong Wan
Da Huang Jiang Zhi Wan	Qing Gu Wan	Yi Guan Jian Wan
Dan Shen Huo Xue Tang Wan	Qing Qi Hua Tan Wan	You Gui Wan
Dan Shen Yin Wan	Qing Wei San Wan	Yi Ping Feng San Wan
Dang Gui Si Ni Wan	Ren Shen Bai Du Wan	Yu Quan Wan
Dang Gui Yin Zi Wan	Run Chang Wan	Zhen Gan Xi Feng Wan
Dao Chi Wan	San Bi Wan	Zhen Wu Tang Wan
Ding Chuan Wan	Sang Ju Yin Wan	Zhi Bai Di Huang Wan
Du Huo Ji Sheng Wan	Sang Piao Xiao Wan	Zhi Gan Cao Wan
Er Chen Wan	Sha Shen Mai Men Dong Tang Wan	Zuo Gui Wan
Er Xian Tang Wan	Shao Fu Zhu Yu Wan	
Fang Feng Tong Shen Wan	Shao Yao Gan Cao Wan	
Fang Ji Huang Qi Wan	Shen Tong Zhu Yu Wan	
Fargelin	Sheng Mai San Wan	
Gan Mai Da Zao Wan	Shi Chuan Da Bu Wan	
Ge Gen Wan	Shou Wu Pian	
Ge Jie Da Bu Wan	Shu Gan Wan	
Ge Xia Zhu Yu Wan	Si Jun Zi Tang Wan	
Guan Jie Yan Wan	Si Miao Wan	
Gui Pi Wan	Si Ni San Wan	
Gui Zhi Fu Ling Wan	Si Wu Tang Wan	
Huai Jiao Wan	Tao Hong Si Wu Tang Wan	
Huan Shao Dan	Tian Ma Gou Ten Yin Wan	
Huang Lian Jie Du Wan	Tian Qi Wan	
Huang Lian Su Wan	Tian Tai Wu Yao Wan	
Huo Luo Xiao Ling Wan		

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

THE SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65): A SUMMARY

The following summary has been prepared by the Office of Environmental Health Hazard Assessment, the lead agency for implementation of the Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as Proposition 65). A copy of this summary must be included as an attachment to any notice of violation served upon an alleged violator of the Act. The summary provides basic information about the provisions of the law, and is intended to serve only as a convenient source of general information. It is not intended to provide authoritative guidance on the meaning or application of the law. The reader is directed to the statute and its implementing regulations (see citations below) for further information. Proposition 65 appears in California law as Health and Safety Code Sections 25249.5 through 25249.13. Regulations that provide more specific guidance on compliance, and that specify procedures to be followed by the State in carrying out certain aspects of the law, are found in Title 22 of the California Code of Regulations, Sections 12000 through 14000.

### WHAT DOES PROPOSITION 65 REQUIRE?

The "Governor's List" Proposition 65 requires the Governor to publish a list of chemicals that are known to the State of California to cause cancer, or birth defects or other reproductive harm. This list must be updated at least once a year. Over 550 chemicals have been listed as of May 1, 1996. Only those chemicals that are on the list are regulated under this law. Businesses that produce, use, release or otherwise engage in activities involving those chemicals must comply with the following:

**Clear and reasonable warnings.** A business is required to warn a person before "knowingly and intentionally" exposing that person to a listed chemical. The warning given must be "clear and reasonable." This means that the warning must: (1) clearly make known that the chemical involved is known to cause cancer or birth defects or other reproductive harm; and (2) be given in such a way that it will effectively reach the person before he or she is exposed. Exposures are exempt from the warning requirement if they occur less than twelve months after the date of listing of the chemical.

**Prohibition from discharges into drinking water.** A business must not knowingly discharge or release a listed chemical into water or onto land where it passes or probably will pass into a source of drinking water. Discharges are exempt from this requirement if they occur less than twenty months after the date of listing of the chemical.

### DOES PROPOSITION 65 PROVIDE ANY EXEMPTIONS?

Yes. The law exempts

**Governmental agencies and public water utilities.** All agencies of the federal, State or local government, as well as entities operating public water systems, are exempt.

**Businesses with nine or fewer employees.** Neither the warning requirement nor the discharge prohibition applies to a business that employs a total of nine or fewer employees.

**Exposures that pose no significant risk of cancer.** For chemicals that are listed as known to the State to cause cancer ("carcinogens"), a warning is not required if the business can demonstrate that the exposure occurs at a level that poses "no significant risk." This means that the exposure is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime.

The Proposition 65 regulations identify specific "no significant risk" levels for more than 250 listed carcinogens.

Exposures that will produce no observable reproductive effect at 1,000 times the level in question. For chemicals known to the State to cause birth defects or other reproductive harm ("reproductive toxicants"), a warning is not required if the business can demonstrate that the exposure will produce no observable effect, even at 1,000 times the level in question. In other words, the level of exposure must be below the "no observable effect level (NOEL)," divided by a 1,000-fold safety or uncertainty factor. The "no observable effect level" is the highest dose level which has not been associated with an observable adverse reproductive or developmental effect.

Discharges that do not result in a "significant amount" of the listed chemical entering into any source of drinking water. The prohibition from discharges into drinking water does not apply if the discharger is able to demonstrate that a "significant amount" of the listed chemical has not, does not, or will not enter any drinking water source and that the discharge complies with all other applicable laws, regulations, permits, requirements or orders. A "significant amount" means any detectable amount, except an amount that would not meet the "no significant risk" or "no observable effect" test if an individual were exposed to such an amount in drinking water.

#### HOW IS PROPOSITION 65 ENFORCED?

Enforcement is carried out through civil lawsuits. These lawsuits may be brought by the Attorney General, any district attorney, or certain city attorneys (those in cities with a population exceeding 750,000). Lawsuits may also be brought by private parties acting in the public interest, but only after providing notice of the alleged violation to the Attorney General, the appropriate district attorney and city attorney, and the business accused of the violation. The notice must provide adequate information to allow the recipient to assess the nature of the alleged violation. A notice must comply with the information and procedural requirements specified in regulations (Title 22, California Code of Regulations, Section 12903). A private party may not pursue an enforcement action directly under Proposition 65 if one of the governmental officials noted above initiates an action within sixty days of the notice.

A business found to be in violation of Proposition 65 is subject to civil penalties of up to \$2,500 per day for each violation. In addition, the business may be ordered by a court of law to stop committing the violation.

**CERTIFICATE OF MERIT**

Re: Stephen D. Gillett's August 29, 2007

Notice of Proposition 65 Violations SHEN HERB, INC.

I, Andrew L. Packard, declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged that the party in the notice has violated Health & Safety Code §25249.6 by failing to provide clear and reasonable warnings.

2. I am an attorney for the noticing party.

3. I have consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemicals that are the subject of the action.

4. Based on the information obtained through those consultations, and on all other information in my possession, I believe there is a reasonable and meritorious case for the private action. I understand that "reasonable and meritorious case for the private action" means that the information provides a credible basis that all elements of the plaintiff's case can be established and that the information did not prove that the alleged violator will be able to establish any of the affirmative defenses set forth in the statute.

5. This copy of this Certificate of Merit served on the Attorney General attaches to it factual information sufficient to establish the basis for this certificate, including the information identified in Health and Safety Code §25249.7(h)(2), i.e., (1) the identity of the persons consulted with and relied on by the certifier, and (2) the facts, studies, or other data reviewed by those persons.

Dated: August 29, 2007



Andrew L. Packard

Attachments (Attorney General Copy only)