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14 MEDICINE COMPANY

14 SUPERIOR COURT OF THE STATE OF CALIFORNIA
15 CITY AND COUNTY OF SAN FRANCISCO – UNLIMITED JURISDICTION
16

17 STEPHEN D. GILLETT,
18 Plaintiff,

19 vs.

20 MADISON ONE ACME, INC., a corporation
21 doing business as SOLSTICE MEDICINE
22 COMPANY,
23 Defendant.

Case No. CGC-07-469239

**[PROPOSED] STIPULATED
SECOND ADDENDUM TO
CONSENT JUDGMENT
ENTERED SEPTEMBER 24, 2008;
ORDER THEREON;**

24 This Stipulated Second Addendum to Consent Judgment (“Second Addendum”) is
25 entered into by and between Plaintiff STEPHEN D. GILLETT (“Plaintiff” or “GILLETT”), a
26 citizen enforcer of California’s Safe Drinking Water & Toxic Enforcement Act of 1986
27
28

ENDORSED
FILED
San Francisco County Superior Court

DEC 29 2017

CLERK OF THE COURT
BY: ERICKA LARNAUTI
Deputy Clerk

1 (hereafter "Proposition 65"), and Defendant MADISON ONE ACME, INC., a corporation
2 doing business as SOLSTICE MEDICINE COMPANY ("Defendant" or "SOLSTICE"). The
3 purpose of this Second Addendum is to resolve a dispute arising out of Plaintiff's contentions
4 that Defendant, over a period of seven and a half years, violated the injunctive terms of the
5 Consent Judgment entered in this matter on September 24, 2008 ("2008 Consent Judgment")
6 as discussed more fully below.

7 A true and correct copy of the 2008 Consent Judgment is attached hereto as **Exhibit A**.
8 Nothing in this Second Addendum is intended to modify the terms of the 2008 Consent
9 Judgment in any way, with two administrative exceptions:

- 10 (1) the additional product testing and reporting requirements necessary for GILLETT's
11 compliance monitoring purposes over the next three years, as set forth in Paragraph II.2, and,
12 (2) the Updated Notice provisions necessary to reflected changes in counsel and contact
13 information, as set forth in Paragraph XIII.1.

14 This Second Addendum shall be enforceable upon entry (the "Effective Date") by the Court.

15 **I. INTRODUCTION**

16 1. Plaintiff asserts he is an individual dedicated to, among other causes, the
17 protection of the environment, the promotion of human health, the improvement of worker and
18 consumer rights, environmental education, corporate accountability and reduction or
19 elimination of toxins in the food supply chain.

20 2. Defendant is a California corporation that sells traditional Chinese patent
21 medicines and other herbal products to California consumers, both directly (by phone order
22 and over the Internet), and indirectly (at wholesale to resellers in California). See Exhibit A to
23 the 2008 Consent Judgment (listing all products covered by 2008 Consent Judgment).

24 *Gillett's Prior Citizen Enforcement Actions*

25 3. Plaintiff asserts that the underlying lawsuit is part of a ten-year campaign
26 undertaken by Plaintiff to address exposures to lead, arsenic, mercury and cadmium from the
27 use of herbal dietary supplements, including the "Traditional Chinese Patent Medicines" at
28

1 issue herein.

2 4. Plaintiff asserts that his efforts have culminated in more than a dozen court-
3 approved Consent Judgments covering thousands of products, all of which require strict
4 compliance with Proposition 65's mandate that consumers be provided "clear and reasonable"
5 warnings prior to exposure to known carcinogens and/or reproductive toxins.

6 5. In addition to ensuring that California consumers are provided the health hazard
7 warnings required by the statute, Plaintiff asserts that his efforts have also provided funding in
8 the form of civil penalties, to the lead agency, the Office of Environmental Health Hazard
9 Assessment ("OEHHA") and to the Rose Foundation for Communities & the Environment for
10 third-party grant work advancing the statute's goals.

11 *Legal and Procedural Background to this Action*

12 6. Pursuant to Health & Safety Code § 25249.8: (a) on February 27, 1987, the
13 State of California listed the chemical lead as a chemical known to cause reproductive toxicity;
14 (b) on October 1, 1992, the State of California listed the chemicals lead and lead compounds
15 as chemicals known to cause cancer; (c) on July 1, 1990 the State of California listed the
16 chemicals mercury and mercury compounds as chemicals known to cause reproductive
17 toxicity; (d) on February 27, 1987, the State of California officially listed the chemical arsenic
18 as a chemical known to cause cancer; (e) on May 1, 1997, the State of California officially
19 listed the chemical arsenic as a chemical known to cause reproductive toxicity; (f) on October
20 1, 1987, the State of California officially listed the chemicals cadmium and cadmium
21 compounds as chemicals known to cause cancer; (g) on May 1, 1997, the State of California
22 officially listed the chemical cadmium as a chemical known to cause reproductive toxicity.
23 For purposes of the 2008 Consent Judgment and this Second Addendum, the foregoing
24 Proposition 65-listed substances are referred to herein as "the Metals."

25 7. Beginning on March 5, 2007 and again on June 25, 2008, Plaintiff served on
26 Defendant and each of the appropriate public enforcement agencies "60-Day Notices" that
27 provided Defendant and the public enforcement agencies with a notice alleging that Defendant
28

1 was in violation of Proposition 65 for failing to warn the purchasers and individuals using the
2 Products that the use of the Products exposes them to certain chemicals known to the State of
3 California to cause cancer and/or reproductive toxicity (each, a “60-Day Notice”). See
4 **Exhibit A** (copies of the March 5, 2007 and June 25, 2008 60-Day Notices issued to
5 Defendant are attached to the 2008 Consent Judgment as Exhibit B).

6 8. On November 15, 2007, Plaintiff, acting in the public interest, filed a Complaint
7 in San Francisco Superior Court alleging violations of Proposition 65 (the “Action”). At that
8 time, none of the public enforcement agencies had commenced and begun “diligently
9 prosecuting” an action against Defendant for such alleged violations within the meaning of
10 Proposition 65; since that time, no public enforcement agencies have commenced and begun
11 “diligently prosecuting” an action against Defendant for such alleged violations within the
12 meaning of Proposition 65.

13 9. The Action alleged that the products (“Products”) contain the Metals, all of
14 which are substances listed by the State of California as known to cause cancer and/or
15 reproductive toxicity pursuant to Proposition 65. For purposes of the 2008 Consent Judgment
16 only, each of the products subject to the Action was deemed to be a “food” within the meaning
17 of Title 27, Cal. Code of Regs. § 25501 (formerly § 12501).

18 10. On July 3, 2008, the Parties entered into a [Proposed] Consent Judgment
19 resolving the claims set forth in the Action, which was then reviewed by the California
20 Attorney General’s Office pursuant to Title 11, Cal. Code of Regs. §3000, *et seq.* After
21 briefing and hearing, the Court granted Plaintiff’s Motion for Approval & Entry of Consent
22 Judgment on September 24, 2008 and entered the judgment.¹

23 _____
24 ¹ At the initial hearing on the motion, on September 4, 2008, the Honorable Judge Peter J. Busch
25 requested, and the parties orally stipulated to, an addendum clarifying (1) that the Rose Foundation for
26 Communities & the Environment would administer the \$25,000 payment in lieu of further civil
27 penalties; and (2) that these funds “shall be paid out on a *pro rata* basis, in conjunction with the Civil
28 Penalty Assessment described in Section 3.2, and after payment of Plaintiff’s fees and costs.” This
first addendum is reflected in the final consent judgment entered at the second hearing on Plaintiff’s
motion to approve the settlement, on September 24, 2008. See **Exhibit A**, 2008 Consent Judgment, at
23:10-16.

1 *The Dispute Giving Rise to This Second Addendum*

2 **11.** On December 3, 2015, Plaintiff initiated the meet and confer process set forth
3 under Paragraph 8.1 of the 2008 Consent Judgment by notifying Defendant and its counsel
4 that Plaintiff's investigations indicated that Defendant was violating the Judgment with respect
5 to specific products, and requested that the Parties "meet and confer within twenty (20) days."

6 A true and correct copy of this letter is attached here as **Exhibit B.**

7 **12.** This letter also proposed that the Parties enter into a bilateral sharing of the
8 Parties' existing test results on all of the 239 Products subject to the 2008 Consent Judgment,
9 and also proposed the development of a testing plan for any Products for which such recent
10 testing is not available, in order avoid a piecemeal approach to achieving full compliance.
11 Solstice has provided Plaintiff with a list of test results of the Products subject to the 2008
12 Consent Judgment as well as additional Products and testing not previously subject to the 2008
13 Consent Judgment.

14 **13.** The Parties' substantive discussions concerning appropriate testing methods,
15 older batch lot issues, and an appropriate payment of stipulated civil payments and payments
16 in lieu of civil penalties were then initiated in January of 2016 and continued through October
17 of 2016. This Second Addendum is the product of these efforts to resolve the conflict without
18 further litigation and does not modify any of the terms of the 2008 Consent Judgment, with
19 two administrative exceptions, as noted in the introduction above.

20 **II. COMPLIANCE PROVISIONS UNDER THIS SECOND ADDENDUM**

21 **1. Defendant's Duty To Comply With All Terms of the 2008 Consent**
22 **Judgment On Or Before January 1, 2017.** On or before January 1, 2017, Defendant shall
23 comply with all terms of the 2008 Consent Judgment, including the following compliance
24 measures:

25 (a) *Scope of Products Subject to the 2008 Consent Judgment; "New Products."*
26 The 2008 Consent Judgment lists, in Exhibit A, 239 Products that are subject to its terms and
27 provides a further mechanism, in Paragraph 9, for adding "New Products." The Parties have
28

1 agreed that the herbal products set forth on **Exhibit C** hereto qualify as “New Products” within
2 the meaning of the 2008 Consent Judgment and that they shall be subject to all of the terms of
3 the 2008 Consent Judgment, including but not limited to testing for Metals and, where
4 necessary, providing health hazard warnings or banning the covered product from sale in
5 California under Paragraph 2.4.

6 (b) *Product Testing for Lead, Arsenic, Cadmium and Mercury.* Consistent with the
7 provisions of the 2008 Consent Judgment, on or before October 21, 2016, Solstice shall
8 complete all required testing of each of the Products subject to the 2008 Consent Judgment,
9 including the New Products, for the Metals. (See **Exhibit A**, 2008 Consent Judgment,
10 *Injunctive Provisions*, Paragraph 2.1.) All of these laboratory test results shall be provided to
11 Plaintiff’s counsel pursuant to the Updated Notice provisions herein by October 28, 2016,
12 together with a tabulated summary of the test results, pill weights, maximum dosages and
13 calculated exposure levels (“Initial Product Testing Summary”).² The Parties shall meet and
14 confer in good faith regarding the sufficiency of this product testing within thirty (30) days of
15 its provision to Plaintiff’s counsel.

16 (c) *Implementation of Health Hazard Warnings Based Upon Test Results.*
17 Consistent with the provisions of the 2008 Consent Judgment, Defendant shall ensure that all
18 Products sold by Defendant in the State of California after January 1, 2017 comply with the
19 on-product warning requirements of the 2008 Consent Judgment or such other amended
20 warning requirements approved by the court. (See **Exhibit A**, 2008 Consent Judgment,
21 *Injunctive Provisions*, Paragraphs 2.2 and 2.3.)
22
23

24 ² The Product Testing Summary shall track the format of the summary of test results exchanged by the
25 Parties in the course of negotiating this Second Addendum and shall be augmented and updated by
26 Defendant every six months beginning on January 1, 2017 to add all Product testing done after
27 October 18, 2016. (See Paragraph II.2, Compliance Monitoring, below.) The updated document is
28 intended to serve as a basis for future discussions between the Parties regarding compliance with the
2008 Consent Judgment, and to guide Plaintiff’s field investigations monitoring Defendant’s
compliance.

1 (d) *Recall of Products Banned from Sale in California Under Paragraph 2.4 of the*
2 *2008 Consent Judgment.* Paragraph 2.4 of the 2008 Consent Judgment prohibits the California
3 sale of any Product that, when used or consumed in accordance with the Defendant's label
4 directions, causes an exposure to lead in excess of ten (10.0) micrograms per day, based upon
5 Defendant's product testing results required above. (See **Exhibit A**, 2008 Consent Judgment,
6 *Injunctive Provisions*, Paragraph 2.4.). Defendant has admitted that each of the Products
7 subject to the ban against sale in California are listed on **Exhibit D** hereto. Defendant has
8 initiated and will continue to initiate its Standard Operating Procedure for Product Recalls
9 (attached as **Exhibit E**) and Defendant will complete the recall of the Products listed on
10 **Exhibit D** by no later than July 31, 2017. Defendant shall provide Plaintiff a report of the
11 status of its recall efforts on or before January 31, 2017 and again on April 30, 2017. That
12 report will include a summary of recall efforts and the number of units, for each of the
13 Products on **Exhibit D**, returned to Defendant. Defendant will notify Plaintiff by no later than
14 April 30, 2017 if additional time is needed to complete the recall efforts and Defendant and
15 Plaintiff will meet and confer regarding the time in which the completion of the product recall
16 will be completed. In any event, Defendant will complete all recall efforts by no later than
17 January 1, 2018.

18 **2. Compliance Monitoring.** For the period from January 1, 2017 through January
19 1, 2020 (including all lots received between October 18, 2016 and January 1, 2017), Defendant
20 shall continue to test each batch lot of each of the Products for the Metals in the manner
21 required by the 2008 Consent Judgment. All of the laboratory test results for the Products
22 obtained by Defendant after the Production of the Initial Product Testing Summary on October
23 28, 2016 shall be incorporated in a Revised Product Testing Summary and produced to
24 Plaintiff with the supporting lab reports on or before January 1, 2017.

25 **3. Semi-Annual Reporting Requirement.** Defendant shall continue to update the
26 Product Testing Summary on a semi-annual basis on July 1st and January 1st of each year
27 through and including January 1, 2020. These updated Product Testing Summaries, together
28

1 with all supporting lab reports, shall be provided to Plaintiff pursuant to the Updated Notice
2 provisions herein within five (5) days of these semi-annual deadlines.

3 **III. PAYMENT OF STIPULATED CIVIL PENALTIES UNDER THIS**
4 **SECOND ADDENDUM**

5 1. **Statutory Penalties Under Proposition 65.** Proposition 65 provides for civil
6 penalties of up to \$2500 per violation per day. Health & Safety Code § 25249.7.

7 2. **Civil Penalties Paid Under 2008 Consent Judgment.** Under the 2008 Consent
8 Judgment, Defendant agreed to pay, and paid, a civil penalty in the amount of \$160,000
9 pursuant to Health & Safety Code § 25249.7(b). Plaintiff then remitted 75% of this amount to
10 the State of California pursuant to Health & Safety Code § 25249.12(b). (See **Exhibit A**, 2008
11 Consent Judgment, *Civil Penalties*, Paragraph 3.1.)

12 3. **Stipulated Civil Penalties Under 2008 Consent Judgment.** The 2008 Consent
13 Judgment provides for stipulated penalties for future violations of its terms, as follows:

14 In the event that after sixty (60) days following the Effective Date Defendant violates
15 Sections 2 or 9 herein, the Parties stipulate that Defendants shall be liable for a
16 stipulated civil penalty in the amount of \$10.00 per unit item sold in violation of this
17 Consent Judgment, unless the Defendant's' actual per unit sale price to the buyer was
18 less than \$10.00, in which case the stipulated penalty shall be fifty percent (50%) of the
19 sale price Defendant received from the relevant buyer for the Products at issue. Total
20 civil penalties concerning all Products sold in violation of this Consent Judgment shall
21 not exceed \$75,000 for such violations in any calendar year. Plaintiff may establish
22 such violation(s) hereunder by a preponderance of the evidence upon a duly noticed
23 motion in the San Francisco Superior Court and subject to the provisions of Section 8
24 herein. Plaintiff shall remit 75% of this amount to the State of California pursuant to
25 Health & Safety Code § 25249.12(b).

26 The Parties have met and conferred at length concerning Plaintiff's allegations that Defendant
27 has failed to comply with nearly all of the injunctive terms of the 2008 Consent Judgment for a
28 period of eight years. Under the 2008 Consent Judgment, the stipulated civil penalties shall
not exceed \$600,000 for an eight year period of violation.

In the interests of reaching a comprehensive and final resolution of all alleged
violations occurring after the September 24, 2008 entry of the Consent Judgment herein and

1 before January 1, 2017, the Parties agree as follows: Defendant agrees to pay stipulated civil
2 penalties in the amount of \$400,000, subject to the terms of Paragraph VI. below.

3 **IV. PAYMENT IN LIEU OF ADDITIONAL STIPULATED CIVIL PENALTIES**
4 **UNDER THIS SECOND ADDENDUM**

5 1. Defendant agrees to make a payment in lieu of additional stipulated civil
6 penalties in the amount of \$35,000, subject to the terms of Paragraph VI. below. Consistent
7 with the provisions of the 2008 Consent Judgment, Plaintiff shall forward this payment to the
8 Rose Foundation for Communities & the Environment (“Rose”) for grants to California non-
9 profit groups “to reduce exposures to toxic chemicals, and to increase consumer, worker and
10 community awareness of the health hazards posed by toxic chemicals.” 2008 Consent
11 Judgment, Section 3.3(a). Specifically, Rose shall use the funds to investigate Proposition 65
12 violations arising out of the consumption of food products sold in the State of California.

13 2. **Penalties are not a credit.** Consistent with the provisions of the 2008 Consent
14 Judgment, no penalties paid herein shall be construed as a credit against future new claims
15 against Defendant. 2008 Consent Judgment, Section 3.4.

16 **V. REIMBURSEMENT OF FEES AND COSTS UNDER THIS SECOND**
17 **ADDENDUM**

18 1. **Reimbursement of Plaintiff's Investigative, Expert and Legal Fees and**
19 **Costs.** Defendant shall reimburse Plaintiff in the amount of \$132,490 for Plaintiff's
20 reasonable investigative, expert, and legal fees and costs incurred as a result of investigating
21 and negotiating a settlement in the public interest. This payment shall be subject to the terms
22 of Paragraph VI. below.

23 **VI. PAYMENT OBLIGATIONS UNDER THIS SECOND ADDENDUM**

24 1. **Installment Plan.** Pursuant to Paragraphs III, IV and V herein, Defendant
25 agrees to remit the total amount of \$567,490 to Plaintiff payable to the “Law Offices of
26 Andrew L. Packard Attorney Client Trust Account” my mailing all remitted funds to the Law
27 Offices of Andrew L. Packard at: 245 Kentucky Street, Suite B3, Petaluma, CA 94952.
28 Defendant shall remit the First Installment payment of one half of the total, or \$283,745,

1 within ten (10) days of the Effective Date of this Consent Judgment; and remit the balance of
2 \$283,745 in seven (7) equal installments of \$40,535 due on April 1, July 1, and October 1 of
3 2017; and January 1, April 1, July 1, and October 1 of 2018.

4 **2.** In the event that any payment owed by Defendant under this Consent Judgment
5 is not remitted or post-marked on or before its due date, Defendant shall be deemed to be in
6 default of its obligations under this Consent Judgment. Plaintiff shall provide written notice to
7 Defendant of any default; if Defendant fails to remedy the default within two (2) business days
8 of such notice, then all future payments due hereunder shall become immediately due and
9 payable, with the prevailing federal funds rate applying to all interest accruing on unpaid
10 balances due hereunder, beginning on the due date of the funds in default.

11 **VII. COURT APPROVAL OF THIS SECOND ADDENDUM**

12 **1. Motion to Approve and Enter This Second Addendum.** Upon execution of
13 this Second Addendum by all Parties, Plaintiff shall notice a Motion for Approval & Entry in
14 the San Francisco Superior Court pursuant to Title 11, Cal. Code of Regs. §3000, *et seq.* This
15 Motion shall be served upon all of the Parties to the Action and upon the California Attorney
16 General's Office.

17 **2. Nullification.** In the event that the Court fails to approve and order entry of this
18 Second Addendum, the Second Addendum shall become null and void upon the election of
19 any Party as to them and upon written notice to all of the Parties to the Action pursuant to the
20 notice provisions herein. If this Second Addendum becomes null and void, or is not approved
21 by the Court within ninety (90) days of its execution by all Parties, Plaintiff shall refund all
22 sums paid by Defendant pursuant to this Second Addendum within fifteen (15) days of written
23 notice to Plaintiff by Defendant that a refund is due.

24 **3. Attorney General Oversight.** Defendant and Plaintiff shall use best efforts to
25 support entry of this Second Addendum in the form submitted to the Office of the Attorney
26 General. If the Attorney General objects in writing to any term in this Consent Judgment, the
27 Parties shall use best efforts to resolve the concern in a timely manner and prior to the hearing
28

1 on the motion to approve this Second Addendum. If the Parties cannot resolve an objection of
2 the Attorney General, then Plaintiff and Defendant shall proceed with seeking entry of an
3 order by the court approving this Second Addendum in the form originally submitted to the
4 Office of the Attorney General, or in such other form as the Parties shall mutually agree upon
5 after consideration of any comments of the Attorney General. If the Attorney General elects to
6 file a notice or motion with the Court stating that the People shall appear at the hearing for
7 entry of this Second Addendum so as to oppose entry, then a party may withdraw from this
8 Second Addendum prior to the date of the hearing, with notice to all parties and the Attorney
9 General, and upon such notice this Second Addendum shall be null and void and any sums
10 paid hereunder shall be returned to Defendant within fifteen (15) days of written notice to
11 Plaintiff. If the Attorney General files a notice of appeal of this Second Addendum, then a
12 party may withdraw from this Second Addendum within forty-five (45) days of the People's
13 notice of appeal and this Second Addendum shall be null and void ab initio five (5) days after
14 notice of the withdrawal and any sums paid hereunder shall be returned to Defendant within
15 fifteen (15) days of the date of voiding.

16 **VIII. UPDATED NOTICE PROVISIONS**

17 **1. Notices.** Any notices or documents required or provided for by the 2008
18 Consent Judgment shall be sent by electronic mail transmission to each of the individuals set
19 forth below, at their respective email address:

20 To Plaintiff:
21 Stephen D. Gillett
21 E-mail: sdgillett47@gmail.com

22 With copies sent to:
23 Andrew L. Packard
23 E-mail: andrew@packardlawoffices.com

24 To Defendant:
25 Wina So, CEO
25 E-mail: winaso@solsticemed.com

26 With copies to:
27 Gregory J. Patterson
27 E-mail: gpatterson@bwslaw.com

1 **IX. COUNTERPARTS**

2 1. **Counterparts.** This Second Addendum may be executed in counterparts, each
3 of which shall be deemed an original, and all of which, when taken together, shall constitute
4 one and the same document.

5 **X. AUTHORIZATION**

6 14.1 **Authorization.** The undersigned are authorized to execute this Agreement on
7 behalf of their respective parties and have read, understood, and agree to all of the terms and
8 conditions of this Agreement.

9 **IT IS SO STIPULATED:**

10 DATED: 11/1/16 STEPHEN D. GILLETT

11 [Signature]
12 By: Stephen D. Gillett

13 DATED: _____ MADISON ONE ACME, INC.,

14 _____
15 By: Wina So
16 Chief Executive Officer

17 **IT IS SO ORDERED:**

18 DATED: _____
19 _____
20 Judge of the Superior Court

- 21 EXHIBIT A – 2008 Consent Judgment
22 EXHIBIT B – December 3, 2015 Notices of Alleged Violations of the 2008 Consent Judgment
23 EXHIBIT C – List of “New Products”
24 EXHIBIT D – List of Products Subject to Lead Ban on Sales in California & Recall
25 EXHIBIT E – Defendant’s Standard Operating Procedure for Product Recalls

1 **IX. COUNTERPARTS**

2 1. **Counterparts.** This Second Addendum may be executed in counterparts, each
3 of which shall be deemed an original, and all of which, when taken together, shall constitute
4 one and the same document.

5 **X. AUTHORIZATION**

6 14.1 **Authorization.** The undersigned are authorized to execute this Agreement on
7 behalf of their respective parties and have read, understood, and agree to all of the terms and
8 conditions of this Agreement.

9 **IT IS SO STIPULATED:**

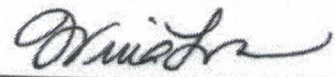
10 DATED: _____

STEPHEN D. GILLETT

11
12 By: Stephen D. Gillett

13 DATED: 11/1/2016

MADISON ONE ACME, INC.,



16 By: Wina So
17 Chief Executive Officer

18 **IT IS SO ORDERED:**

19 DATED: DEC 29 2016

HAROLD KAHN

20 Judge of the Superior Court

- 21
- 22 EXHIBIT A – 2008 Consent Judgment
- 23 EXHIBIT B – December 3, 2015 Notices of Alleged Violations of the 2008 Consent Judgment
- 24 EXHIBIT C – List of “New Products”
- 25 EXHIBIT D – List of Products Subject to Lead Ban on Sales in California & Recall
- 26 EXHIBIT E – Defendant’s Standard Operating Procedure for Product Recalls
- 27
- 28

EXHIBIT A

LAW OFFICES
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9 Attorneys for Plaintiff
10 STEPHEN D. GILLETT

ENDORSED
FILED
San Francisco County Superior Court

SEP 24 2003

GORDON PARK-LI, Clerk
BY: AUDREY HUIE
Deputy Clerk

11 SUPERIOR COURT OF THE STATE OF CALIFORNIA


12 CITY AND COUNTY OF SAN FRANCISCO – UNLIMITED JURISDICTION

13 STEPHEN D. GILLETT,
14 Plaintiff,

15 vs.

16 MADISON ONE ACME, INC., a corporation
17 doing business as SOLSTICE MEDICINE
18 COMPANY,
19 Defendant.

Case No. CGC-07-469239


~~PROPOSED~~ CONSENT JUDGMENT

20 This Consent Judgment is entered into by and between Plaintiff Stephen D. Gillett, and
21 MADISON ONE ACME, INC., a corporation doing business as SOLSTICE MEDICINE
22 COMPANY (“Defendant”). This Consent Judgment shall be effective upon entry (the “Effective
23 Date”) by the court. Plaintiff and Defendant (each a “Party” and collectively, “the Parties”) agree
24 to the terms and conditions set forth below.

25 **1. INTRODUCTION**

26 1.1 Stephen Gillett is a citizen enforcer of Proposition 65 who resides in San
27 Francisco, California.

28 1.2 Defendant sells herbal products to California consumers by mail order and over
the Internet. Plaintiff alleges that certain of the products contain substances listed by the State of

1 California as known to cause cancer and/or reproductive toxicity pursuant to the Safe Drinking
2 Water and Toxic Enforcement Act of 1986 ("Proposition 65"), California Health and Safety Code
3 § 25249.5 et seq.; Title 22, California Code of Regulations § 12000 et seq. For purposes of this
4 Consent Judgment only, each of the products is deemed to be a "food" within the meaning of
5 Title 22, California Code of Regulations § 12501.

6 **1.3** The specific products covered by this Consent Judgment as of the Effective Date
7 are set forth in Exhibit A hereto (the "Products"). Any products not set forth in Exhibit A hereto
8 are not subject to the injunctive provisions herein, except as specifically provided in Section 9:
9 *New Products*, and are not covered by the release of liability set forth in Section 6 herein.

10 **1.4** Pursuant to Health & Safety Code § 25249.8: (a) on February 27, 1987, the State
11 of California listed the chemical lead as a chemical known to cause reproductive toxicity; and (b)
12 on October 1, 1992, the State of California listed the chemicals lead and lead compounds as
13 chemicals known to cause cancer; (c) on July 1, 1990 the State of California listed the chemicals
14 mercury and mercury compounds as chemicals known to cause reproductive toxicity; (d) on
15 February 27, 1987, the State of California officially listed the chemical arsenic as a chemical
16 known to cause cancer; (e) on May 1, 1997, the State of California officially listed the chemical
17 arsenic as a chemical known to cause reproductive toxicity; (f) on October 1, 1987, the State of
18 California officially listed the chemicals cadmium and cadmium compounds as chemicals known
19 to cause cancer; (g) on May 1, 1997, the State of California officially listed the chemical
20 cadmium as a chemical known to cause reproductive toxicity. For purposes of this Consent
21 Judgment, the foregoing chemicals as listed under Proposition 65 shall be referred to as the
22 "Metals".

23 **1.5** Beginning on March 5, 2007 and again on or about June 25, 2008, Plaintiff served
24 on Defendant and each of the appropriate public enforcement agencies "60-Day Notices" that
25 provided Defendant and the public enforcement agencies with a notice alleging that Defendant
26 was in violation of Proposition 65 for failing to warn the purchasers and individuals using the
27 Products that the use of the Products exposes them to certain chemicals known to the State of
28 California to cause cancer and/or reproductive toxicity (each, a "60-Day Notice"). A copy of

1 each such 60-Day Notice issued to Defendant is attached hereto as Exhibit B. Defendant
2 stipulates for the purpose of this Consent Judgment only that the 60-Day Notices sent to it are
3 adequate to comply with Title 22, California Code of Regulations §12903.

4 **1.6** On November 15, 2007, Plaintiff filed a Complaint (the "Action") in San
5 Francisco Superior Court, alleging violations of Proposition 65. Plaintiff brings the Action in the
6 public interest. Plaintiff has provided 60-Day Notice(s) to Defendant and the appropriate public
7 enforcement agencies and none of the public enforcement agencies has commenced and begun
8 diligently prosecuting an action against Defendant for such alleged violations.

9 **1.7** For purposes of this Consent Judgment, each Party stipulates that venue is proper
10 and that this Court has subject matter jurisdiction over the allegations contained in the Action.
11 Defendant stipulates it employs ten (10) or more employees and employed ten (10) or more
12 employees for one year prior to the date of the first 60-Day Notice Letter. The Parties enter into
13 this Consent Judgment to settle disputed claims between them and to avoid prolonged litigation.
14 By execution of this Consent Judgment, Defendant does not admit any facts, violations of law,
15 conclusions of law, the applicability of Proposition 65, or the applicability or violation of any
16 other law or standard governing warnings or disclosures in connection with the manufacture,
17 packaging, labeling, distribution and/or sale of the Products. Except for the stipulations made in
18 Sections 1.5 and 1.7 by Defendant, nothing in this Consent Judgment shall be construed as an
19 admission by Defendant of any fact, issue of law, conclusion of law, or violation of law, nor shall
20 compliance with this Consent Judgment constitute or be construed as an admission by Defendant
21 of any fact, issue of law, conclusion of law, or violation of law. Except for the stipulations made
22 in this Section 1.7 by Plaintiff, nothing in this Consent Judgment shall be construed as an
23 admission by Plaintiff of any fact, issue of law, conclusion of law, or violation of law, nor shall
24 compliance with this Consent Judgment constitute or be construed as an admission by Plaintiff of
25 any fact, issue of law, conclusion of law, or violation of law.

26 **1.8** Except as expressly provided herein, nothing in this Consent Judgment shall
27 prejudice, waive or impair any right, remedy or defense any Party may have in any other or
28 further legal proceeding. This paragraph shall not diminish or otherwise affect the obligations,

1 responsibilities, and duties of any Party to this Consent Judgment. This Consent Judgment is a
2 full and final settlement of all claims that were raised in the Action, or which could have been
3 raised in the Action arising out of the facts or conduct alleged therein.

4 **2. INJUNCTIVE PROVISIONS**

5 **2.1 Defendant's Duty To Ascertain The Metals Content of Products On Or**
6 **Before Sixty Days Following the Effective Date.** On or before sixty (60) days following the
7 Effective Date, Defendant shall ascertain the concentration of Metals in each of the Products as
8 follows.

9 **2.1.1 Lead, Arsenic And Cadmium Testing Protocol.** In accordance with
10 Sections 2.1.5 and 2.1.6, to ascertain a Product's concentration of lead, arsenic and cadmium,
11 respectively, Defendant shall test the Product (or rely on testing of the Product by others provided
12 it is undertaken in the manner set forth herein), using inductively coupled plasma mass
13 spectrometry ("ICP-MS") under the protocol set forth in EPA Method 6020 as set forth in this
14 Section 2.1.

15 **2.1.2 Mercury Testing Protocol.** In accordance with Sections 2.1.5 and 2.1.6,
16 to ascertain a Product's concentration of mercury, Defendant shall test the Product (or rely on
17 testing of the Product by others provided it is undertaken in the manner set forth herein) using the
18 protocol set forth in EPA Method 7471A (including, at Defendant's option, conformity with EPA
19 Method 3052), or the protocol set forth in EPA Method 7473, or the protocol set forth in EPA
20 Method 6020.

21 **2.1.3 Additional Testing Protocols.** In the event that equally or more accurate
22 testing methods are developed or identified and accepted by the scientific community as accurate
23 enough to allow for detection and quantification of Metals to ascertain compliance under this
24 Consent Judgment, any Party shall have the right to move the court to modify this Consent
25 Judgment as set forth in Section 8 herein, to allow testing by such equally or more accurate
26 testing method in addition to the methods authorized herein.

27 **2.1.4 Approved Laboratories.** Product or raw material testing may be
28 undertaken at Defendant's in-house laboratories or by third-party testing laboratories; however,

1 all third-party laboratory testing shall be performed only at laboratories that are certified,
2 accredited, or registered by an agency of the United States, Canada, California or another State of
3 the United States or Province of Canada, including but not limited to the U.S. Environmental
4 Protection Agency, the U.S. Food and Drug Administration, or the California Department of
5 Health Services, for the purposes of administering the specific protocol used in such testing. If a
6 given agency does not certify specific protocols for testing for Metals in dietary supplements, the
7 certification, accreditation or registration customarily bestowed upon laboratories testing dietary
8 supplements or ingredients in dietary supplements for Metals in accordance with that agency's
9 standards shall be required; if no such agency standards exist specifically for dietary supplements,
10 then the standards for foods shall be required.

11 **2.1.5 Sampling Protocol For Ascertaining Metals Content.** In fulfilling its
12 duty to ascertain the concentration of Metals in each Product, Defendant may at its option, test (or
13 rely on testing of the Product by others) Representative Samples of the finished Products, or test
14 (or rely on testing of raw materials by others) Representative Samples of each of the raw
15 materials comprising the finished Product(s). Any results relied upon must use the analytical
16 methods and sampling requirements specified herein, except that a Defendant (or a laboratory
17 conducting tests for Defendant) may modify or adjust an analytical method if necessary to ensure
18 accurate results in light of the nature, composition, quantity, or other characteristic of the test
19 specimen, the nature of the test, or the specific equipment being used to conduct the test so as to
20 enhance the quality and reliability of the test results. If Defendant (or a laboratory conducting
21 tests for Defendant) modifies or adjusts any analytical method specified in this Consent
22 Judgment, in the event of an enforcement action by Plaintiff under this Consent Judgment
23 contesting such modification or adjustment, Defendant shall bear the burden of showing by a
24 preponderance of the evidence that the modification or adjustment was (a) necessary, appropriate
25 and reasonable under the circumstances; and (b) fully consistent with generally accepted
26 scientific principles and practices concerning analytical testing and test methods for Metals in
27 foods, including dietary supplements.

1 **2.1.6 Representative Sampling.**

2 (a) Finished Products. “Representative Sampling” as used herein shall mean with respect
3 to the testing of finished Products, any of the following, at Defendant’s option: (a) testing of two
4 (2) or more samples, each from a different final Product of the most recent manufacturing,
5 labeling or processing lot or batch (“Manufacturing Lot”) of that Product; or (b) testing of one (1)
6 sample from the most recent Manufacturing Lot of a Product, provided that the one sample
7 actually tested is a composite of three (3) or more samples taken from three (3) or more final
8 Products from such Manufacturing Lot of that Product. Each of the three (3) or more samples
9 taken from three (3) or more final Products must be equal to the other samples (e.g., 4 capsules
10 taken from each of three final Products, or 1 gram taken from each of three final Products).

11 (b) Raw Materials. “Representative Sampling” as used herein shall mean with respect to
12 the testing of raw material, testing of one (1) or more samples from the most recent shipping lot
13 received by Defendant of each raw material comprising the Product, provided that the sample
14 actually tested is a composite of three (3) or more samples from the most recent shipping lot of
15 that raw material. Each of the three (3) or more raw material samples which comprise the
16 composite sample actually tested shall be equal to the other samples.

17 (c) First Two Year’s Frequency of Sampling. During each of the two years after the
18 Effective Date, for purposes of documenting compliance with Sections 2.2, 2.4 and 9 of this
19 Consent Judgment after sixty (60) days from the Effective Date, Defendant shall conduct (or have
20 conducted on its behalf) Representative Sampling of each Product meeting the definition of either
21 Section 2.1.5(a) or 2.1.5(b), or any combination of the two, as Defendant shall elect in its sole
22 discretion. The Parties agree that this frequency of Representative Sampling of each Product for
23 the first two years after the Effective Date shall be the minimum amount of sampling required
24 under this Consent Judgment. Defendant shall retain laboratory test data documenting the
25 foregoing Representative Sampling with respect to each Product Defendant ships for sale to
26 California between the Effective Date and the second anniversary of the Effective Date. Such
27 laboratory test data for the initial two year testing period shall be retained for at least four years
28 from the date of testing.

1 (d) Sampling Frequency After Second Anniversary of Effective Date. After the second
2 anniversary of the Effective Date, Defendant shall conduct (or have conducted on its behalf)
3 Representative Sampling on raw materials or finished Products, as the case may be, but
4 Defendant may adjust the frequency of the sampling regime set forth in Section 2.1.5(c). Any
5 adjustments to the sampling regime shall be sufficient to allow Defendant to continue to
6 accurately determine levels of Metals in Products or in raw materials. Any adjustments to the
7 sampling regime shall be based upon Defendant's consideration of the following factors: (i)
8 existing data, (ii) the variability of Metals levels in a raw material or in a Product, as documented
9 through testing, (iii) the predictability of the distribution of the range of Metals levels in a raw
10 material, based on prior laboratory test data, (iv) the amount of a raw material used in a finished
11 Product, and (v) other relevant considerations. In any proceeding to enforce this Consent
12 Judgment, Defendant bears the burden of showing by a preponderance of the evidence that any
13 testing regime adopted under this Section 2.1.5(d) is reasonable and is sufficient to accurately
14 determine Metals levels in raw materials or finished Products. This Section 2.1.5(d) governs the
15 frequency of sampling, and does not alter the definitions of Representative Sampling set forth in
16 Sections 2.1.5(a), or (b), or the testing protocols set forth herein. Defendant is not limited to
17 providing only Representative Sampling data to Plaintiff in the event Plaintiff conducts
18 compliance monitoring under Section 2.1.7 or otherwise moves to enforce this Consent Judgment.

19 **2.1.7 Compliance Monitoring.** At any time following 60 days after the
20 Effective Date, Plaintiff may request that Defendant provide, within thirty-five (35) days of the
21 date of its request, documentation supporting the sale in California of any Product without the
22 health hazard warnings specified in this Consent Judgment. For the first two years after the
23 Effective Date, such requests may be made with respect to as many as twenty-five (25) percent,
24 annually, of the number of Products listed on Defendant's then current list of Products subject to
25 this Consent Judgment, up to a maximum of twenty (20) requests in total for the year, concerning
26 up to twenty (20) different Products in that year. After year two after the Effective Date, Plaintiff
27 may request information on no more than ten (10) percent, annually, of the number of Products
28 listed on Defendant's then current list of Products subject to this Consent Judgment, up to a

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1 maximum of ten (10) requests in total for the year, concerning up to ten (10) different Products in
2 that year. After year three after the Effective Date, Plaintiff shall not be entitled to request
3 information pursuant to this Section 2.1.7, unless a violation of this Consent Judgment previously
4 was established within the three years preceding the date of the Plaintiff request, in which case
5 Plaintiff shall be entitled to tender up to twelve (12) requests in total for information respecting
6 up to twelve (12) different Products for up to one more year after the date of Plaintiff's request.
7 For any Product for which Plaintiff's request for such documentation is not provided within sixty
8 (60) days of the date of the request, such Product will be deemed sold in violation of this Consent
9 Judgment as to all sales in California of that Product after the date of Plaintiff's request through
10 the date upon which such documentation is received by Plaintiff and therefore will be subject to
11 the provisions of Section 3.1; provided, however, that Defendant's mere contesting of any
12 assertion by Plaintiff concerning inadequacies in the documentation produced to Plaintiff shall
13 not, in and of itself, be deemed a violation of this Section 2.1.7. For Plaintiff to establish a
14 violation of this Section, the documentation provided or other documentation must show that a
15 health hazard warning was required under this Consent Judgment. Violations of this Section 2.1.7
16 may be enforced as specified hereinbelow and are not exclusive of other remedies, if any,
17 available to Plaintiff.

18 **2.1.8 Limited Exemptions from Testing.** Defendant need not test (or have
19 tested on its behalf) all excipients, fillers, flavors, colors, binders or other ingredients of uniform
20 manufacture or consistently uniform high purity ("Standardized Ingredients") if it reasonably and
21 in good faith believes, after conducting the research and analysis described below, that it can
22 demonstrate, with admissible evidence, such Standardized Ingredients do not contain Metals at
23 levels that might cause or contribute to a violation of this Consent Judgment. Defendant's good
24 faith belief shall be based on periodic laboratory test data, vendor certifications, or other such
25 reasonable and appropriate information including consideration of the reliability and consistency
26 of the supplier, the nature of the ingredient, the amount used and other relevant scientific factors.
27 Defendant periodically shall monitor and evaluate such Standardized Ingredients for Metals
28 levels. In the event that Plaintiff should move to enforce this Consent Judgment, Defendant bears

1 the burden of establishing by a preponderance of the evidence that any failure to test a
2 Standardized Ingredient for Metals content was reasonable and in good faith, and must produce
3 all such supporting evidence in the context of the meet and confer process concerning
4 enforcement of this Consent Judgment contemplated under Section 8.1 herein. Defendant's
5 failure to test a Standardized Ingredient for Metals content, in the absence of a reasonable and
6 good faith belief that such ingredient does not contain Metals at levels that might cause or
7 contribute to a violation of this Consent Judgment, shall constitute a material breach of this
8 Consent Judgment and be subject to stipulated civil penalties as provided for herein if such failure
9 to test causes or contributes to a failure to provide a warning when required under Section 2.2 or
10 causes or contributes to a violation of Section 2.4 of this Consent Judgment.

11 **2.2 Provision of Clear and Reasonable Warnings.**

12 **2.2.1 On-Product Warnings.** On or before the date that is sixty (60) days
13 following the Effective Date, Defendant shall permanently cease and no longer ship for sale or
14 use in California any Products (as defined in Sections 1.3 and 9.1) which require a warning under
15 the terms of this Consent Judgment, unless each individual Product (in the form intended for sale
16 to the end-user) bears the warning statement specified below on its individual unit label or unit
17 packaging:

18 (a) Subject to Sections 2.3 and 2.4 herein, if use or consumption of the Product in
19 accordance with Defendant's label directions results in an exposure exceeding 10.0
20 micrograms/day of arsenic, but otherwise would not require a warning under this Consent
21 Judgment, then the warning shall state:

22 **WARNING: The use of this product will expose you to**
23 **chemicals known to the State of California to cause cancer.**

24 (b) Subject to Sections 2.3 and 2.4 herein, if use or consumption of the Product in
25 accordance with Defendant's label directions results in an exposure exceeding 10.0
26 micrograms/day of arsenic, and exceeding any of the levels set for lead, mercury, or
27 cadmium in this Consent Judgment, then the warning shall state:

28

1 **WARNING: The use of this product will expose you to**
2 **chemicals known to the State of California to cause cancer and**
3 **birth defects or other reproductive harm.**

4 (c) Subject to Sections 2.3 and 2.4 herein, if use or consumption of the Product in
5 accordance with Defendant's label directions results in an exposure that does not
6 exceed 10.0 micrograms/day of arsenic, but that does exceed any of the levels set for
7 lead, mercury, or cadmium in this Consent Judgment, then the warning shall state:

8 **WARNING: The use of this product will expose you to**
9 **chemicals known to the State of California to cause birth defects**
10 **or other reproductive harm.**

11 (d) The warning statement shall be prominent and displayed on the label or packaging of
12 each Product with such conspicuousness, as compared with other words, statements, or designs,
13 so as to render it likely to be read and understood by an ordinary individual prior to purchasing or
14 using the Product. The warning statement shall be printed on the label or packaging in a font size
15 no smaller than any other precautionary statements or warnings printed on the Product's label or
16 packaging.

17 **2.2.2 Additional Warnings Concerning Mail Order & Internet Sales.** If
18 Defendant sells a Product that requires a warning under this Consent Judgment, by telephone,
19 mail order or over the Internet to a purchaser in the State of California on or after the date that is
20 sixty (60) days after the Effective Date, the following additional requirements shall apply.

21 (a) For such mail order sales, the warning language required under this Consent Judgment
22 shall also be included in the mail order catalogue, either on the same page as any order form, or
23 on the same page(s) upon which the Product's price is listed, in the same type size as the
24 surrounding, non-heading text (this requirement shall be applicable only to all catalogues
25 featuring Products printed after the Effective Date). If Defendant determines, after a mail order
26 catalogue is printed, that a Product featured therein requires a warning under this Consent
27 Judgment, Defendant may provide a warning in compliance with Section 2.2.1 until the next
28 printing of a mail order catalogue featuring that Product.

1 (b) For such Internet sales, the warning language required under this Consent Judgment
2 shall be displayed in the same type size as the surrounding, non-heading text, either: (a) on the
3 same page upon which the Product is displayed or referenced; (b) on the same page as the order
4 form for the Product; (c) on the same page as the price for the Product is displayed; or (d) in a
5 dialogue box (which cannot be suppressed by “pop up” box blocking software) which appears
6 when a California address for delivery is provided by the consumer, so long as the dialogue box
7 appears prior to the completion of the internet sale and requires the consumer to affirmatively
8 accept receipt of the warning set forth in the dialogue box (which shall be displayed in the same
9 type size as the surrounding, non-heading text on the screen at the time of the appearance of the
10 dialogue box), as a condition precedent to completing the sale.

11 **2.3 Exceptions To Warning Requirements.** No Product that meets each of the
12 following criteria shall require a warning pursuant to this Consent Judgment:

13 **2.3.1 For Lead Warnings, Exposure Below “No Observable Effect Level.”**

14 Use or consumption of a Product causes total daily exposure¹ to lead of less than 0.5 micrograms
15 when consumed or used in accordance with the Defendant’s label directions, excluding any
16 naturally occurring lead, as defined for purposes of this Consent Judgment in Section 2.3.2
17 (“Naturally Occurring Lead”), in such Product. Prior to shipment for sale to California
18 consumers, Defendant shall provide consumer use instructions on the label or packaging of each
19 individual Product unit (in the form intended for sale to the end-user). If the consumer use
20 instructions include a range of consumption levels (e.g., “take 2 to 4 tablets daily”), then for
21 purposes of determining compliance with Sections 2.2, 2.4, 9 and otherwise under this Consent
22 Judgment, the highest dose instructed shall be the dose.

23 **2.3.2 “Naturally Occurring” Allowance For Lead for Products Shipped for**
24 **Sale After Sixty Days Following The Effective Date.**

25
26
27
28 ¹ For purposes of this Consent Judgment only, the term “exposure” is deemed to mean
“ingestion”, consistent with Title 22, Cal. Code Regs., section 12102(i) (which defines the term
“expose” as “to cause to ingest....”).

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1 (a) Initial Naturally Occurring Lead Level. Unless a Product contains a warning in
2 compliance with this Consent Judgment, the initial Naturally Occurring Lead level in any Product
3 subject to this Consent Judgment Defendant ships for sale or use in California after the date that is
4 sixty (60) days following the Effective Date, shall not exceed a concentration that will result in
5 2.25 micrograms lead ingested/day, assuming the Product is used or consumed in accordance with
6 the Defendant's consumer use instructions. Products where the concentration results in lead
7 levels that exceed: (i) this initial 2.25 micrograms ingested level or (ii) Products which exceed
8 any future Naturally Occurring Lead level subsequently established pursuant to this Consent
9 Judgment (plus, in either the case of (i) or (ii), an additional 0.5 micrograms lead as allowed by
10 regulation and under Section 2.3.1), shall be subject to the warning requirements set forth in
11 Sections 2.2.1, 2.2.2 and 9 herein, unless Defendant can show by a preponderance of the evidence
12 that all lead in such Products (except 0.5 micrograms ingested in a daily dose) is naturally
13 occurring per 22 Cal. Code Reg. § 12501. If Defendant in the future elects to make this showing
14 that more than 2.25 micrograms of lead is naturally occurring, Defendant agrees to provide all
15 information on which it relies to support such a showing to Plaintiff in the context of the meet and
16 confer process concerning enforcement of this Consent Judgment contemplated under Section 8.1
17 herein. Defendant's failure to produce complete information during the meet and confer process,
18 or Defendant's failure to establish to the Court, based on such information, by a preponderance
19 of the evidence, that lead in excess of 0.5 micrograms in a daily dose, plus Naturally Occurring
20 Lead, is naturally occurring under the criteria in 22 Cal. Code Reg. § 12501 shall constitute a
21 material breach of this Consent Judgment and be subject to stipulated civil penalties as provided
22 for herein if a Product which requires a health hazard warning under this Consent Judgment was
23 sold in California without such warning. Nothing in this Section 2.3.2 constitutes a waiver of
24 Defendant's right to establish, in accordance with the procedures set forth in Sections 2.3.2 and
25 8.1, that levels of metals other than lead are naturally occurring under the criteria of 22 Cal. Code
26 Reg. § 12501. The Parties agree that the initial 2.25 micrograms Naturally Occurring Lead level
27 is the result of negotiations and a review of the available information and shall be applicable to
28 the Products subject to this Consent Judgment and shall have no application to other products.

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1 (b) Evaluation of Future Naturally Occurring Lead Levels. In recognition of the
2 possibility that the “lowest level feasible” of lead may change over time, the Parties agree that for
3 at least three years after the Effective Date, Defendant shall have the right to tender a statement of
4 determination to Plaintiff as to whether an adjustment to the Naturally Occurring Lead level can
5 be supported by a preponderance of the evidence. If tendered, such statement of determination
6 shall be tendered to Plaintiff on or before April 15th for the years 2009, 2010 and 2011. Such a
7 determination respecting the Naturally Occurring Lead level shall be made in good faith and be
8 based on Representative Sampling and “Feasibility.” “Feasibility” for purposes of this Consent
9 Judgment shall mean consideration of the following: (1) the availability and reliability of a
10 supply to Defendant of raw materials in question; (2) the reasonable cost to Defendant of
11 Products or raw materials therein; (3) any resulting unreasonable increase in cost to a Defendant
12 to procure a Product or raw materials with lower levels of lead; (4) performance characteristics,
13 including formulation, performance, safety, taste, efficacy and stability, of any raw materials or
14 finished Product; (5) the lawfulness of alternatives (no alternative shall result in a violation of
15 law, or a breach of a standard of identity); and (6) other relevant and reasonable considerations.
16 If upon determination of Defendant a change in the Naturally Occurring Lead level is warranted
17 under the criteria above, then Defendant within sixty (60) days of the statement date may proceed
18 to modify this Consent Judgment in accordance with Section 8 herein. Defendant’s obligations
19 under this Section 2.3.2(b) are without prejudice to any rights of Plaintiff under Section 8 or
20 otherwise herein. If either Party seeks to modify the initial or any subsequently established
21 Naturally Occurring Lead level as defined herein, such modification shall only be effective upon
22 an order by the Court, after a noticed motion, notice of which motion shall be served on the
23 Office of the Attorney General at least forty-five (45) days prior to the hearing date, and which
24 motion shall include the information supporting the request for modification.

25 (c) Defendant also shall be entitled to exclude from the calculation of the daily lead
26 exposure the amount of naturally occurring lead in the following non-herbal ingredients only, if
27 used in a Product: calcium, ferrous fumarate, zinc oxide, magnesium oxide, magnesium chloride,
28 magnesium hydroxide, zinc gluconate and potassium chloride. The amount of lead in each of

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1 these ingredients deemed naturally occurring shall be conclusively and irrefutably presumed to be
2 the amount of lead that would be deemed naturally occurring under the consent judgment entered
3 on November 11, 1998 in *People v. Warner Lambert*, San Francisco Superior Court Case No.
4 984403.

5 **2.3.3 Conditions Under Which “Naturally Occurring” Allowance For Lead**
6 **Applies.** For purposes of compliance with Section 2.2, Defendant shall exclude that amount of
7 lead specified in Section 2.3.2, provided Defendant has not intentionally or unintentionally added
8 any lead to a Product and Defendant has done or caused to be done all of the following: (a) used,
9 or required the manufacturer of the Product to use, “Good Manufacturing Practices” in
10 connection with the Product; (b) used or, if Defendant is purchasing an ingredient used in a
11 Product directly from the grower of that ingredient, required the grower to use, in those instances
12 where Defendant has the commercially reasonable ability to do so, Good Agricultural Practices;
13 (c) used, at all times relevant to the production of the Product, quality control measures that
14 reduce natural chemical contaminants to the “lowest level currently feasible,” as that phrase is
15 used in Title 21 Code of Federal Regulations, Section 110.110(c) (2001).]

16 **2.3.4 Stipulated Exposure Levels Triggering Warning Requirements For**
17 **Arsenic, Cadmium and Mercury.** Prior to shipment for sale to California consumers,
18 Defendant shall provide consumer use instructions on the label or packaging of each individual
19 Product (in the form intended for sale to the end-user). If the consumer use instructions include a
20 range of consumption levels (e.g., “take 2 to 4 tablets daily”), then for purposes of compliance
21 with Sections 2.2 and 9 and otherwise under this Consent Judgment, the highest dose instructed
22 shall be the dose. For arsenic, cadmium and mercury, the health hazard warnings set forth in
23 Section 2.2.1 shall be required if use or consumption of a Product in accordance with Defendant’s
24 label directions results in an exposure exceeding any of the following levels: (a) (1) mercury and
25 mercury compounds, except inorganic mercury, 0.30 micrograms/day; (2) inorganic mercury, 3.0
26 micrograms/day; (b) cadmium, 4.10 micrograms/day; (c) arsenic, 10.0 micrograms/day. For
27 purposes of this Consent Judgment, and in the absence of knowledge to the contrary on the part of
28 Defendant, Defendant shall presume that all mercury in a Product is not inorganic mercury and

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1 therefore is subject to the standard in 2.3.4(a)(1) unless Defendant, through laboratory testing and,
2 if applicable, other relevant information, establishes that a Product contains only inorganic
3 mercury, in which case that Product shall be subject to the standard in 2.3.4(a)(2). Records
4 supporting Defendant's determination respecting inorganic mercury content in a Product shall be
5 provided to Plaintiff in accordance with Defendant's obligations under Section 2.1.7, Section 8
6 and Section 9.1.

7 **2.4 Ban on Sales of Products Causing Exposures to Lead in Excess of 10**
8 **Micrograms Per Day.** No Product subject to this Consent Judgment may be shipped by
9 Defendant for sale in the State of California after sixty (60) days following the Effective Date if,
10 when used or consumed in accordance with the Defendant's label directions, it causes an
11 exposure to lead in excess of ten (10.0) micrograms/day.

12 **3. CIVIL PENALTIES**

13 **3.1 Stipulated Civil Penalties For Future Violations of This Agreement.**

14 Proposition 65 provides for civil penalties of up to \$2500 per violation per day, pursuant to
15 California Health & Safety Code § 25249.7. In the event that after sixty (60) days following the
16 Effective Date Defendant violates Sections 2 or 9 herein, the Parties stipulate that Defendants
17 shall be liable for a stipulated civil penalty in the amount of \$10.00 per unit item sold in violation
18 of this Consent Judgment, unless the Defendant's actual per unit sale price to the buyer was less
19 than \$10.00, in which case the stipulated penalty shall be fifty percent (50%) of the sale price
20 Defendant received from the relevant buyer for the Products at issue. Total civil penalties
21 concerning all Products sold in violation of this Consent Judgment shall not exceed \$75,000 for
22 such violations in any calendar year. Plaintiff may establish such violation(s) hereunder by a
23 preponderance of the evidence upon a duly noticed motion in the San Francisco Superior Court
24 and subject to the provisions of Section 8 herein. Plaintiff shall remit 75% of this amount to the
25 State of California pursuant to Health & Safety Code § 25249.12(b).

26 **3.2 Civil Penalty Assessment.** Defendant shall pay a civil penalty in the amount of
27 \$160,000 to Plaintiff, pursuant to Health & Safety Code § 25249.7(b). Plaintiff shall remit 75%
28 of this amount to the State of California pursuant to Health & Safety Code § 25249.12(b).

1 **3.3 Payment in Lieu of Additional Civil Penalties.**

2 (a) Defendant shall make a payment in lieu of additional penalties in the amount of
3 \$25,000 to Plaintiff. Plaintiff shall forward these funds to California non-profit groups to reduce
4 exposures to toxic chemicals, and to increase consumer, worker and community awareness of the
5 health hazards posed by toxic chemicals.

6 **3.4 Penalties are not a credit.** No penalties paid herein shall be construed as a
7 credit against future new claims against Defendant.

8 **4. REIMBURSEMENT OF FEES AND COSTS**

9 **4.1 Reimbursement of Plaintiff's Investigative, Expert and Legal Fees and Costs.**
10 Defendant shall reimburse Plaintiff in the amount of \$50,000 for Plaintiff's reasonable
11 investigative, expert, and legal fees and costs incurred as a result of investigating and negotiating
12 a settlement in the public interest.

13 **5. PAYMENT OBLIGATIONS**

14 **5.1** Pursuant to Sections 3.2, 3.3 and 4.1 herein, Defendant agrees to remit the total
15 amount of \$235,000 to Plaintiff, payable to the Law Offices of Andrew L. Packard Attorney
16 Client Trust Account. Defendant shall remit these funds in five (5) equal Installments of \$47,000
17 as follows: Defendant shall (a) remit the First Installment payment within fifteen (15) days of the
18 Effective Date of this Consent Judgment; (b) remit the Second Installment payment on or before
19 November 15, 2008; (c) remit the Third Installment payment on or before February 1, 2009; (d)
20 remit the Fourth Installment payment on or before April 15, 2009; and remit the Fifth Installment
21 payment on or before July 1, 2009. In the event that any payment owed by Defendant under this
22 Consent Judgment is not remitted or post-marked on or before its due date, Defendant shall be
23 deemed to be in default of its obligations under this Consent Judgment. Plaintiff shall provide
24 written notice to Defendant of any default; if Defendant fails to remedy the default within two (2)
25 business days of such notice, then all future payments due hereunder shall become immediately
26 due and payable, with the prevailing federal funds rate applying to all interest accruing on unpaid
27 balances due hereunder, beginning on the due date of the funds in default.

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6. RELEASE OF LIABILITY

6.1 Release of Liability. Plaintiff, on its own behalf, and on behalf of the general public, waives all rights to institute or participate in, directly or indirectly, any claim or form of legal action against Defendant, its officers, directors, employees, agents, attorneys, representatives, shareholders, parents, subsidiaries, affiliates, divisions, predecessors, successors, subdivisions, downstream distributors, downstream retailers, downstream customers, and upstream suppliers (including manufacturers of the Products and manufacturers of the raw materials of the Products) under Proposition 65 based upon Defendant's alleged failure to warn, within the meaning of Proposition 65, about exposure to Metals in any of the Products sold in California or to California consumers on or before sixty (60) days after the Effective Date or based on any other legal claim or theory that was or could have been alleged in the Action based on the facts alleged in the Action.

6.2 Release of Liability of Plaintiff. Defendant waives all of its rights to institute any claim, or form of legal action against Plaintiff, its officers, directors, employees, agents, attorneys and representatives (the "Plaintiff Releasees") for all actions or statements made or undertaken by the Plaintiff Releasees in the course of seeking enforcement of Proposition 65 through the Action.

7. CONSENT JUDGMENT

7.1 Consent Judgment. Upon execution of this Consent Judgment by all Parties, Plaintiff shall notice a Motion for Approval & Entry of Consent Judgment in the San Francisco Superior Court pursuant to Title 11, Cal. Code of Regs. §3000, *et seq.* This Motion shall be served upon all of the Parties to the Action and upon the California Attorney General's Office. In the event that the Court fails to approve and order entry of the judgment, this Consent Judgment shall become null and void upon the election of any Party as to them and upon written notice to all of the Parties to the Action pursuant to the notice provisions herein. If this Consent Judgment becomes null and void, or is not approved by the Court within one hundred and eighty (180) days of its execution by all Parties, Plaintiff shall refund all sums paid by Defendant pursuant to Sections 3.2, 3.3 and 4.1 within fifteen (15) days of written notice to Plaintiff by Defendant that a refund is due. Defendant and Plaintiff shall use best efforts to support entry of this Consent

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1 Judgment in the form submitted to the Office of the Attorney General. If the Attorney General
2 objects in writing to any term in this Consent Judgment, the Parties shall use best efforts to
3 resolve the concern in a timely manner and prior to the hearing on the motion to approve this
4 Consent Judgment. If the Parties cannot resolve an objection of the Attorney General, then
5 Plaintiff and Defendant shall proceed with seeking entry of an order by the court approving this
6 Consent Judgment in the form originally submitted to the Office of the Attorney General, or in
7 such other form as the Parties shall mutually agree upon after consideration of any comments of
8 the Attorney General. If the Attorney General elects to file a notice or motion with the Court
9 stating that the People shall appear at the hearing for entry of this Consent Judgment so as to
10 oppose entry of the Consent Judgment, then a party may withdraw from this Consent Judgment
11 prior to the date of the hearing, with notice to all parties and the Attorney General, and upon such
12 notice this Consent Judgment shall be null and void and any sums paid hereunder shall be
13 returned to Defendant within fifteen (15) days of the date of the notice. If the Attorney General
14 files a notice of appeal of this Consent Judgment, then a party may withdraw from this Consent
15 Judgment within forty-five (45) days of the People's notice of appeal and this Consent Judgment
16 shall be null and void ab initio five (5) days after notice of the withdrawal and any sums paid
17 hereunder shall be returned to Defendant within fifteen (15) day of the date of voiding.

18 **7.2 Amendment To Complaint.** Upon the expiration of the 60-Day Notice issued on
19 or about June 25, 2008, and in the event that no public prosecutors have commenced diligent
20 prosecution against Defendant for such violations, the Complaint herein shall be deemed
21 amended to include all violations described in that 60-Day Notice.

22 **8. ENFORCEMENT AND MODIFICATION**

23 **8.1 Enforcement and Stipulated Civil Penalties.** In the event that a dispute arises
24 with respect to any of the provisions of this Consent Judgment, the Parties shall meet and confer
25 within twenty (20) days after any Party receives written notice of an alleged violation of this
26 Consent Judgment from another Party. In the event the affected Parties cannot resolve the
27 dispute, this Consent Judgment may be enforced pursuant to Code of Civil Procedure § 664.6 or
28 any other valid provision of law. The prevailing party in any dispute regarding compliance with

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1 the terms of this Consent Judgment shall be awarded its reasonable fees and costs incurred, in
2 addition to any other relief otherwise ordered by the Court, including but not limited to civil
3 penalties assessed pursuant to Section 3 herein.

4 **8.2 Modification of Judgment - Grounds.** This Consent Judgment shall not
5 obligate Defendant to provide a health hazard warning (as described in Section 2 herein) for a
6 Product if that Product causes an exposure below the “No Significant Risk Level” or “Maximum
7 Allowable Daily Level,” as those terms are defined in Proposition 65 and its implementing
8 regulations. Any such levels adopted in a final regulation or law pursuant to Proposition 65 after
9 the Effective Date shall become the standard under this Consent Judgment on the date of adoption
10 without need for formal modification of this Consent Judgment, but Defendant retains its rights
11 and obligations under Section 2.3.2. to establish naturally occurring levels of lead. The Parties
12 acknowledge that new toxicological information or exposure assessments concerning hazardous
13 substances and testing methodologies are continuously becoming available, and that statutory and
14 regulatory standards applicable to the Products may evolve in the future. Accordingly, the Parties
15 agree that any Party may file a motion pursuant to § 664.6 of the California Code of Civil
16 Procedure, and under the conditions set forth below, move the Court for modification of the
17 warning requirement or any other term set forth in Section 2 herein on the grounds that (a) they
18 conflict with the applicable legal standards concerning the Products or any ingredient therein, or
19 (b) the warning requirement or any other term set forth in Section 2 herein are more stringent than
20 the warning requirements Plaintiff agrees to after the Effective Date in an order, judgment or
21 settlement under Proposition 65 with respect to any dietary supplements that are substantially
22 similar to the Products herein. Absent good cause shown by Plaintiff, Plaintiff shall allow
23 modification of this Consent Judgment to permit Defendant to adhere to such less stringent
24 warning requirements. Any disputes regarding the issues set forth in this subsection shall be
25 resolved in accordance with the procedures set forth in Section 8.3 below.

26 **8.3 Modification of Judgment – Procedure.** In the spirit of cooperation and in the
27 interests of minimizing the investigative, expert and attorneys’ fees and costs associated with
28 such a motion, the Parties agree to meet and confer in good faith as follows. Prior to filing a

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1 motion pursuant to Section 8.2 herein, the Party seeking to modify the judgment shall first
2 provide the non-moving Party and the California Attorney General's Office with any legal or
3 scientific information upon which the motion would rely. The non-moving Party and the
4 California Attorney General's Office shall be allowed a period of forty-five (45) days to review
5 that information and to provide the moving Party with its formal written response (the Attorney
6 General's Office's failure to respond to this submission shall not be construed in any manner to
7 reflect any particular view, on the part of the Attorney General's Office, of this Consent Judgment
8 or of the applicable law or science). The Parties shall then meet and confer within twenty (20)
9 days of the non-moving Party's written response. If, after meeting and conferring, the moving
10 Party elects to proceed with a motion to amend this Consent Judgment, it may do so with proper
11 notice to the other Party and the Attorney General's Office as required under the California Code
12 of Civil Procedure. Such a motion may be accompanied by scientific data, studies, written
13 declarations, and live testimony or discovery responses. In the event that the Court determines
14 that a Party seeking or opposing a motion to modify this Consent Judgment did so without
15 justification or failed to meet and confer in good faith prior to moving for such modification, the
16 other Party shall be awarded reasonable fees and costs incurred.

17 **9. NEW PRODUCTS.**

18 **9.1 New Product Testing Prior to Sale in California.** If, after the date that is sixty
19 (60) days after the Effective Date, Defendant elects to ship for sale in California any new herbal
20 products not identified on Exhibit A hereto, Defendant shall, before shipping the new product(s)
21 for sale in California, conduct the testing set forth in Section 2.1 and adhere to the requirements
22 of this Consent Judgment with respect to such new product(s). Failure to provide the warning if
23 required under Section 2.2 shall be a violation of this Consent Judgment subject to stipulated
24 penalties in accordance with Section 3.1. Such new herbal product(s) shall then be deemed
25 Product(s) subject to all of the terms of this Consent Judgment. Before the date that is sixty (60)
26 days after the Effective Date, Defendant may ship for sale to California customers new or
27 reformulated products of the type set forth in Section 1.2 that are not listed on Exhibit A, and the
28 sales of such products shall not be deemed in violation of any term of this Consent Judgment.

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1 **9.2 Annual New Product Update List.** Commencing on April 15, 2009 and annually
2 on that date through and including April 15, 2011, Defendant shall provide Plaintiff with an
3 annual updated list of new Products Defendant shipped for sale or use in California in the
4 preceding calendar year for which Defendant has ascertained that warnings are not required under
5 this Consent Judgment. Defendant shall include, for each new Product identified on the annual
6 updated list, either: (a) at least one finished product test result documenting the Metals level in
7 each new Product or (b) a calculation of the total Metals level in the Product, expressed in
8 micrograms/day, based on Defendant's Representative Sampling data. If Plaintiff cannot
9 ascertain and in good faith inquires in writing as to whether a specific Product is a new Product in
10 a given year, Defendant shall promptly (and in any event within thirty-five (35) days the date of
11 Plaintiff's request) reply to advise whether the Product is a new Product for that year or is an
12 existing Product. Defendant's obligations under this Paragraph 9.2 shall end on August 15, 2011,
13 except that Defendant shall remain obligated to respond to any questions from Plaintiff
14 regarding the New Product Update List provided on or before April 15, 2011.

15 **10. GOVERNING LAW**

16 **10.1 Governing Law.** The terms of this Consent Judgment shall be governed by the
17 laws of the State of California. This Consent Judgment shall not govern Products or products
18 sold to consumers or other persons outside the State of California.

19 **11. NOTICES**

20 **11.1 Notices.** All correspondence and notices required to be provided under this
21 Agreement shall be in writing and shall be sent by first class registered or certified mail, or via a
22 reputable overnight delivery service with a tracking mechanism, addressed as follows:

23 All correspondence to Plaintiff shall be mailed to:

24 Attn: Stephen D. Gillett
25 Post Office Box 170142
26 San Francisco, CA 94117

26 All correspondence to Defendant shall be mailed to:

27 Wina So, CEO
28 Solstice Medicine Company
29 215 W. Ann Street
30 Los Angeles, CA 90012

23 With a copy to:

24 Andrew L. Packard, Esq.
25 Law Offices of Andrew L. Packard
26 319 Pleasant Street
27 Petaluma, CA 94952

26 With a copy in each case to:

27 Richard Egger
28 Best Best & Krieger LLP
29 3500 Porsche Way, Suite 200
30 Ontario, CA 91764

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12. INTEGRATION AND MODIFICATION

12.1 Integration & Modification. This Consent Judgment, together with the Exhibits hereto which are specifically incorporated herein by this reference, constitutes the entire agreement between the Parties relating to the rights and obligations herein granted and assumed, and supersedes all prior agreements and understandings between the Parties. Except as set forth in Section 8, this Consent Judgment may be modified only upon the written agreement of the Parties to be bound. If any term of this Consent Judgment is found by the court to be invalid, then such term shall be stricken and the remaining terms shall not be affected thereby. In the interpretation hereof, references to general "Sections" (e.g., "Section 8") shall include all subsections within said section (e.g., Sections 8.1, 8.2 and 8.3), but references to specific subsections (e.g., "Section 2.2.1") shall refer only to that specific subsection.

13. COUNTERPARTS

13.1 Counterparts. This Consent Judgment may be executed in counterparts, each of which shall be deemed an original, and all of which, when taken together, shall constitute one and the same document.

14. AUTHORIZATION

14.1 Authorization. The undersigned are authorized to execute this Agreement on behalf of their respective parties and have read, understood, and agree to all of the terms and conditions of this Agreement.

IT IS SO STIPULATED:

DATED: June 27, 2008

STEPHEN D. GILLETT


By: Stephen D. Gillett

DATED: _____

MADISON ONE ACME, INC.,

SEE PAGE 22(a)
By: Wina So
Chief Executive Officer

IT IS SO ORDERED.

DATED: SEP 24 2008

PETER J. BUSCH
JUDGE OF THE SUPERIOR COURT

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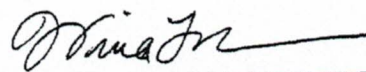
DATED: _____

STEPHEN D. GILLETT

DATED: July 3, 2008

SEE PAGE 22
By: Stephen D. Gillett

MADISON ONE ACME, INC.,


By: Wina So
Chief Executive Officer

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IT IS SO ORDERED:

DATED: _____ Judge of the Superior Court

al

EXHIBIT A – Product List

EXHIBIT B - Notices of Proposition 65 Violations

Addendum

Pursuant to the parties' oral stipulations at the September 4, 2008 hearing on Plaintiff's Motion To Approve Consent Judgment, Section 3.3(a) herein, regarding payment in lieu of further civil penalties, is clarified as follows:

Plaintiff shall forward the \$25,000 payment in lieu of civil penalties referenced in Sections 3.3(a) and Section 5.1 to the Rose Foundation for Communities & the Environment, Attn: Tim Little, 6008 College Ave., Ste. 10 Oakland, California 94618. Tel. (510) 658-0702. The funds shall be paid out on a *pro rata* basis, in conjunction with the Civil Penalty Assessment described in Section 3.2, and after payment of Plaintiff's fees and costs. The funds shall be used "to reduce exposures to toxic chemicals, and to increase consumer, worker and community awareness of the health hazards posed by toxic chemicals." Consent Judgment, Section 3.3(a).

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EXHIBIT A

CONSENT JUDGMENT - EXHIBIT A

Item Number	Item Description
AWGT	AMERICAN WINDSER GINSENG TEA (48 tea bags)
BTW	BAN TU WAN (100 pills)
BYS1	HE CHE DA ZAO WAN (100 pills)
BYS2	SIANG SHA YANG WEI PILLS (100 pills)
CCB	CHING CHUN BAO ANTI-AGING TABLETS (80 pills)
CCD	CROCODILE TRADE MARK PILL (24 pills)
CCD1	CROCODILE TRADE MARK TABLETS (100 tables)
CJT1P	L'AMOUR Q TABLETS WITH VITAMINS (150 tables)
CJT1W	L'AMOUR TABLET (220 tables)
CJT206	(6pks) CHUJOTO HERBAL SUPPLEMENT TEA
CJT212	(12pks) CHUJOTO HERBAL SUPPLEMENT TEA
CJT224	(24pks) CHUJOTO HERBAL SUPPLEMENT TEA
CLC01	SO HUP YUEN (10 balls)
CLC02	NING SAN YUEN (10 balls)
CLC03	LI CHUNG YUEN (10 balls)
CLC04	WOO GARM YUEN (10 balls)
CLC05	BO WO YUEN (10 balls)
CLC06	BAK FUNG YUEN (10 balls)
CLC07	PO LUNG YUEN (10 balls)
CLC08	BO SAN YUEN (10 balls)
CLC09	WOOD LOCK YUEN (10 balls)
CLC10	WU CHI PAI FENG WAN (10 balls)
CLC11	YIK MO YUEN (10 balls)
CLC12	SAP HEUNG YUEN (10 balls)
CLC13	NING KWAND DAN (10 balls)
CLC14	RAW LOOK MAY DAY WONG YUEN (12 pks)
CLC15	STEAMED LOOK MAY DAY WONG YUEN (12pks)
CLC16	KWAI LOOK YUEN (12 pks)
CLC17	AU WONG YUEN (10 balls)
CML105	YUNNAN PAIYAO (16 Capsules x 5)
CML110	YUNNAN PAIYAO (16 Capsules x 10)
CML1P	YUNNAN PAIYAO (Powder 10 Bottles)
CML2R	RAW TIENCHI GINSENG PIAN (36 pills x 10)
CML2S	STEAMED TIENCHI GINSENG PIAN (36 pills x 10)
CML3R	RAW TIENCHI POWDER (1.4 oz)
CML3S	STEAMED TIENCHI POWDER (1.4 oz)
CML5	TIENCHI HERBAL SUPPLEMENT TEA (5.29 oz x 10)
CML6	TIENMA CHU FENG PU PIEN (50 tablets)
DDP	DOUBLE DRAGON PILL (120 pills)
ELT1	ELEVEN TIGERS BRAND HERBAL TEA (0.5 oz.)
FC01LW	LAN ZHOU FOCI - LIU WEI DI HUANG WAN (200 pills)
FC02JK	LAN ZHOU FOCI - JIN KUI SHEN QI WAN (200 pills)
FC03XY	LAN ZHOU FOCI - XIAO YAO WAN (200 pills)

CONSENT JUDGMENT - EXHIBIT A (Cont.)

FC04ZB	LAN ZHOU FOCI - ZHI BAI BA WEI WAN (200 pills)
FC05MM	LAN ZHOU FOCI - MING MU DI HUANG WAN (200 pills)
FC06NK	LAN ZHOU FOCI - NU KE BA ZHEN WAN (200 pills)
FC07TW	LAN ZHOU FOCI - TIAN WANG BU XIN DAN (200 pills)
FC08SQ	LAN ZHOU FOCI - SHI QUAN DA BU WAN (200 pills)
FC09CR	LAN ZHOU FOCI - CONG RONG BU SHEN WAN (200 pills)
FC10BX	LAN ZHOU FOCI - MAI WEI DI HUANG WAN (200 pills)
FC11ER	LAN ZHOU FOCI - ER MING ZUO CI WAN (200 pills)
FC12BZ	LAN ZHOU FOCI - BU ZHONG YI QI WAN (200 pills)
FC13QJ	LAN ZHOU FOCI - QI JU DI HUANG WAN (200 pills)
FC14YX	LAN ZHOU FOCI - BAI ZI YANG XIN WAN (200 pills)
FC15SG	LAN ZHOU FOCI - SHU GAN WAN (200 pills)
FC16QQ	LAN ZHOU FOCI - QING QI HUA TAN WAN (200 pills)
FC17XL	LAN ZHOU FOCI - XIANG SHA LIU JUN WAN (200 pills)
FC18XW	LAN ZHOU FOCI - XIANG SHA YANG WEI WAN (200 pills)
FC19DG	LAN ZHOU FOCI - DANG GUI SU (200 pills)
FC20RC	LAN ZHOU FOCI - RUN CHANG WAN (200 pills)
FC21GP	LAN ZHOU FOCI - GUI PI WAN (200 pills)
FC22MX	LAN ZHOU FOCI - MU XIANG SHUN QI WAN (200 pills)
FC23EC	LAN ZHOU FOCI - ER CHEN WAN (200 pills)
FC24SB	LAN ZHOU FOCI - SHEN QI DA BU WAN (200 pills)
FC25HX	LAN ZHOU FOCI - HUO XIANG ZHENG QI WAN (200 pills)
FC26JB	LAN ZHOU FOCI - JIAN BU ZHUANG GU WAN (200 pills)
FC27FZ	LAN ZHOU FOCI - FUZI LIZHONG WAN (200 pills)
FC28CX	LAN ZHOU FOCI - CHEN XIANG HUA QI WAN (200 pills)
FC29CH	LAN ZHOU FOCI - XIAO CHAI HU TANG WAN (200 pills)
FC30ZS	LAN ZHOU FOCI - ZI SHENG WAN (200 pills)
FC31JS	LAN ZHOU FOCI - JIN SUO GU JING WAN (200 pills)
FC32BH	LAN ZHOU FOCI - BAOHE WAN (200 pills)
FC33HL	LAN ZHOU FOCI - XIAO HUO LUO DAN (200 pills)
FC34FK	LAN ZHOU FOCI - FU KE ZHONG ZI WAN (200 pills)
FC35JP	LAN ZHOU FOCI - REN SHEN JIAN PI WAN (200 pills)
FC36AN	LAN ZHOU FOCI - ANSHEN BUXIN WAN (200 pills)
FC37JW	LAN ZHOU FOCI - JIA WEI XIAO YAO WAN (200 pills)
FC38LD	LAN ZHOU FOCI - LONG DAN XIE GAN WAN (200 pills)
FC39FT	LAN ZHOU FOCI - FANG FENG TONG SHENG WAN (200 pills)
FC40YD	LAN ZHOU FOCI - YU DAI WAN (200 pills)
FC41DB	LAN ZHOU FOCI - DA BU YIN WAN (200 pills)
FC42BG	LAN ZHOU FOCI - BAI HE GU JIN WAN (200 pills)
FC43YR	LAN ZHOU FOCI - FU KE YANG RONG WAN (200 pills)
FC44JG	LAN ZHOU FOCI - JIE GENG WAN (200 pills)
FC45YY	LAN ZHOU FOCI - REN SHEN YANG YING WAN (200 pills)
FC46NX	LAN ZHOU FOCI - NEI XIAO LUO LI WAN (200 pills)
FC47CT	LAN ZHOU FOCI - CHUAN XIONG CHA TIAO SAN (200 pills)
FP1	FIVE PHOTOS BRAND - TIEN TA WAN DIETARY SUPPLEMENT (0.6 oz.)

CONSENT JUDGMENT - EXHIBIT A (Cont.)

FP3	YA-HOM POWDER FIVE PAGODAS BRAND HERBAL SUPPLEMENT (0.88 oz.)
FPMK	FOSHAN PE MIN KAN WAN (50 pills)
GW01	JEN SHEN LU YUNG WAN (120 pills)
GW02	WU CHI PAIFENG WAN (120 pills)
GW03	ZHI SOU DING CHUAN WAN (150 pills)
GW04	SEA HORSE BUSHING WAN (120 pills)
GW05	CHIEN CHIN CHIH TAI WAN (120 pills)
GW06	YINCHIAO TABLET - Antihistamine Pain Reliever-Fever Reducer (120 tablets)
GW07	YINCHIAO TABLET- Herbal Supplement- (120 pills)
GW09	WU CHI PAI FENG WAN (1.76fl. x 10balls)
GW10	CHING FEI YI HUO PIEN (8 tablets x 12)
GW11	HUO HSIANG CHENG CHI PIEN (8 tablets x 12)
GW12	YIN CHIAO CHIEH TU PIEN - For Cold (8 tablets x 12)
GW13	YIN CHIAO CHIEH TU PIEN - Herbal Supplement - (8 tablets x 12)
GW14	HUANG LIEN SHANG CHING PIEN (8 tablets x 12)
GW15	SHENG FA CAPSULES (40 pills)
GW16	CHIN KOO TIEH SHANG WAN (120 pills)
GW17	YANG YIN QING FEI TANG JIANG (120ml)
GW19	FENG SHIH HSIAO TUNG WAN (120 pills)
GW20	SHU KAN WAN (CONDENSED) (120 pills)
GW21	LIEN CHIAO PAI TU PIEN (8tablets x 12)
GW22	MING MU SHANG CHING PIEN (8tablets x 12)
GW23	HUO HSIANG CHENG CHI SHUEI (10ml x 12)
GW24	HSIANG SHA YANG WEI PILLS (60 pills)
GW25	SANG CHU YIN PIEN (60 pills)
GW26	QI JU DI HUANG WAN (10 balls)
GW27	SHI HU YE GUANG WAN (10 balls)
GW28	SHISANTAIBAO WAN (10 balls)
GW29	GUANXIN SU HO CAPSULES (40 Capsules)
HK110	HIYA KIOGAN (110 pills)
HK315	HIYA KIOGAN (315 pills)
HK75	HIYA KIOGAN (75 pills)
ID2	HINDU SHING YUEN (60 pills)
JT1	JIN TAN BREATH FRESHENER BEADS (400 pills x 40)
KF1P	COMPOUND WATERMELON FROST (2g x 6)
KF1S	COMPOUND WATERMELON FROST (3 g) Spray
KF3	SUPERIOR FU FANG JIN QIAN CHAO PILL (100 pills)
KKP	KAI KIT PILL (54 pills)
KKW	PROSTATE GLAND PILLS "KAI KIT WAN" (90 pills)
KYP	KAI YEUNG PILL (45 pills)
LPKP	LEUNG PUI KEE PILLS HERBAL SUPPLEMEMT (60 pills x 12 vials)
LZ1	ANGELICAE NATURAL EXTRACTIVES (100 pills)
LZ2	LIU WEI DI HUANG WAN (200 pills)
LZ3	HSIAO YAO WAN (200 pills)
LZ4	SEXTON YAM (200 pills)

CONSENT JUDGMENT - EXHIBIT A (Cont.)

MS1	CORTEX EUCOMMIAE (100 pills)
MS11	DIEDAYAOWAN PILL (30pills)
MS1-1	DU ZHONG ZHUANG GU WAN (100 pills)
MS12	MAODUNGCHING (30 pills)
MS13	JIANG ZHI JIAN FEI WAN (20pills)
MS14	TEXIAO XIAOKE WAN (20pills)
MS15	SPECIFIC LUMBAGLIN (24pills)
MS16	LUNG TAN XIE GAN PILL (100pills)
MS17	KANG GU ZENG SHENG PIAN (100pills)
MS18	GINSENG WITH POLYGONUM MULLIFLORIUM (30 Capsules)
MS19	DR. TC. YALES PHOSTOSE BRAIN TONIC (5 fl oz.)
MS2	TIN TZAT TO CHUNG PILLS (100 pills x 10)
MS22	ZHANG ZHOU PIEN TZE HUANG (3g X 10)
MS23	LAI YUNG SHANG LU-SHENG PILLS (100 PILLS)
MS3	TANG SHENG HAIR NOURISHMENT CAPSULES (40 pills)
MS4	MARGARITE PILLS (60 pills)
MS5	DU HUO JISHENG WAN (100 pills)
MS6	PEKING LINGCHIH ROYAL JELLY (10 BOTTLES (0.34 fl oz x 10)
NGP1P	SIT WO TONG NG PO POWDER (0.635 oz.)
NGP1W	SIT WO TONG NG PO WAN (0.76 oz.)
PC1	ANMIEN PIEN (SUGAR COATED) (60 pills)
PC2	JIANG YA PIAN (100 pills)
PC3	FRITILLARIA EXTRACT (60pills)
PC4	PULMONARY TONIC TABLETS (60 pills)
PCP1	PO CHAI PILLS HERBAL SUPPLEMENT (300x10 vials x 0.067oz.)
QCB	QING CHUN BAO ANTI-AGING TABLETS (80 PILLS)
QCBE	QING CHUN BAO ANTI-AGING ORAL LIQUID (10 ml x 10)
RKS1C	RYUKAKUSAN - HERBAL CANDY- BAG - (3.5 oz. x 10)
RKS1C/BC	RYUKAKUSAN - BLACK CURRANT & BLUEBERRY HERBAL DROPS (10 drops x 10)
RKS1C/H	RYUKAKUSAN - HERBAL DROPS (10 drops x 10)
RKS1C/K	RYUKAKUSAN - KUMQUAT HERBAL DROPS (10 drops x 10)
RKS1C/P	RYUKAKUSAN - PLUM HERBAL DROPS (10 drops x 10)
RKS1C/RJ	RYUKAKUSAN - ROYAL JELLY & MILK HERBAL DROPS (10 drops x 10)
RKS1P	RYUKAKUSAN - HERBAL POWDER (0.7 oz.)
RKS1PL	RYUKAKUSAN - HERBAL POWDER (1.5 oz.)
RKS2BC	RYUKAKUSAN - BLACK CURRANT & BLUEBERRY HERBAL CANDY - BAG - (2.4 oz x 10)
SDA	SHUI DE AN CAPSULES (12 Capsules)
SJ1C	SANJIN WATERMELON FROST LOZENGES BREATH FRESHENER (12 pills x 12)
SJ1S	SANJIN WATERMELON FROST BREATH FRESHENER (3g)
SLT1	SAPLINGTAN PAIN RELIEVER (100vials - 80g)
SS1	HIGH STRENGTH ROYAL JELLY (30 Capsules)
SS2	PANAX GINSENG EXTRACT CAPSULES (30 Capsules)
SS4	GINSENG TONIC CAPSULES (30 Capsules)
SS5	MAREN SOFT CAPSULES (20capsules x 10bxes)
SV1	GOLDEN GINGER HARD CANDY HOT (5.3 oz.)

CONSENT JUDGMENT - EXHIBIT A (Cont.)

SW1L	(L.) SAN WA SAILOR GWAN (480 pills)
SW1S	(S.) SAN WA SAILOR GWAN (120 pills)
SWP	SHOU WU PIAN (100 pills)
THY	TIN HEE YUEN (Dietary Supplement) (1.06 oz.)
TJW	TO JING WAN (80pills)
TPSPE	TZEPAO SANPIEN EXTRACT (10 ml x 10)
TPSPP	TZEPAO SANPIEN PILLS (5 vials x 6 bxes)
TPSPW	TZEPAO SANPIEN WAN (LARGE PILL) (2.11oz. x 10 balls)
TPSPWS	TZEPAO SANPIEN WAN (SMALL PILLS) (10 balls)
TRT1	SHUN CHI WAN (300 pills)
TRT10	SHENJING SHUAIKUO WAN (300 pills)
TRT11	BEIJING BAIFENG WAN (10 balls)
TRT11A	BEIJING BAIFENG WAN (Brocade Box) (6 balls)
TRT13	RENSHEN JIANPI WAN (300 pills)
TRT14	SHI QUAN DA BU WAN (360 pills)
TRT15	LIU WEI DI HUANG WAN (360 pills)
TRT16	ZHI BAI DI HUANG WAN (360 pills)
TRT17	JIN GUI SHEN CHI WAN (360 pills)
TRT18	JINSENG TSAI TSAO WAN (10 balls)
TRT19	YIN QIAO JIE DU PIAN (100 tablets)
TRT2	CHIEN PU HU CHIEN WAN (200 pills)
TRT3100	NIU HUANG JIE DU PIAN (100 pills)
TRT320	NIU HUANG JIE DU PIAN (20 pills)
TRT350	NIU HUANG JIE DU PIAN (50 pills)
TRT396	(8 x 12) NIU HUANG JIE DU PIAN
TRT4	NIU HUANG QING XIN WAN (10 balls)
TRT5	TONGREN DAHUOLUO WAN (10 balls)
TRT6	JEN SHEN LU JUNG WAN (10 balls)
TRT7	QING YIN WAN (10 balls)
TRT8	ANGONG NIUHUANG WAN (10 balls)
TRT9	HUOXIANG ZHENGQI PIAN (12pills x 12vials)
TST1	TIEN SAU TONG - GUSAO PILL (10 pills)
TST2	TIEN SAU TONG - JIANSHEN PILL (30 pills)
VEP	VINE ESSENCE PILLS (60pills)
WYN1	(10 balls x 10) WONG YIU NAM POKOW YUEN
WYN2	(10 vials x 10) WONG YIU NAM POKOW YUEN
WYT1	FU ZHENG YANG YIN WAN (6.0 oz. - 24 pills per can)
XA1	SHENLING BAIZHU TABLETS (80 pills)
XA2	CEREBRAL TONIC PILLS (300 pills)
YC10	ZHUANG YAO TONIC TABLETS(100Tables)
YC11	BUTIAO TABLETS (100 Tablets)
YC2	CHUAN XIN LIAN (100 pills)
YC3	GAN MAO LING (100 pills)
YC4	TRISNAKE PILLS (36 pills)
YC5	SHILINGTON (100 pills)

CONSENT JUDGMENT - EXHIBIT A (Cont.)

YC6	CULING WAN (1 oz. x 10 bottles)
YC7	HIGH STRENGTH FARGELIN (36 pills)
YC7A	YANG CHENG BRAND FARGELIN (60pills)
YC8	YANG CHENG BRAND WUCHI PAIFENG WAN (10 balls)
YC9	ZHUANG YAO TONIC WAN (10 balls)
YL1	GEJIE DA BU WAN (50 pills)
YL2	GEJIE BU SHING WAN (50 pills)
YL3	JIGUCAO WAN (50 pills)
YL5	LOHANKUO ZHI-KE-LU SYRUP (100ml)
YPMK	YU LAM PE MIN KAN WAN (50 pills)
ZL1	ANSHEN BUNAO TABLETS (100 tablets)
ZL2	BI YAN PIAN (100 pills)
ZQ1	LIDAN PAISHI TABLETS (120 tablets)
ZQ2	"204" WEI TE LING (120 pills)
ZQ3	LIDAN TABLETS (120 tablets)
ZQ4	HEALTHY BRAIN PILLS (300pills)

EXHIBIT B

LAW OFFICES OF
ANDREW L. PACKARD

319 PLEASANT STREET, PETALUMA, CALIFORNIA 94952
PHONE (707) 763-7227 FAX (707) 763-9227
INFO@PACKARDLAWOFFICES.COM

March 5, 2007

VIA CERTIFIED MAIL

Wina Tran, President
Madison One Acme, Inc.
Solstice Medicine Company
215 West Ann Street
Los Angeles, CA 90012

Wina Tran, Registered Agent
Madison One Acme, Inc
1022 Trafalgar Drive
Glendale, CA 91207

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

Dear President Tran,

This firm represents Stephen D. Gillett in connection with this notice of violations of California's 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 intends 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.

The name of the violator covered by this notice is Madison One Acme, Inc. dba Solstice Medicine Company (hereafter, the "Violator"). The violator operates as a wholesaler of drugs, proprietaries or sundries, specializing in herbal patent medicines, with sales on the internet, and to both the general public and resellers. These dietary supplements and herbal products are causing ongoing violations of Proposition 65 due to exposures to lead and lead compounds from the ingestion of these products. 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.

Products At Issue. The following dietary supplements and herbal products are the subject of this notice:

YIN CHIAO, CHIEHTUPIEN (Great Wall Brand)

Route of exposure. The consumer exposures that are the subject of this notice result from the purchase, acquisition, handling and use of these products by consumers as recommended by the Violator. 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 March 5, 2006, as well as every day since the products were introduced in 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:
OEHHA Summary
Certificate of Merit (w/o AG attachment)
Certificate of Service

CERTIFICATE OF MERIT

**(re: Stephen D. Gillett's March 5, 2007 Notice of Proposition 65 Violation
Issued to Madison One Acme, Inc. dba Solstice Medicine Company)**

I, Andrew L. Packard, declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged 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. The 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: March 5, 2007



Andrew L. Packard

Attachments (for Attorney General Copy only)

CERTIFICATE OF SERVICE

I, the undersigned, declare under penalty of perjury under the laws of the State of California that the following is true and correct:

I am a citizen of the United States, over the age of 18 years of age, and am not a party to the within entitled action. My business address is 319 Pleasant Street, Petaluma, California 94952.

On March 5, 2007, I served the following documents: **NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT; "SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986: A SUMMARY"** on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it in a US Postal Service Office for delivery by Certified Mail:

Wina Tran, President
Madison One Acme, Inc.
Solstice Medicine Company
215 West Ann Street
Los Angeles, CA 90012

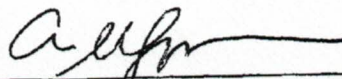
Wina Tran, Registered Agent
Madison One Acme, Inc
1022 Trafalgar Drive
Glendale, CA 91207

On March 5, 2007, I served the following documents: **NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT (including supporting documentation required by Title 11 CCR §3102)** on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it in a US Postal Service Office for delivery by Certified Mail:

Office of the California Attorney General
Prop 65 Enforcement Reporting
1515 Clay Street, Suite 2000
Post Office Box 70550
Oakland, CA 94612-0550

On March 5, 2007, I served the following documents: **NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.; CERTIFICATE OF MERIT** on each of the parties on the Service List attached hereto by placing a true and correct copy thereof in a sealed envelop, addressed to each of the parties on the service list attached hereto, and depositing it in a US Postal Service Office for delivery by First Class Mail.

Executed on March 5, 2007, in Petaluma, California.



Erin Seymour

Service List (Page 1 of 4)

The Honorable Tom Orloff
District Attorney, Alameda County
1225 Fallon Street, Room 900
Oakland, CA 94612

The Honorable William Richmond
District Attorney, Alpine County
P.O. Box 248
Markleeville, CA 96120

The Honorable Todd Riebe
District Attorney, Amador County
708 Court Street, #202
Jackson, CA 95642

The Honorable Michael Ramsey
District Attorney, Butte County
25 County Center Drive
Oroville, CA 95965

The Honorable Jeffrey Tuttle
District Attorney, Calaveras County
891 Mountain Ranch Road
San Andreas, CA 95249

The Honorable John Poyner
District Attorney, Colusa County
547 Market Street
Colusa, CA 95932

The Honorable Robert Kochly
District Attorney, Contra Costa County
725 Court Street
Martinez, CA 94553

The Honorable Michael Riese
District Attorney, Del Norte County
450 H Street, Ste. 171
Crescent City, CA 95531

The Honorable Gary Lacy
District Attorney, El Dorado County
515 Main Street
Placerville, CA 95667

The Honorable Elizabeth Egan
District Attorney, Fresno County
2220 Tulare Street, #1000
Fresno, CA 93721

The Honorable Robert Holzapfel
District Attorney, Glenn County
Post Office Box 430
Willows, CA 95988

The Honorable Paul Gallegos
District Attorney, Humboldt County
825 5th Street
Eureka, CA 95501

The Honorable Gilbert G. Otero
District Attorney, Imperial County
939 West Main Street
El Centro, CA 92243

The Honorable Arthur Maillet
District Attorney, Inyo County
Post Office Drawer D
Independence, CA 93526

The Honorable Edward R. Jagels
District Attorney, Kern County
1215 Truxtun Avenue
Bakersfield, CA 93301

The Honorable Ronald Calhoun
District Attorney, Kings County
1400 West Lacey Boulevard
Hanford, CA 93230

The Honorable Gerhard Luck
District Attorney, Lake County
255 N. Forbes Street
Lakeport, CA 95453

The Honorable Robert Burns
District Attorney, Lassen County
220 South Lassen Street, Ste. 8
Susanville, CA 96130

The Honorable Steve Cooley
District Attorney, Los Angeles County
210 West Temple Street, Rm 345
Los Angeles, CA 90012

The Honorable Ernest LiCalsi
District Attorney, Madera County
209 West Yosemite Avenue
Madera, CA 93637

Service List (Page 2 of 4)

The Honorable Edward Barbarian
District Attorney, Marin County
3501 Civic Center, Room 183
San Rafael, CA 94903

The Honorable Robert Brown
District Attorney, Mariposa County
Post Office Box 730
Mariposa, CA 95338

The Honorable Norman Vroman
District Attorney, Mendocino County
Post Office Box 1000
Ukiah, CA 95482

The Honorable Gordon Spencer
District Attorney, Merced County
2222 "M" Street
Merced, CA 95340

The Honorable Jordan Funk
District Attorney, Modoc County
204 S Court Street
Alturas, CA 96101-4020

The Honorable George Booth
District Attorney, Mono County
Post Office Box 617
Bridgeport, CA 93517

The Honorable Dean Flippo
District Attorney, Monterey County
PO Box 1131
Salinas, CA 93901

The Honorable Gary Lieberstein
District Attorney, Napa County
931 Parkway Mall
Napa, CA 94559

The Honorable Michael Ferguson
District Attorney, Nevada County
201 Church Street, Suite 8
Nevada City, CA 95959

The Honorable Tory Rackauckas
District Attorney, Orange County
401 Civic Center Drive West
Santa Ana, CA 92701

The Honorable Brad Fenocchio
District Attorney, Placer County
11562 "B" Avenue, Dewitt Center
Auburn, CA 95603

The Honorable Jeff Cunan
District Attorney, Plumas County
520 Main Street, Room 404
Quincy, CA 95971

The Honorable Grover C. Trask, II
District Attorney, Riverside County
4075 Main Street, 1st Floor
Riverside, CA 92501

The Honorable Jan Scully
District Attorney, Sacramento County
901 "G" Street
Sacramento, CA 95814

The Honorable John Sarsfield
District Attorney, San Benito County
419 Fourth Street, 2nd Floor
Hollister, CA 95023

The Honorable Michael Ramos
District Attorney, San Bernardino County
316 N. Mountain View Avenue
San Bernardino, CA 92415-0004

The Honorable Bonnie Dumanis
District Attorney, San Diego County
330 West Broadway, Room 1320
San Diego, CA 92112

The Honorable Kamala Harris
District Attorney, San Francisco County
850 Bryant Street, Room 325
San Francisco, CA 94103

The Honorable James Willett
District Attorney, San Joaquin County
Post Office Box 990
Stockton, CA 95201

The Honorable Gerald Shea
District Attorney, San Luis Obispo County
1050 Monterey Street, Room 450
San Luis Obispo, CA 93408

Service List (Page 3 of 4)

The Honorable James P. Fox
District Attorney, San Mateo County
400 County Ctr., 3rd Floor
Redwood City, CA 94063

The Honorable Thomas W. Sneddon, Jr.
District Attorney, Santa Barbara County
1105 Santa Barbara Street
Santa Barbara, CA 93101

The Honorable George Kennedy
District Attorney, Santa Clara County
70 West Hedding Street
San Jose, CA 95110

The Honorable Bob Lee
District Attorney, Santa Cruz County
701 Ocean Street, Room 200
Santa Cruz, CA 95060

The Honorable Gerald Benito
District Attorney, Shasta County
1525 Court Street, Third Floor
Redding, CA 96001-1632

The Honorable Lawrence Allen
District Attorney, Sierra County
Courthouse, Post Office Box 457
Downieville, CA 95936

The Honorable James Andrus
District Attorney, Siskiyou County
Post Office Box 986
Yreka, CA 96097

The Honorable David Paulson
District Attorney, Solano County
600 Union Avenue
Fairfield, CA 94533

The Honorable Stephan Passalacqua
District Attorney, Sonoma County
600 Administration Drive, Room 212J
Santa Rosa, CA 95403

The Honorable Jim Brazelton
District Attorney, Stanislaus County
800 11th Street, Room 200
Modesto, CA 95353

The Honorable Carl V. Adams
District Attorney, Sutter County
446 Second Street
Yuba City, CA 95991

The Honorable Gregg Cohen
District Attorney, Tehama County
Post Office Box 519
Red Bluff, CA 96080

The Honorable David L. Cross
District Attorney, Trinity County
Post Office Box 310
Weaverville, CA 96093

The Honorable Phillip Cline
District Attorney, Tulare County
221 S. Mooney Avenue, Room 224
Visalia, CA 93291

The Honorable Donald Segerstrom, Jr.
District Attorney, Tuolumne County
2 South Green
Sonora, CA 95370

The Honorable Gregory Totten
District Attorney, Ventura County
800 South Victoria Avenue
Ventura, CA 93009

The Honorable David C. Henderson
District Attorney, Yolo County
301 2nd Street
Woodland, CA 95695

The Honorable Patrick McGrath
District Attorney, Yuba County
215 Fifth Street
Marysville, CA 95901

Service List (Page 4 of 4)

The Honorable Rockard Delgadillo
Los Angeles City Attorney's Office
Room 1800, City Hall East
200 N. Main Street
Los Angeles, CA 90012

The Honorable Michael Aguirre
San Diego City Attorney's Office
1200 3rd Avenue, 12th Floor
San Diego, CA 92101

The Honorable Dennis Herrera
San Francisco City Attorney's Office
City Hall, Room 234
San Francisco, CA 94102

The Honorable Richard Doyle
San Jose City Attorney's Office
151 West Mission Street
San Jose, CA 95110

Edward G. Weil, Deputy Attorney General
California Attorney General's Office
Proposition 65 Enforcement Reporting Coordinator
1515 Clay Street, Ste. 2000
Oakland, CA 94612

LAW OFFICES OF

ANDREW L. PACKARD

319 PLEASANT STREET, PETALUMA, CALIFORNIA 94952

PHONE (707) 763-7227 FAX (707) 763-9227

INFO@PACKARDLAWOFFICES.COM

June 25, 2008

VIA CERTIFIED MAIL

Wina Tran, President
Madison One Acme, Inc.
Solstice Medicine Company
215 West Ann Street
Los Angeles, CA 90012

May Choy, Registered Agent
Madison One Acme, Inc.
3129 S. Hacienda Blvd, #676
Hacienda Heights, CA 91745

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

Dear Ms. Tran,

This firm represents Stephen D. Gillett in connection with this notice of violations of California's 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 intends 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.

The name of the violator covered by this notice is **Madison One Acme, Inc. dba Solstice Medicine Company** (hereafter, the "Violator"). The violator operates as a wholesaler of drugs, proprietaries or sundries, specializing in herbal patent medicines, with sales on the internet, and to both the general public and resellers. These dietary supplements and herbal products are causing ongoing violations of Proposition 65 due to exposures to lead and lead compounds from the ingestion of these products. 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.

Products At Issue. The dietary supplements and herbal products listed on Exhibit A hereto are the subject of this notice:

Route of exposure. The consumer exposures that are the subject of this notice result from the purchase, acquisition, handling and use of these products by consumers as recommended by the Violator. 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 June 25, 2007, as well as every day since the products were introduced in the California marketplace, and will continue every day until clear and reasonable warnings are provided to product purchasers and users. This notice supplements the notice of violations issued by Mr. Gillett on March 5, 2007.

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: Product List
OEHHA Summary
Certificate of Merit (w/o AG attachment)
Certificate of Service

Exhibit A

Item Number	Item Description
AWGT	AMERICAN WINDSER GINSENG TEA (48 tea bags)
BTW	BAN TU WAN (100 pills)
BYS1	HE CHE DA ZAO WAN (100 pills)
BYS2	SIANG SHA YANG WEI PILLS (100 pills)
CCB	CHING CHUN BAO ANTI-AGING TABLETS (80 pills)
CCD	CROCODILE TRADE MARK PILL (24 pills)
CCD1	CROCODILE TRADE MARK TABLETS (100 tables)
CJT1P	L'AMOUR Q TABLETS WITH VITAMINS (150 tables)
CJT1W	L'AMOUR TABLET (220 tables)
CJT206	(6pks) CHUJOTO HERBAL SUPPLEMENT TEA
CJT212	(12pks) CHUJOTO HERBAL SUPPLEMENT TEA
CJT224	(24pks) CHUJOTO HERBAL SUPPLEMENT TEA
CLC01	SO HUP YUEN (10 balls)
CLC02	NING SAN YUEN (10 balls)
CLC03	LI CHUNG YUEN (10 balls)
CLC04	WOO GARM YUEN (10 balls)
CLC05	BO WO YUEN (10 balls)
CLC06	BAK FUNG YUEN (10 balls)
CLC07	PO LUNG YUEN (10 balls)
CLC08	BO SAN YUEN (10 balls)
CLC09	WOOD LOCK YUEN (10 balls)
CLC10	WU CHI PAI FENG WAN (10 balls)
CLC11	YIK MO YUEN (10 balls)
CLC12	SAP HEUNG YUEN (10 balls)
CLC13	NING KWAND DAN (10 balls)
CLC14	RAW LOOK MAY DAY WONG YUEN (12 pks)
CLC15	STEAMED LOOK MAY DAY WONG YUEN (12pks)
CLC16	KWAI LOOK YUEN (12 pks)
CLC17	AU WONG YUEN (10 balls)
CML105	YUNNAN PAIYAO (16 Capsules x 5)
CML110	YUNNAN PAIYAO (16 Capsules x 10)
CML1P	YUNNAN PAIYAO (Powder 10 Bottles)
CML2R	RAW TIENCHI GINSENG PIAN (36 pills x 10)
CML2S	STEAMED TIENCHI GINSENG PIAN (36 pills x 10)
CML3R	RAW TIENCHI POWDER (1.4 oz)
CML3S	STEAMED TIENCHI POWDER (1.4 oz)
CML5	TIENCHI HERBAL SUPPLEMENT TEA (5.29 oz x 10)
CML6	TIENMA CHU FENG PU PIEN (50 tablets)
DDP	DOUBLE DRAGON PILL (120 pills)
ELT1	ELEVEN TIGERS BRAND HERBAL TEA (0.5 oz.)

FC01LW	LAN ZHOU FOCI - LIU WEI DI HUANG WAN (200 pills)
FC02JK	LAN ZHOU FOCI - JIN KUI SHEN QI WAN (200 pills)
FC03XY	LAN ZHOU FOCI - XIAO YAO WAN (200 pills)
FC04ZB	LAN ZHOU FOCI - ZHI BAI BA WEI WAN (200 pills)
FC05MM	LAN ZHOU FOCI - MING MU DI HUANG WAN (200 pills)
FC06NK	LAN ZHOU FOCI - NU KE BA ZHEN WAN (200 pills)
FC07TW	LAN ZHOU FOCI - TIAN WANG BU XIN DAN (200 pills)
FC08SQ	LAN ZHOU FOCI - SHI QUAN DA BU WAN (200 pills)
FC09CR	LAN ZHOU FOCI - CONG RONG BU SHEN WAN (200 pills)
FC10BX	LAN ZHOU FOCI - MAI WEI DI HUANG WAN (200 pills)
FC11ER	LAN ZHOU FOCI - ER MING ZUO CI WAN (200 pills)
FC12BZ	LAN ZHOU FOCI - BU ZHONG YI QI WAN (200 pills)
FC13QJ	LAN ZHOU FOCI - QI JU DI HUANG WAN (200 pills)
FC14YX	LAN ZHOU FOCI - BAI ZI YANG XIN WAN (200 pills)
FC15SG	LAN ZHOU FOCI - SHU GAN WAN (200 pills)
FC16QQ	LAN ZHOU FOCI - QING QI HUA TAN WAN (200 pills)
FC17XL	LAN ZHOU FOCI - XIANG SHA LIU JUN WAN (200 pills)
FC18XW	LAN ZHOU FOCI - XIANG SHA YANG WEI WAN (200 pills)
FC19DG	LAN ZHOU FOCI - DANG GUI SU (200 pills)
FC20RC	LAN ZHOU FOCI - RUN CHANG WAN (200 pills)
FC21GP	LAN ZHOU FOCI - GUI PI WAN (200 pills)
FC22MX	LAN ZHOU FOCI - MU XIANG SHUN QI WAN (200 pills)
FC23EC	LAN ZHOU FOCI - ER CHEN WAN (200 pills)
FC24SB	LAN ZHOU FOCI - SHEN QI DA BU WAN (200 pills)
FC25HX	LAN ZHOU FOCI - HUO XIANG ZHENG QI WAN (200 pills)
FC26JB	LAN ZHOU FOCI - JIAN BU ZHUANG GU WAN (200 pills)
FC27FZ	LAN ZHOU FOCI - FUZI LIZHONG WAN (200 pills)
FC28CX	LAN ZHOU FOCI - CHEN XIANG HUA QI WAN (200 pills)
FC29CH	LAN ZHOU FOCI - XIAO CHAI HU TANG WAN (200 pills)
FC30ZS	LAN ZHOU FOCI - ZI SHENG WAN (200 pills)
FC31JS	LAN ZHOU FOCI - JIN SUO GU JING WAN (200 pills)
FC32BH	LAN ZHOU FOCI - BAOHE WAN (200 pills)
FC33HL	LAN ZHOU FOCI - XIAO HUO LUO DAN (200 pills)
FC34FK	LAN ZHOU FOCI - FU KE ZHONG ZI WAN (200 pills)
FC35JP	LAN ZHOU FOCI - REN SHEN JIAN PI WAN (200 pills)
FC36AN	LAN ZHOU FOCI - ANSHEN BUXIN WAN (200 pills)
FC37JW	LAN ZHOU FOCI - JIA WEI XIAO YAO WAN (200 pills)
FC38LD	LAN ZHOU FOCI - LONG DAN XIE GAN WAN (200 pills)
FC39FT	LAN ZHOU FOCI - FANG FENG TONG SHENG WAN (200 pills)
FC40YD	LAN ZHOU FOCI - YU DAI WAN (200 pills)
FC41DB	LAN ZHOU FOCI - DA BU YIN WAN (200 pills)
FC42BG	LAN ZHOU FOCI - BAI HE GU JIN WAN (200 pills)
FC43YR	LAN ZHOU FOCI - FU KE YANG RONG WAN (200 pills)

Notice of Violation of California Health & Safety Code §25249.5 *et seq.*

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FC44JG	LAN ZHOU FOCI - JIE GENG WAN (200 pills)
FC45YY	LAN ZHOU FOCI - REN SHEN YANG YING WAN (200 pills)
FC46NX	LAN ZHOU FOCI - NEI XIAO LUO LI WAN (200 pills)
FC47CT	LAN ZHOU FOCI - CHUAN XIONG CHA TIAO SAN (200 pills)
FP1	FIVE PHOTOS BRAND - TIEN TA WAN DIETARY SUPPLEMENT (0.6 oz.)
FP3	YA-HOM POWDER FIVE PAGODAS BRAND HERBAL SUPPLEMENT (0.88 oz.)
FPMK	FOSHAN PE MIN KAN WAN (50 pills)
GW01	JEN SHEN LU YUNG WAN (120 pills)
GW02	WU CHI PAIFENG WAN (120 pills)
GW03	ZHI SOU DING CHUAN WAN (150 pills)
GW04	SEA HORSE BUSHING WAN (120 pills)
GW05	CHIEN CHIN CHIH TAI WAN (120 pills)
GW06	YINCHIAO TABLET - Antihistamine Pain Reliever-Fever Reducer (120 tablets)
GW07	YINCHIAO TABLET- Herbal Supplement- (120 pills)
GW09	WU CHI PAI FENG WAN (1.76fl. x 10balls)
GW10	CHING FEI YI HUO PIEN (8 tablets x 12)
GW11	HUO HSIANG CHENG CHI PIEN (8 tablets x 12)
GW12	YIN CHIAO CHIEH TU PIEN - For Cold (8 tablets x 12)
GW13	YIN CHIAO CHIEH TU PIEN - Herbal Supplement - (8 tablets x 12)
GW14	HUANG LIEN SHANG CHING PIEN (8 tablets x 12)
GW15	SHENG FA CAPSULES (40 pills)
GW16	CHIN KOO TIEH SHANG WAN (120 pills)
GW17	YANG YIN QING FEI TANG JIANG (120ml)
GW19	FENG SHIH HSIAO TUNG WAN (120 pills)
GW20	SHU KAN WAN (CONDENSED) (120 pills)
GW21	LIEN CHIAO PAI TU PIEN (8tablets x 12)
GW22	MING MU SHANG CHING PIEN (8tablets x 12)
GW23	HUO HSIANG CHENG CHI SHUEI (10ml x 12)
GW24	HSIANG SHA YANG WEI PILLS (60 pills)
GW25	SANG CHU YIN PIEN (60 pills)
GW26	QI JU DI HUANG WAN (10 balls)
GW27	SHI HU YE GUANG WAN (10 balls)
GW28	SHISANTAIBAO WAN (10 balls)
GW29	GUANXIN SU HO CAPSULES (40 Capsules)
HK110	HIYA KIOGAN (110 pills)
HK315	HIYA KIOGAN (315 pills)
HK75	HIYA KIOGAN (75 pills)
ID2	HINDU SHING YUEN (60 pills)
JT1	JIN TAN BREATH FRESHENER BEADS (400 pills x 40)
KF1P	COMPOUND WATERMELON FROST (2g x 6)
KF1S	COMPOUND WATERMELON FROST (3 g) Spray
KF3	SUPERIOR FU FANG JIN QIAN CHAO PILL (100 pills)
KKP	KAI KIT PILL (54 pills)

KKW	PROSTATE GLAND PILLS "KAI KIT WAN" (90 pills)
KYP	KAI YEUNG PILL (45 pills)
LPKP	LEUNG PUI KEE PILLS HERBAL SUPPLEMEMT (60 pills x 12 vials)
LZ1	ANGELICAE NATURAL EXTRACTIVES (100 pills)
LZ2	LIU WEI DI HUANG WAN (200 pills)
LZ3	HSIAO YAO WAN (200 pills)
LZ4	SEXTON YAM (200 pills)
MS1	CORTEX EUCOMMIAE (100 pills)
MS11	DIEDAYAOWAN PILL (30pills)
MS1-1	DU ZHONG ZHUANG GU WAN (100 pills)
MS12	MAODUNGCHING (30 pills)
MS13	JIANG ZHI JIAN FEI WAN (20pills)
MS14	TEXIAO XIAOKE WAN (20pills)
MS15	SPECIFIC LUMBAGLIN (24pills)
MS16	LUNG TAN XIE GAN PILL (100pills)
MS17	KANG GU ZENG SHENG PIAN (100pills)
MS18	GINSENG WITH POLYGONUM MULLIFLORIUM (30 Capsules)
MS19	DR. TC. YALES PHOSTOSE BRAIN TONIC (5 fl oz.)
MS2	TIN TZAT TO CHUNG PILLS (100 pills x 10)
MS22	ZHANG ZHOU PIEN TZE HUANG (3g X 10)
MS23	LAI YUNG SHANG LU-SHENG PILLS (100 PILLS)
MS3	TANG SHENG HAIR NOURISHMENT CAPSULES (40 pills)
MS4	MARGARITE PILLS (60 pills)
MS5	DU HUO JISHENG WAN (100 pills)
MS6	PEKING LINGCHIH ROYAL JELLY (10 BOTTLES (0.34 fl oz x 10)
NGP1P	SIT WO TONG NG PO POWDER (0.635 oz.)
NGP1W	SIT WO TONG NG PO WAN (0.76 oz.)
PC1	ANMIEN PIEN (SUGAR COATED) (60 pills)
PC2	JIANG YA PIAN (100 pills)
PC3	FRITILLARIA EXTRACT (60pills)
PC4	PULMONARY TONIC TABLETS (60 pills)
PCP1	PO CHAI PILLS HERBAL SUPPLEMENT (300x10 vials x 0.067oz.)
QCB	QING CHUN BAO ANTI-AGING TABLETS (80 PILLS)
QCBE	QING CHUN BAO ANTI-AGING ORAL LIQUID (10 ml x 10)
RKS1C	RYUKAKUSAN - HERBAL CANDY- BAG - (3.5 oz. x 10)
RKS1C/BC	RYUKAKUSAN - BLACK CURRANT & BLUEBERRY HERBAL DROPS (10 drops x 10)
RKS1C/H	RYUKAKUSAN - HERBAL DROPS (10 drops x 10)
RKS1C/K	RYUKAKUSAN - KUMQUAT HERBAL DROPS (10 drops x 10)
RKS1C/P	RYUKAKUSAN - PLUM HERBAL DROPS (10 drops x 10)
RKS1C/RJ	RYUKAKUSAN - ROYAL JELLY & MILK HERBAL DROPS (10 drops x 10)
RKS1P	RYUKAKUSAN - HERBAL POWDER (0.7 oz.)
RKS1PL	RYUKAKUSAN - HERBAL POWDER (1.5 oz.)
RKS2BC	RYUKAKUSAN - BLACK CURRANT & BLUEBERRY HERBAL CANDY - BAG - (2.4 oz x 10)

SDA	SHUI DE AN CAPSULES (12 Capsules)
SJ1C	SANJIN WATERMELON FROST LOZENGES BREATH FRESHENER (12 pills x 12)
SJ1S	SANJIN WATERMELON FROST BREATH FRESHENER (3g)
SLT1	SAPLINGTON PAIN RELIEVER (100vials - 80g)
SS1	HIGH STRENGTH ROYAL JELLY (30 Capsules)
SS2	PANAX GINSENG EXTRACT CAPSULES (30 Capsules)
SS4	GINSENG TONIC CAPSULES (30 Capsules)
SS5	MAREN SOFT CAPSULES (20capsules x 10bxes)
SV1	GOLDEN GINGER HARD CANDY HOT (5.3 oz.)
SW1L	(L.) SAN WA SAILOR GWAN (480 pills)
SW1S	(S.) SAN WA SAILOR GWAN (120 pills)
SWP	SHOU WU PIAN (100 pills)
THY	TIN HEE YUEN (Dietary Supplement) (1.06 oz.)
TJW	TO JING WAN (80pills)
TPSPE	TZEPAO SANPIEN EXTRACT (10 ml x 10)
TPSPP	TZEPAO SANPIEN PILLS (5 vials x 6 bxes)
TPSPW	TZEPAO SANPIEN WAN (LARGE PILL) (2.11oz. x 10 balls)
TPSPWS	TZEPAO SANPIEN WAN (SMALL PILLS) (10 balls)
TRT1	SHUN CHI WAN (300 pills)
TRT10	SHENJING SHUAIKUO WAN (300 pills)
TRT11	BEIJING BAIFENG WAN (10 balls)
TRT11A	BEIJING BAIFENG WAN (Brocade Box) (6 balls)
TRT13	RENSHEN JIANPI WAN (300 pills)
TRT14	SHI QUAN DA BU WAN (360 pills)
TRT15	LIU WEI DI HUANG WAN (360 pills)
TRT16	ZHI BAI DI HUANG WAN (360 pills)
TRT17	JIN GUI SHEN CHI WAN (360 pills)
TRT18	JINSENG TSAI TSAO WAN (10 balls)
TRT19	YIN QIAO JIE DU PIAN (100 tablets)
TRT2	CHIEN PU HU CHIEN WAN (200 pills)
TRT3100	NIU HUANG JIE DU PIAN (100 pills)
TRT320	NIU HUANG JIE DU PIAN (20 pills)
TRT350	NIU HUANG JIE DU PIAN (50 pills)
TRT396	(8 x 12) NIU HUANG JIE DU PIAN
TRT4	NIU HUANG QING XIN WAN (10 balls)
TRT5	TONGREN DAHUOLUO WAN (10 balls)
TRT6	JEN SHEN LU JUNG WAN (10 balls)
TRT7	QING YIN WAN (10 balls)
TRT8	ANGONG NIUHUANG WAN (10 balls)
TRT9	HUOXIANG ZHENGQI PIAN (12pills x 12vials)
TST1	TIEN SAU TONG - GUSAO PILL (10 pills)
TST2	TIEN SAU TONG - JIANSHEN PILL (30 pills)
VEP	VINE ESSENCE PILLS (60pills)

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WYN1	(10 balls x 10) WONG YIU NAM POKOW YUEN
WYN2	(10 vials x 10) WONG YIU NAM POKOW YUEN
WYT1	FU ZHENG YANG YIN WAN (6.0 oz. - 24 pills per can)
XA1	SHENLING BAIZHU TABLETS (80 pills)
XA2	CEREBRAL TONIC PILLS (300 pills)
YC10	ZHUANG YAO TONIC TABLETS(100Tables)
YC11	BUTIAO TABLETS (100 Tablets)
YC2	CHUAN XIN LIAN (100 pills)
YC3	GAN MAO LING (100 pills)
YC4	TRISNAKE PILLS (36 pills)
YC5	SHILINGTON (100 pills)
YC6	CULING WAN (1 oz. x 10 bottles)
YC7	HIGH STRENGTH FARGELIN (36 pills)
YC7A	YANG CHENG BRAND FARGELIN (60pills)
YC8	YANG CHENG BRAND WUCHI PAIFENG WAN (10 balls)
YC9	ZHUANG YAO TONIC WAN (10 balls)
YL1	GEJIE DA BU WAN (50 pills)
YL2	GEJIE BU SHING WAN (50 pills)
YL3	JIGUCAO WAN (50 pills)
YL5	LOHANKUO ZHI-KE-LU SYRUP (100ml)
YPMK	YU LAM PE MIN KAN WAN (50 pills)
ZL1	ANSHEN BUNAO TABLETS (100 tablets)
ZL2	BI YAN PIAN (100 pills)
ZQ1	LIDAN PAISHI TABLETS (120 tablets)
ZQ2	"204" WEI TE LING (120 pills)
ZQ3	LIDAN TABLETS (120 tablets)
ZQ4	HEALTHY BRAIN PILLS (300pills)


CERTIFICATE OF MERIT

**(re: Stephen D. Gillett's June 25, 2008 Notice of Proposition 65 Violation
Issued to Madison One Acme, Inc. dba Solstice Medicine Company)**

I, Andrew L. Packard, declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged 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. The 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: June 25, 2008



Andrew L. Packard

Attachments (for Attorney General Copy only)

CERTIFICATE OF SERVICE

I, the undersigned, declare under penalty of perjury under the laws of the State of California that the following is true and correct:

I am a citizen of the United States, over the age of 18 years of age, and am not a party to the within entitled action. My business address is 319 Pleasant Street, Petaluma, California 94952.

On June 25, 2008, I served the following documents: NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT; "SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986: A SUMMARY" on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it in a U.S. Postal Service Office for delivery by Certified Mail:

Wina Tran, President
Madison One Acme, Inc.
Solstice Medicine Company
215 West Ann Street
Los Angeles, CA 90012

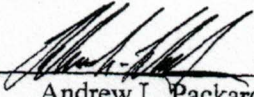
May Choy, Registered Agent
Madison One Acme, Inc.
3129 S. Hacienda Blvd, #676
Hacienda Heights, CA 91745

On June 25, 2008, I served the following documents: NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT (including supporting documentation required by Title 11 CCR §3102) on the following parties by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below and depositing it in a U.S. Postal Service Office for delivery by Certified Mail:

Office of the California Attorney General
Prop 65 Enforcement Reporting
1515 Clay Street, Suite 2000
Post Office Box 70550
Oakland, CA 94612-0550

On June 25, 2007, I served the following documents: NOTICE OF VIOLATION, CALIFORNIA HEALTH & SAFETY CODE §25249.5 *ET SEQ.*; CERTIFICATE OF MERIT on each of the parties on the Service List attached hereto by placing a true and correct copy thereof in a sealed envelope, addressed to each of the parties on the service list attached hereto, and depositing it in a U.S. Postal Service Office for delivery by First Class Mail.

Executed on June 25, 2008, in Petaluma, California.



Andrew L. Packard

Service List (Page 1 of 4)

The Honorable Tom Orloff
District Attorney, Alameda County
1225 Fallon Street, Room 900
Oakland, CA 94612

The Honorable William Richmond
District Attorney, Alpine County
P.O. Box 248
Markleeville, CA 96120

The Honorable Todd Riebe
District Attorney, Amador County
708 Court Street, #202
Jackson, CA 95642

The Honorable Michael Ramsey
District Attorney, Butte County
25 County Center Drive
Oroville, CA 95965

The Honorable Jeffrey Tuttle
District Attorney, Calaveras County
891 Mountain Ranch Road
San Andreas, CA 95249

The Honorable John Poyner
District Attorney, Colusa County
547 Market Street
Colusa, CA 95932

The Honorable Robert Kochly
District Attorney, Contra Costa County
725 Court Street
Martinez, CA 94553

The Honorable Michael Riese
District Attorney, Del Norte County
450 H Street, Ste. 171
Crescent City, CA 95531

The Honorable Gary Lacy
District Attorney, El Dorado County
515 Main Street
Placerville, CA 95667

The Honorable Elizabeth Egan
District Attorney, Fresno County
2220 Tulare Street, #1000
Fresno, CA 93721

The Honorable Robert Holzapfel
District Attorney, Glenn County
Post Office Box 430
Willows, CA 95988

The Honorable Paul Gallegos
District Attorney, Humboldt County
825 5th Street
Eureka, CA 95501

The Honorable Gilbert G. Otero
District Attorney, Imperial County
939 West Main Street
El Centro, CA 92243

The Honorable Arthur Maillet
District Attorney, Inyo County
Post Office Drawer D
Independence, CA 93526

The Honorable Edward R. Jagels
District Attorney, Kern County
1215 Truxtun Avenue
Bakersfield, CA 93301

The Honorable Ronald Calhoun
District Attorney, Kings County
1400 West Lacey Boulevard
Hanford, CA 93230

The Honorable Gerhard Luck
District Attorney, Lake County
255 N. Forbes Street
Lakeport, CA 95453

The Honorable Robert Burns
District Attorney, Lassen County
220 South Lassen Street, Ste. 8
Susanville, CA 96130

The Honorable Steve Cooley
District Attorney, Los Angeles County
210 West Temple Street, Rm 345
Los Angeles, CA 90012

The Honorable Ernest LiCalsi
District Attorney, Madera County
209 West Yosemite Avenue
Madera, CA 93637

Service List (Page 2 of 4)

The Honorable Edward Berbarian
District Attorney, Marin County
3501 Civic Center, Room 183
San Rafael, CA 94903

The Honorable Robert Brown
District Attorney, Mariposa County
Post Office Box 730
Mariposa, CA 95338

The Honorable Norman Vroman
District Attorney, Mendocino County
Post Office Box 1000
Ukiah, CA 95482

The Honorable Gordon Spencer
District Attorney, Merced County
2222 "M" Street
Merced, CA 95340

The Honorable Jordan Funk
District Attorney, Modoc County
204 S Court Street
Alturas, CA 96101-4020

The Honorable George Booth
District Attorney, Mono County
Post Office Box 617
Bridgeport, CA 93517

The Honorable Dean Flippo
District Attorney, Monterey County
PO Box 1131
Salinas, CA 93901

The Honorable Gary Lieberstein
District Attorney, Napa County
931 Parkway Mall
Napa, CA 94559

The Honorable Michael Ferguson
District Attorney, Nevada County
201 Church Street, Suite 8
Nevada City, CA 95959

The Honorable Tory Rackauckas
District Attorney, Orange County
401 Civic Center Drive West
Santa Ana, CA 92701

The Honorable Brad Fenocchio
District Attorney, Placer County
11562 "B" Avenue, Dewitt Center
Auburn, CA 95603

The Honorable Jeff Cunan
District Attorney, Plumas County
520 Main Street, Room 404
Quincy, CA 95971

The Honorable Grover C. Trask, II
District Attorney, Riverside County
4075 Main Street, 1st Floor
Riverside, CA 92501

The Honorable Jan Scully
District Attorney, Sacramento County
901 "G" Street
Sacramento, CA 95814

The Honorable John Sarsfield
District Attorney, San Benito County
419 Fourth Street, 2nd Floor
Hollister, CA 95023

The Honorable Michael Ramos
District Attorney, San Bernardino County
316 N. Mountain View Avenue
San Bernardino, CA 92415-0004

The Honorable Bonnie Dumanis
District Attorney, San Diego County
330 West Broadway, Room 1320
San Diego, CA 92112

The Honorable Kamala Harris
District Attorney, San Francisco County
850 Bryant Street, Room 325
San Francisco, CA 94103

The Honorable James Willett
District Attorney, San Joaquin County
Post Office Box 990
Stockton, CA 95201

The Honorable Gerald Shea
District Attorney, San Luis Obispo County
1050 Monterey Street, Room 450
San Luis Obispo, CA 93408

Service List (Page 3 of 4)

The Honorable James P. Fox
District Attorney, San Mateo County
400 County Ctr., 3rd Floor
Redwood City, CA 94063

The Honorable Thomas W. Sneddon, Jr.
District Attorney, Santa Barbara County
1105 Santa Barbara Street
Santa Barbara, CA 93101

The Honorable George Kennedy
District Attorney, Santa Clara County
70 West Hedding Street
San Jose, CA 95110

The Honorable Bob Lee
District Attorney, Santa Cruz County
701 Ocean Street, Room 200
Santa Cruz, CA 95060

The Honorable Gerald Benito
District Attorney, Shasta County
1525 Court Street, Third Floor
Redding, CA 96001-1632

The Honorable Lawrence Allen
District Attorney, Sierra County
Courthouse, Post Office Box 457
Downieville, CA 95936

The Honorable James Andrus
District Attorney, Siskiyou County
Post Office Box 986
Yreka, CA 96097

The Honorable David Paulson
District Attorney, Solano County
600 Union Avenue
Fairfield, CA 94533

The Honorable Stephan Passalacqua
District Attorney, Sonoma County
600 Administration Drive, Room 212J
Santa Rosa, CA 95403

The Honorable Jim Brazelton
District Attorney, Stanislaus County
800 11th Street, Room 200
Modesto, CA 95353

The Honorable Carl V. Adams
District Attorney, Sutter County
446 Second Street
Yuba City, CA 95991

The Honorable Gregg Cohen
District Attorney, Tehama County
Post Office Box 519
Red Bluff, CA 96080

The Honorable David L. Cross
District Attorney, Trinity County
Post Office Box 310
Weaverville, CA 96093

The Honorable Phillip Cline
District Attorney, Tulare County
221 S. Mooney Avenue, Room 224
Visalia, CA 93291

The Honorable Donald Segerstrom, Jr.
District Attorney, Tuolumne County
2 South Green
Sonora, CA 95370

The Honorable Gregory Totten
District Attorney, Ventura County
800 South Victoria Avenue
Ventura, CA 93009

The Honorable David C. Henderson
District Attorney, Yolo County
301 2nd Street
Woodland, CA 95695

The Honorable Patrick McGrath
District Attorney, Yuba County
215 Fifth Street
Marysville, CA 95901

Service List (Page 4 of 4)

The Honorable Rockard Delgadillo
Los Angeles City Attorney's Office
Room 1800, City Hall East
200 N. Main Street
Los Angeles, CA 90012

The Honorable Michael Aguirre
San Diego City Attorney's Office
1200 3rd Avenue, 12th Floor
San Diego, CA 92101

The Honorable Dennis Herrera
San Francisco City Attorney's Office
City Hall, Room 234
San Francisco, CA 94102

The Honorable Richard Doyle
San Jose City Attorney's Office
151 West Mission Street
San Jose, CA 95110

Edward G. Weil, Deputy Attorney General
California Attorney General's Office
Proposition 65 Enforcement Reporting Coordinator
1515 Clay Street, Ste. 2000
Oakland, CA 94612

EXHIBIT B

LAW OFFICES OF
ANDREW L. PACKARD
100 PETALUMA BLVD N, STE 301, PETALUMA, CA 94952
PHONE (707) 763-7227 FAX (707) 763-9227
INFO@PACKARDLAWOFFICES.COM

December 2, 2015

Via E-mail & Certified U.S. Mail

Richard T. Egger, Esq.
Best, Best & Krieger LLP
400 Capitol Mall, #1650
Sacramento, CA 95814

Ms. Wina So/Current CEO
Solstice Medicine Company
215 West Ann Street
Los Angeles, CA 90012

Richard T. Egger, Esq.
Best, Best & Krieger LLP
2855 East Guasti Road, Suite 400
Ontario, CA 91761

Re: *Stephen D. Gillett v. Madison One Acme, Inc., dba Solstice Medicine Company*; San Francisco Superior Court, Case No. CGC-07-469239; Notice of Ongoing Violations of 2008 Consent Judgment and Request to Meet & Confer Pursuant to Paragraph 8.1

Dear Ms. So and Mr. Egger,

This firm continues to represent Plaintiff Stephen D. Gillet in the above-referenced matter, which was settled pursuant to the terms of the Consent Judgment ("Judgment") entered on September 24, 2008. For your convenience, a copy of the Judgment is attached hereto as Exhibit A. This letter is directed to your attention pursuant to the Notice provisions set forth in Paragraph 11.1 of the Judgment.

Violations of the Judgment

Plaintiff's ongoing statewide investigation of the sales of herbal products containing lead, arsenic, cadmium and mercury in violation of California's Safe Drinking Water & Toxic Enforcement Act ("Proposition 65") indicates that Defendant Madison One Acme, Inc. ("Solstice") is currently violating the Judgment. Specifically, Solstice is selling in California the following "Products" (as defined in Paragraph 1.3 of the Judgment, and set forth on Exhibit A of the Judgment) without the health hazard warnings required under Paragraphs 2.2 and 2.3 of the Judgment:

CHEN XIANG HUA QI WAN
YIN CHIAO FOR COLD

In addition, my client's further testing of Solstice's products sold in California indicates that the product **CHIN KOO TIEH SHANG WAN** has a calculated daily lead exposure level above 10 micrograms. Any California sales of this Product are a violation of Paragraph 2.4 of the Judgment, which prohibits the sale of any Products causing lead exposures above 10 micrograms per day.

Stipulated Civil Penalties under the Judgment

Paragraph 3.1 of the Judgment, entitled "Stipulated Civil Penalties for Future Violations of This Agreement", states, in pertinent part:

Proposition 65 provides for civil penalties of up to \$2500 per violation per day, pursuant to California Health & Safety Code § 25249.7. In the event that after sixty (60) days following the Effective Date Defendant violates Sections 2 or 9 herein, the Parties stipulate that Defendants shall be liable for a stipulated civil penalty in the amount of \$10.00 per unit item sold in violation of this Consent Judgment, unless the Defendant's actual per unit sale price to the buyer was less than \$10.00, in which case the stipulated penalty shall be fifty percent (50%) of the sale price Defendant received from the relevant buyer for the Products at issue. Total civil penalties concerning all Products sold in violation of this Consent Judgment shall not exceed \$75,000 for such violations in any calendar year. Plaintiff may establish such violation(s) hereunder by a preponderance of the evidence upon a duly noticed motion in the San Francisco Superior Court and subject to the provisions of Section 8 herein.

The violations described above are the results of our testing a small subset of the 239 Products subject to the Judgment. Moreover, it does not appear that Solstice has implemented any on-product or on line warnings scheme whatsoever; therefore, it is statistically probable that further Product testing will establish that a substantial number of additional Products are currently being sold in violation of the Judgment, either for failure to provide warnings or for failure to prevent the California sale of Products causing daily lead exposures above 10 micrograms.

Request to Meet & Confer Regarding Ongoing Violations

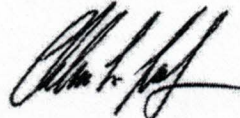
This letter constitutes Plaintiff's formal notice under Paragraph 8.1 of the Judgment, which requires the Parties to "meet and confer within twenty (20) days after any Party receives written notice of an alleged violation of this Consent Judgment from another Party." My client is interested in working out a way to resolve these compliance issues as they relate to all of the 239 Products subject to the Judgment, rather than a more piecemeal approach. To that end, Plaintiff is interested in discussing a bilateral sharing of the Parties' existing test results on all of the Products, and the development of a testing plan for any Products for which such recent testing is not available.

Ms. Mina So, CEO
Richard Egger, Esq.
December 2, 2015
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In the event that our meet and confer efforts cannot resolve the dispute, Plaintiff will enforce the judgment pursuant to Code of Civil Procedure § 664.6 or any other valid provision of law, and if he prevails, shall be awarded his reasonable fees and costs incurred, in addition to any other relief otherwise ordered by the Court, including but not limited to civil penalties. Judgment, Paragraph 8.1.

I am hopeful that we can reach a prompt resolution in the public interest without the need for protracted motion practice, and look forward to discussing these issues with you in the coming weeks.

Very Truly Yours,

A handwritten signature in black ink, appearing to read "Andrew L. Packard", written in a cursive style.

Andrew L. Packard

cc: Stephen D. Gillett

EXHIBIT C

EXHIBIT C

"New Products" Under Second Addendum to the 2008 Consent Judgment in
Gillett v Madison One Acme (dba Solstice Medicine Company);
 SFSC Case No. CGC-07-469239

Item Code	Description
CTL1A	Coltalin Cold Tablet
CTL1K	Coltalin Chewable Tablet
CTL1ND	Coltalin Non-Drowsy Cold Tablet
CTL3DM	Coltalin DM Cold Tablet
EYS1	Bo Ying Compound
FC48DG	Dang Gui Pian
GLCZW	Golden Leaf Brand Cheng Zi
GLKWL	Golden Leaf Brand Kang Wei Ling
GLSTP	Golden Leaf Brand Sci-Tica Herbal Pill
GLYYC	Golden Leaf Brand Fuke Yueyuehong
GW06EX	Yin Chiao Extra Fast
KF1C	Sanjin Watermelon Frost Lozenge
KWC20	Kanyu Drop C20
KWM400	Kanyu Drop M400
KWS	Kanyu Drop S
RKSIB18	Ice Taps Mint
RKS2CK	Kumquat Drop
SHDSP	Fu Fang Dan Shen Pian
SHLSW	Liu Shen Wan
SHSWP	Shou Wu Pian
WSU1L	Weisen 100 ct
WSU1S	Weisen 30 ct
YNBY2CS16	Yunnan Baiyao Capsule
YNBY2CS36	Yunnan Baiyao Tong-shu Capsule
YNBY2PD	Yunnan Baiyao Powder
YNBY3CS	San Qi Capsule
YNBY3PD	San Qi Powder
YNBY3RT	San Qi Slice

EXHIBIT D

EXHIBIT D

Products Causing Exposure to Lead in Excess of 10 µg and Banned From Sale in California under Paragraph 2.4 of the 2008 Consent Judgment in *Gillett v Madison One Acme (dba Solstice Medicine Company)*; SFSC Case No. CGC-07-469239

	Item Code	Description
1.	CLC10	Wu Chi Pai Feng Wan
2.	CLC12	Sap Heung Yuen
3.	CLC13	Ning Kwand Dan
4.	CLC16	Kwai Look Yuen
5.	CML2S	Steamed Tienchi Ginseng Pian
6.	CML3S	Steamed Tienchi
7.	FP3	Ya-Hom
8.	GLCZW	Golden Leaf Brand Cheng Zi Wan
9.	GW01	Jen Shen Lu Yung Wan
10.	GW16	Chin Koo Tien Shang Wan
11.	MS12	Maodungching
12.	MS3	Tang Shen Hair Nourishment
13.	PCP1	Po Chai Pill
14.	TJW	To Jing Wan
15.	TPSPP	Tzepao Sanpien
16.	TRT6	Ren Shen Lu Jung Wan
17.	TRT5	Tong Ren Dahuoluo Dan
18.	TRT10	Shengjing Shuairuo
19.	TRT13	Renshen Jianpi Wan
20.	XA1	Shenling Baizhu
21.	YC7A	Yang Cheng Brand Fargelin
22.	YC9	Zhuang Yao Tonic Wan
23.	YC10	Zhuang Yao Tonic Tablet
24.	YL1	Gejie Da Bu Wan
25.	YL2	Gejie Bu Shing Wan
26.	YL3	Jigucao Wan

EXHIBIT E

CONFIDENTIAL STANDARD OPERATING PROCEDURE

CATEGORY: Warehouse and Post - Distribution		
TITLE: Product Recalls, Corrections, Market Withdrawals, and Stock Recoveries		
DOCUMENT ID : C01	REVISION : 1	EFFECTIVE DATE :
SUPERSEDES DOC ID : C01	REVISION : 0	PAGE 1 of 4

APPROVAL

	Department Head	Quality Unit	Executive Management
Printed Name			
Signature & Date			

File Name: SOP C01.1.doc

1.0 PURPOSE:

To provide guidance on how to recall products in the market that represents an undue public health risk. This procedure defines the responsibilities and minimum guidelines for initiating, conducting, and completing a product recall, correction, market withdrawal, and stock recovery.

2.0 POLICY:

It is the policy of Solstice Medicine Company (SMC) that no product marketed and/or distributed by SMC shall pose a health hazard to the public. Any product that is defective and capable of causing a health hazard shall be immediately recalled or corrected.

3.0 SCOPE:

This procedure applies to all recalls, corrections, market withdrawals, and stock recoveries for products marketed and/or distributed by SMC.

4.0 RESPONSIBILITY:

- The SMC executive management is responsible for making decisions concerning product recalls and corrections.
- The Quality Unit is responsible for ensuring compliance with all provisions of this SOP and maintaining record storage.
- It is the responsibility of the Recall Coordinator to communicate to the customer a potential recall and its progress including sending related reports.

5.0 DEFINITION:

- **Agency:** means the Food and Drug Administration (FDA).
- **Consignee:** means anyone who received, purchased, or used the product being recalled.
- **Correction:** repair, modification, adjustment, re-labeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.
- **Product:** means an article subject to the jurisdiction of the FDA, including any food, drug, or supplement intended for human or animal use.
- **Responsible individual:** includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.
- **Recall type:** a designation based on whether the recall is voluntary, FDA requested (at the request of the Commissioner or his designee), or ordered under section 518(e) of the FD & C Act [21 USC 360h(e)].
- **Market withdrawal:** means SMC's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA, or which involves no violation (e.g. normal stock rotation practices).
- **Stock Recovery:** means SMC removal or correction of a product that has not been marketed or that has not left the direct control of SMC (i.e. the product is located on premises owned by, or under the control of SMC, and no portion of the lot has been released for sale or use).
- **Recall:** SMC's removal or correction of a marketed product that FDA considers to be in violation of the laws it administers, and against which the Agency would initiate legal action (e.g., seizure). Recall does not include a market withdrawal or a stock recovery. See the Agency recall policy outlined in 21 CFR §§ 7.1 through 7.59.
- **Recalling firm:** the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.
- **Recall strategy:** is a planned specific course of action to be taken in conducting a specific recall, which addresses the depth of the recall, need for public warnings, and extent of effectiveness checks for the recall.

CONFIDENTIAL STANDARD OPERATING PROCEDURE

Solstice Medicine Company, 215 W. Ann Street, Los Angeles, CA 90012, www.solsticemed.com, (323) 221-8180, Fax: (323) 221-2448	
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Recall classification: is the numerical designation: I, II, or III; assigned by the FDA to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

- **Class I recall:** is a situation in which there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** is a situation in which use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of adverse health consequences is remote.
- **Class III recall:** is a situation in which use of, or exposure to a violative product is not likely to cause adverse health consequences.
- **Recall Number:** a number assigned by the responsible Center for each recalled product they initiate. This number consists first of a letter designating the responsible Center, a 3-digit sequential number indicating the number of recalls initiated by that Center during the fiscal year, and a 1-digit number indicating the fiscal year the recall was initiated. For example: F-100-9 identifies the 100th recall initiated by the Center for Food Safety and Applied Nutrition in FY-2009.
- **Media Release:** voluntary action taken by industry and coordinated with the FDA to inform the public through electronic and print media about an actual or potential consumer product problem.

6.0 REFERENCE:

- FDA Guidance document on product recalls (www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm)
- 21 CFR Sections 7.1, 7.3 and 7.40 - 7.59
- FDA's Regulatory Procedures Manual, Chapter 7: Recall Procedures (<http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177304.htm>)
- FDA's Investigations Operations Manual, Chapter 7, Recall Activities (<http://www.fda.gov/ICECI/Inspections/IOM/ucm123363.htm>)

7.0 CONTACT INFORMATION:

- Solstice Medicine Company:
 - (24 Hours) 1 – 888 – 221 - 3496
 - Wina So, (323) 221 – 8180 ext. 110
 - Timothy Stewart (208) 724-9032
- USFDA: Los Angeles District Office, (LOS-DO), 19701 Fairchild, Irvine, CA 92612-2506, Fax: 949-608-4401
 - Main Number: (949) 608 – 2900
 - Emergency (after hours): (949) 644 – 7050
 - Recall Coordinator Thanh Tran, thanh.tran@fda.hhs.gov 949-608-3504
 - Recall Coordinator Rochelle Rolnik, rochelle.rolnik@fda.hhs.gov 949-608-4496
 - USFDA: ORA District and Headquarters Recall Coordinators (<http://www.fda.gov/safety/recalls/industryguidance/ucm129334.htm>)
 - California Department of Public Health Headquarters
Food and Drug Branch
1500 Capitol Avenue MS 7602
PO Box 997435
Sacramento, CA 95899-7435

8.0 PROCEDURE:

8.1 Initiating a product recall.

- Solstice Medicine Company (SMC) may freely decide, under any circumstances, to remove or correct any of its distributed products. However, FDA has the ultimate authority to review / approve / modify items such as: recall strategy, communications to the consumer, level of effectiveness checks, frequency of status reports, and where and how recalled product will be stored and destroyed.
- Whenever there is a finding that a marketed product is in violation of the laws administered by the FDA and against which the FDA would take legal action, e.g., seizure, the Chief Executive Officer (CEO) shall initiate a recall of the violative lot(s) of product in accordance with FDA guidelines.
- The CEO shall schedule a meeting of the Recall Committee consisting of the Quality Unit, the Chairman, Company Manager, SafetyCall International and other individuals whose functions or input would facilitate the decision making and implementation of an expedient and effective recall. The committee shall:
 - Identify the product(s) involved.
 - Discuss the reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.

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- Evaluate the probability of other lots or other products involved. What is the total amount of effected products produced? During what production time span? How much is estimated to be in distribution channels?
- Evaluate the health hazard or risk presented by the product in accordance with 21 CFR § 7.41.
- Determine the classification from the following:
 - Class I recall
 - Class II recall
 - Class III recall
 - Market withdrawal
 - Stock recovery

8.2 The recall committee is responsible for developing a recall strategy in accordance with 21 CFR Sections 7.42, 7.45, 7.46, 7.49, 7.53 and 7.55, as appropriate, including:

- Determination of the depth of the recall (i.e. wholesale, retail, or consumer level) in accordance with 21 CFR § 7.42(b)(1).
- Determine the amount production and the amount of unused product remaining in the marketplace.
- Determination of the method of notification in accordance with 21 CFR § 7.49. Promptly notify each affected consignee about the recall. The format, content, and extent of this recall communication should be commensurate with the hazard of the product and the strategy developed for the recall. The recall notification should communicate those items found at (<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>) including but not limited to the following:
 - Product information.
 - Codes.
 - Recalling firm.
 - Manufacturer.
 - Identify firm responsible for the violation/problem.
 - Reason for the recall.
 - Health hazard assessment.
 - Volume of recalled product.
 - Distribution pattern.
 - Recall strategy.
- Determination of whether or not a public warning is necessary and, if it is, the method of public warning, in accordance with 21 CFR § 7.42 (b)(2). Public warnings are generally reserved for urgent situations where other means for preventing use of the recall product would be inadequate. The FDA will ordinarily issue publicity notices. SMC issued public notices must be coordinated through FDA.
- Determination of what is to be done with the recalled product.
- Determination of the level and method of effectiveness checks in accordance with 21 CFR § 7.42 (b) (3).
- In the event of a Class I or II recall, SMC will submit a proposed recall strategy and mode of communication to the district office for review and approval. No activities will be carried with regard to the distribution chain until FDA has approved SMC recall strategy. FDA will determine how the recalled product will be stored, were it will be stored, level of effectiveness checks and how it will be disposed of.
- SMC CEO will select a Recall Coordinator to assure that the recall strategy is carried out. This person must be very familiar with the requirements of 21 CFR Sections 7.1, 7.3, and 7.40 through 7.59 as well as have a thorough understanding SMC's documentation system.
- The selected individual will be the principal contact with the FDA concerning the recall (preferably the Quality Unit Director or a senior manager designated Recall Coordinator).

8.3 If SMC initiates a recall, the person chosen as the Recall Coordinator or principal FDA contact shall:

- Immediately notify the local Food and Drug Administration District Recall Coordinator, by phone and in writing in accordance with 21 CFR § 7.46 (a) and FDA's Guidance for Industry: Product Recalls, Including Removals and Corrections (<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>).
- Notify the local State of California Department of Public Health Services, Food and Drug Branch office by phone and in writing (see section 7.2.6).
- The recall correspondence is always a first class letter, with both letter and envelope conspicuously marked in bold red type "FOOD DRUG, COSMETIC, DIETARY SUPPLEMENT or MEDICAL DEVICE (as appropriate) RECALL or CORRECTION" (as appropriate). Class I and Class II recalls must have the letter and envelope marked "URGENT". The letter and envelope for a Class III recall may be marked "URGENT" if required by FDA.

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8.4 In the case of a voluntary decision or an FDA request, SMC recall committee provides the following information to the FDA (see section 8.1 and Section A of Guidance for Industry: Product Recalls, Including Removals and Corrections (<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>).

8.5 The Recall Committee shall meet as many times as necessary to effectively implement the recall.

- The Recall Coordinator shall provide the members of the Recall Committee with status reports at two week intervals, in accordance with 21 CFR § 7.53(b). He shall provide the FDA with status reports in accordance with 21 CFR § 7.53 at the intervals requested by the FDA. Recall status reports are to be discontinued when the recall is terminated by the FDA.

8.6 Unless otherwise specified by FDA, the recall status report contains the following information:

- Number of consignees notified of the recall and the date(s) when the correspondence / communication were sent.
- Number of consignees who have responded to the notification and the quantity of product stocked.
- Number of consignees who have not responded to the notification.
- Quantity of product returned or disposed of by each consignee.
- Total quantity of product accounted for.
- Number and results of effectiveness checks performed.
- Estimated time frame for completion of the recall.

8.7 Effectiveness checks.

- Effectiveness checks must be conducted to verify that all consignees of the recall have received notification and have taken appropriate action. (Class I and II are set by FDA, Class III SMC effective check is 10%).
- The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, e-mails, or a combination thereof. All such contacts must be documented.
- FDA reserves the right to assist in this task.
- The recall strategy will determine and specify the method(s) to be used and the level of effectiveness checks conducted unless otherwise given by FDA (i.e. Class I and II). SMC levels are as follows:
 - Level A – 100% of the total number of consumers are to be contacted (if possible).
 - Level B – a percentage greater than 10% and less than 100% of the total number of consumers are to be contacted.
 - Level C – 10% of the total consumers are to be contacted.
 - Level D – 2% of the total consumers are to be contacted.
 - Level E – No effectiveness checks are required.

8.8 Completion or termination of a product recall.

- A recall will terminate when the FDA determines that all reasonable efforts have been made to remove or correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recall product. Written notification that a recall is terminated will be issued by FDA.
- SMC may request termination of a recall by submitting a written request to the appropriate FDA district office stating that the recall is effective in accordance with the criteria agreed upon, and by accompanying the request with the most current recall status report and a description of the disposition of the recalled product.
- FDA will notify SMC by written correspondence as to its decision to terminate the recall. If the recall cannot be considered terminated, the correspondence will indicate any activities that must be performed prior to termination.
- All pertinent records of a product recall must be maintained by SMC for a minimum of seven years.

9.0 MOCK RECALL:

- Conduct a mock recall periodically to test traceability (consignee) and track-ability (supplier) of product lots for effective recall following SOP guidelines.
- A product for recall will be identified by the Recall Coordinator and organized with the consignee representatives who will be involved in the mock recall process.
- Recall should be completed in 24 hours.
- 100% of product should be accounted for.
- A Mock Recall Summary Report will be prepared and reviewed by management.

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10.0 REVISION HISTORY:

REVISION #	REASON	DATE	MODIFICATION
0	New document	12/21/2012	none
1	periodic review	6/30/2015	minor text