

Report of Judgment to the Attorney General of a Proposition 65 Claim

As You Sow v. Irwin Naturals, Inc., Case No. 429279

THE CONSENT JUDGMENT ENTERED BY THE COURT PROVIDES:

1. Permanent Prohibition: No Product may be shipped by Defendant Irwin Naturals, Inc. for sale in the State of California after sixty (60) days following the Effective Date if, when used or consumed in accordance with the Defendant's label directions, it causes an exposure to lead in excess of 14 micrograms/day. (Par. 2.4 of the Consent Judgment)
2. Product Testing: Irwin Naturals will test each product (or all of each product's ingredients) listed in Attachment A of the Consent Judgment for Lead, Arsenic, Cadmium and Mercury. (Section 2.1 of the Consent Judgment)
3. Warnings (Section 2.2 of the Consent Judgment):
 - a. Package warnings: Irwin Naturals will not sell products that contain Lead, Arsenic, Cadmium or Mercury in excess of the amounts listed in Paragraphs 2.3.1-2.3.4 of the Consent Judgment without providing a clear and reasonable warning to consumers as set forth in the Consent Judgment.
 - b. Mail-order and Internet warnings: Irwin Naturals will not sell products that contain Lead, Arsenic, Cadmium or Mercury in excess of the amounts listed in Paragraph 2.3.1-2.3.4 of the Consent Judgment without providing a clear and reasonable warning to consumers as set forth in the Consent Judgment.
4. Civil Penalties: Pursuant to Health & Safety Code § 25249.7(b), Irwin Naturals will pay \$5,000 in civil penalties. (Par. 3.2 of the Consent Judgment). If Irwin Naturals violates the terms of the Consent Judgment, it shall be liable for a stipulated civil penalty in the amount of \$5.00 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 \$5.00, 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 \$70,000 for such violations in any calendar year. (Par. 3.1 of the Consent Judgment).
5. Payment in Lieu of Civil Penalties: Irwin Naturals will pay \$55,300 to As You Sow, which shall forward these funds to (a) California non-profit groups; and (b) the AYS Foundation Environmental Enforcement Fund; these 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. (Par. 3.3 of the Consent Judgment)
6. Payment of AYS' Investigation & Legal Fees: Irwin Naturals has agreed to pay AYS' reasonable investigation, expert and attorney's fees and costs in the amount of \$59,700. (Par. 4.1 of the Consent Judgment)

1 ANDREW L. PACKARD (State Bar No. 168690)
2 MICHAEL P. LYNES (State Bar No. 230462)
3 Law Offices of Andrew L. Packard
4 294 Page Street
5 San Francisco, CA 94102
6 Tel. (415) 431-2970
7 Fax. (415) 431-0410
8 Attorneys for Plaintiff
9 AS YOU SOW

ENDORSED
FILED
San Francisco County Superior Court

JUN 30 2005

GORDON PARK-LI, Clerk
BY: S. PENG
Deputy Clerk

SUPERIOR COURT OF THE STATE OF CALIFORNIA

CITY AND COUNTY OF SAN FRANCISCO – UNLIMITED JURISDICTION

11 AS YOU SOW, a non-profit corporation,
12 Plaintiff,

13 vs.

14 IRWIN NATURALS, GENERAL RESEARCH
15 LABORATORIES, INC., ROBINSON
16 PHARMA, INC., and DOES 3 through 20,
inclusive,

17 Defendants.

Case No. 429279

~~PROPOSED~~ CONSENT JUDGMENT

18
19 This Consent Judgment is entered into by and between AS YOU SOW, a non-profit
20 organization (“Plaintiff” or “AYS”), and Irwin Naturals (“Defendant” or “IRWIN”). Defendant
21 is a California corporation in good standing. This Consent Judgment shall be effective upon entry
22 (the “Effective Date”) by the court. Plaintiff and Defendant (each a “Party” and collectively, “the
23 Parties”) agree to the terms and conditions set forth below.

24 1. INTRODUCTION

25 1.1 AYS is a Section 501(c)(3) non-profit foundation dedicated to, among other
26 causes, the protection of the environment, the promotion of human health, the improvement of
worker and consumer rights, environmental education, and corporate accountability. AYS is

[PROPOSED] CONSENT JUDGMENT

1 based in San Francisco, California and incorporated under the laws of the State of California.
2 AYS is a corporation in good standing.

3 **1.2** Defendant directly or indirectly sells to California consumers certain herbs, herbal
4 products, traditional patent medicines (defined as “herbal and patent medicines consisting of
5 single or multiple herbal ingredients, including botanical, mineral and animal products,
6 formulated into tablets, capsules, pills, powders and liquids”), bulk herbs, infusions, extracted
7 powders, tea pills, traditional pills, patent formulas, teas, bulk teas, liquid herbal extracts and/or
8 capsules (the “Products”), all of which AYS alleges contain chemicals listed by the State of
9 California as known to cause cancer and/or reproductive toxicity pursuant to the Safe Drinking
10 Water and Toxic Enforcement Act of 1986 (“Proposition 65”), California Health and Safety Code
11 § 25249.5 et seq.; Title 22, California Code of Regulations § 12000 et seq. For purposes of this
12 Consent Judgment only, each of the Products is deemed to be a “food” within the meaning of
13 Title 22, California Code of Regulations § 12501.

14 **1.3** The specific Products covered by this Consent Judgment as of the Effective Date
15 are set forth in Exhibit A hereto. Any products not set forth in Exhibit A hereto are not covered
16 by the injunctive provisions herein, except as specifically provided in Section 9: *New Products*,
17 and are not covered by the release of liability set forth in Section 6 herein.

18 **1.4** Pursuant to Health & Safety Code § 25249.8: (a) on February 27, 1987, the State
19 of California listed the chemical lead as a chemical known to cause reproductive toxicity; (b) on
20 October 1, 1992, the State of California listed the chemicals lead and lead compounds as
21 chemicals known to cause cancer; (c) on July 1, 1990 the State of California listed the chemicals
22 mercury and mercury compounds as chemicals known to cause reproductive toxicity; (d) on
23 February 27, 1987, the State of California officially listed the chemical arsenic as a chemical
24 known to cause cancer; (e) on May 1, 1997, the State of California officially listed the chemical
25 arsenic as a chemical known to cause reproductive toxicity; (f) on October 1, 1987, the State of
26 California officially listed the chemicals cadmium and cadmium compounds as chemicals known
to cause cancer; (g) on May 1, 1997, the State of California officially listed the chemical

1 cadmium as a chemical known to cause reproductive toxicity. For purposes of this Consent
2 Judgment, the foregoing chemicals as listed under Proposition 65 shall be the "Metals".

3 **1.5** Beginning on December 23, 2003, AYS began serving Defendant and each of the
4 appropriate public enforcement agencies with "60-Day Notices" that provided Defendant and the
5 public enforcement agencies with a notice alleging that Defendant was in violation of Proposition
6 65 for failing to warn the purchasers and individuals using the Products that the use of the
7 Products exposes them to certain chemicals known to the State of California to cause cancer
8 and/or reproductive toxicity (each, a "60-Day Notice"). A copy of each such 60-Day Notice
9 issued to Defendant is attached hereto as Exhibit B. AYS served an additional 60-Day Notice on
10 or about April 8, 2005, a copy of which has been filed and served with AYS' Motion for
11 Approval & Entry of Consent Judgment. (See Section 7 hereinbelow). Defendant stipulates for
12 the purpose of this Consent Judgment that the 60-Day Notice or 60-Day Notices sent to it are
13 adequate to comply with Title 22, California Code of Regulations §12903.

14 **1.6** On March 3, 2004, AYS filed a Complaint (the "Action") in San Francisco
15 Superior Court, alleging violations of Proposition 65 and California Business and Professions
16 Code § 17200 et seq.

17 **1.7** AYS brings the Action in the public interest. AYS has provided 60-Day Notice(s)
18 to Defendant and the appropriate public enforcement agencies and none of the public enforcement
19 agencies has commenced and begun diligently prosecuting an action against Defendant for such
20 alleged violations.

21 **1.8** For purposes of this Consent Judgment, each Party stipulates that venue is proper
22 and that this Court has subject matter jurisdiction over the allegations contained in the Action and
23 to enter this Consent Judgment as a full and final resolution of all causes of action pled, or which
24 could have been pled based on the facts alleged in the Action. The Parties enter into this Consent
25 Judgment to settle disputed claims between them and to avoid prolonged litigation. By execution
26 of this Consent Judgment, Defendant does not admit any violations or the applicability of

Proposition 65 or the Business and Professions Code, or any other law or standard applicable to

1 warning or disclosure concerning the manufacture, distribution and/or sale of the Products.
2 Except for the representations made above, nothing in this Consent Judgment shall be construed
3 as an admission by Defendant or Plaintiff of any fact, issue of law, or violation of law, nor shall
4 compliance with this Consent Judgment constitute or be construed as an admission by Defendant
5 or Plaintiff of any fact, issue of law, or violation of law.

6 1.9 Except as expressly provided herein, nothing in this Consent Judgment shall
7 prejudice, waive or impair any right, remedy or defense the Parties may have in any other or
8 further legal proceeding. This paragraph shall not diminish or otherwise affect the obligations,
9 responsibilities, and duties of any Party to this Consent Judgment.

10 2. INJUNCTIVE PROVISIONS

11 2.1 **Defendant's Duty To Ascertain The Metals Content of The Products On Or**
12 **Before Sixty Days Following the Effective Date.** On or before sixty (60) days following the
13 Effective Date, Defendant shall ascertain the concentration of Metals in each of the Products as
14 follows.

15 2.1.1 **Lead, Arsenic And Cadmium Testing Protocol.** In accordance with
16 Sections 2.1.5 and 2.1.6, to ascertain a Product's concentration of lead, arsenic and cadmium,
17 respectively, Defendant shall test the Product (or rely on testing of the Product by others provided
18 it is undertaken in the manner set forth herein), using inductively coupled plasma mass
19 spectrometry ("ICP-MS") under the protocol set forth in EPA Method 6020.

20 2.1.2 **Mercury Testing Protocol.** In accordance with Section 2.1.5, to ascertain
21 a Product's concentration of mercury, Defendant shall test the Product (or rely on testing of the
22 Product by others provided it is undertaken in the manner set forth herein) using the protocol set
23 forth in EPA Method 7471A (including, at Defendant's option, conformity with EPA Method
24 3052), or the protocol set forth in EPA Method 7473, or the protocol set forth in EPA Method
25 6020.

26 2.1.3 **Additional Testing Protocols.** In the event that equally or more accurate
testing methods are developed or identified and accepted by the scientific community as accurate

1 enough to allow for detection and quantification of any Metal to ascertain compliance under this
2 Consent Judgment, any Party shall have the right to move the court to modify this Consent
3 Judgment as set forth in Section 8 herein, to allow testing by such equally or more accurate
4 testing method in addition to the methods authorized herein.

5 **2.1.4 Approved Laboratories.** Product or raw material testing may be
6 undertaken at Defendant's in-house laboratories or by third-party testing laboratories; however,
7 all third-party laboratory testing shall be performed only at laboratories that are certified,
8 accredited, or registered by a federal or California state agency, including but not limited to the
9 U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, or the California
10 Department of Health Services for the purposes of administering the specific protocol used in
11 such testing. If a given agency does not certify specific protocols for testing for Metals in dietary
12 supplements, the certification, accreditation or registration customarily bestowed upon
13 laboratories testing dietary supplements or ingredients in dietary supplements for Metals in
14 accordance with that agency's standards shall be required; if no such agency standards exist
15 specifically for dietary supplements, then the standards for foods shall be required.

16 **2.1.5 Sampling Protocol For Ascertaining Metals Content.** In fulfilling its
17 duty to ascertain the concentration of each Metal in each Product, Defendant may at its option,
18 test (or rely on testing of the Product by others) Representative Samples of the finished Products,
19 or test (or rely on testing of raw materials by others) Representative Samples of each of the raw
20 materials comprising the finished Product(s). Any results relied upon must use the analytical
21 methods and sampling requirements specified herein, except that a Defendant (or a laboratory
22 conducting tests for Defendant) may modify or adjust an analytical method if necessary to ensure
23 accurate results in light of the nature, composition, quantity, or other characteristic of the test
24 specimen, the nature of the test, or the specific equipment being used to conduct the test so as to
25 enhance the quality and reliability of the test results. If Defendant (or a laboratory conducting
26 tests for Defendant) modifies or adjusts any analytical method specified in this Consent

Judgment, in the event of an enforcement action by AYS under this Consent Judgment contesting

1 such modification or adjustment, Defendant shall bear the burden of showing by a preponderance
2 of the evidence that the modification or adjustment was (a) necessary, appropriate and reasonable
3 under the circumstances; and (b) fully consistent with generally accepted scientific principles and
4 practices concerning analytical testing and test methods for Metals in foods, including dietary
5 supplements.

6 **2.1.6 Representative Sampling.**

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

17 **(b) Raw Materials.** "Representative Sampling" as used herein shall mean
18 with respect to the testing of raw material, testing of one (1) sample from the most recent
19 shipping lot received by Defendant of each raw material comprising the Product, provided that
20 the one sample actually tested is a composite of three (3) or more samples from the most recent
21 shipping lot of that raw material. Each of the three (3) or more raw material samples which
22 comprise the composite sample actually tested shall be equal to the other samples.

23 **(c) First Two Year's Frequency of Sampling.** During each of the two years
24 after the Effective Date, for purposes of documenting compliance with Sections 2.2, 2.4 and 9 of
25 this Consent Judgment after sixty (60) days from the Effective Date, Defendant shall conduct (or
26 have conducted on its behalf) Representative Sampling meeting the definition of either Section
2.1.6(a) or 2.1.6(b), or any combination of the two, as Defendant shall elect in its sole discretion.

1 The Parties agree that Representative Sampling shall for the first two years after the Effective
2 Date mean the testing either of (1) each Manufacturing Lot of a finished Product pursuant to
3 2.1.6(a), or (2) each raw material comprising a finished Product, or (3) any combination of the
4 two, provided Defendant has laboratory test data with respect to each Product Defendant ships for
5 sale to California between the Effective Date and the second anniversary of the Effective Date.

6 (d) Sampling Frequency After Second Anniversary of Effective Date. After
7 the second anniversary of the Effective Date, Defendant shall conduct (or have conducted on its
8 behalf) Representative Sampling on raw materials or finished Products, as the case may be, but
9 Defendant may adjust the frequency of the sampling regime set forth in Section 2.1.6(c). Any
10 adjustments to the sampling regime shall be sufficient to allow Defendant to continue to
11 accurately determine levels of Metals in Products or in raw materials. Any adjustments to the
12 sampling regime shall be based upon Defendant's consideration of the following factors: (i)
13 existing data, (ii) the variability of Metals levels in a raw material or in a Product, as documented
14 through testing, (iii) the predictability of the distribution of the range of Metals levels in a raw
15 material, based on prior laboratory test data, (iv) the amount of a raw material used in a finished
16 Product, and (v) other relevant considerations. In any proceeding to enforce this Consent
17 Judgment, Defendant bears the burden of showing by substantial evidence that any testing regime
18 adopted under this Section 2.1.6(d) is reasonable and is sufficient to accurately determine Metals
19 levels in raw materials or finished Products. This Section 2.1.6(d) governs the frequency of
20 sampling, and does not alter the definitions of Representative Sampling set forth in Sections
21 2.1.6(a), (b), or (c) the testing protocols set forth herein. Defendants are not limited to providing
22 only Representative Sampling data to Plaintiff in the event Plaintiff conducts compliance
23 monitoring under Section 2.1.7 or otherwise moves to enforce this Consent Judgment.

24 **2.1.7 Compliance Monitoring.** At any time following 60 days after the
25 Effective Date, AYS may request that Defendant provide, within thirty-five (35) days of the date
26 of its request, documentation supporting the sale in California of any Product without the health
hazard warnings specified in this Consent Judgment. For the first three years after the Effective

1 Date, such requests may be made with respect to as many as twenty-five (25) percent, annually,
2 of the number of Products listed on Defendant's then current Product list, up to a maximum of
3 thirty (30) requests in total for up to thirty (30) different Products in a year. For subsequent years
4 four and five after the Effective Date, AYS may request information on no more than ten (10)
5 percent, annually, of the number of Products listed on Defendant's then current Product list, up to
6 a maximum of twelve (12) requests in total for up to twelve (12) Products in a year. After the
7 fifth year after the Effective Date, AYS shall not be entitled to request information pursuant to
8 this Section 2.1.7, unless a violation of this Consent Judgment previously was established within
9 the three years preceding the date of the AYS request, in which case AYS shall be entitled to
10 tender up to twelve (12) requests in total for information respecting up to twelve (12) different
11 Products for up to one more year after the date of the AYS request. With respect to each Product
12 for which any request under this Section 2.1.7 is made, the Defendant shall provide a declaration
13 from the persons responsible for the testing, verifying quality assurance and quality control
14 procedures, and verifying that the testing was conducted in strict accord with Section 2.1. For
15 any Product for which AYS' request for such documentation is not provided within sixty (60)
16 days of the date of the request, such Product will be deemed sold in violation of this Consent
17 Judgment as to all sales in California of that Product after the date of AYS' request through the
18 date upon which such documentation is received by AYS and therefore will be subject to the
19 provisions of Section 3.1 (Civil Penalties) herein; provided, however, that Defendant's mere
20 contesting of any assertion by AYS concerning inadequacies in the documentation produced to
21 AYS shall not, in and of itself, be deemed a violation of this Section 2.1.7. For AYS to establish
22 a violation of this Section, the documentation provided or other documentation must show that a
23 health hazard warning was required under this Consent Judgment. Violations of this Section 2.1.7
24 may be enforced as specified hereinbelow and are not exclusive of other remedies, if any,
25 available to Plaintiff.

26 **2.1.8 Limited Exemptions from Testing.** Defendant need not test (or have
tested on its behalf) excipients, fillers, flavors, colors or binders ("Standardized Ingredients") if it

1 reasonably and in good faith believes such Standardized Ingredients do not contain Metals at
2 levels that might cause or contribute to a violation of this Consent Judgment. Defendant's good
3 faith belief shall be based on periodic laboratory test data, vendor certifications, or other such
4 reasonable and appropriate information including consideration of the reliability and consistency
5 of the supplier, the nature of the ingredient, the amount used and other relevant factors.

6 Defendant periodically shall monitor and evaluate such Standardized Ingredients for Metals
7 levels. In the event that AYS should move to enforce this Consent Judgment, Defendant bears
8 the burden of establishing by a preponderance of evidence that any failure to test an excipient,
9 filler, flavor, color or binder for Metals content was reasonable and in good faith, and must
10 produce all such supporting evidence in the context of the meet and confer process concerning
11 enforcement of this Consent Judgment contemplated under Section 8.1 herein. Defendant's
12 failure to test an excipient, filler, flavor, color or binder for Metals content, in the absence of a
13 reasonable and good faith belief that such ingredient does not contain Metals at levels that might
14 cause or contribute to a violation of this Consent Judgment, shall constitute a material breach of
15 this Consent Judgment and be subject to stipulated civil penalties as provided for herein if such
16 failure to test causes or contributes to a failure to provide a warning when required under Section
17 2.2 or causes or contributes to a violation of Section 2.4 of this Consent Judgment.

18 **2.1.9 Product or Ingredient Specifications.** On or before the date that is sixty
19 (60) days after the Effective Date, Defendant shall establish, at its option, either: (a) specifications
20 for the Metals content of all raw materials used in the Products, or (b) specifications for the
21 Metals content in finished Products. Defendant shall not use raw materials which fail to meet the
22 Metals specifications Defendant established for raw materials used in the manufacture of
23 Products. Defendant shall not ship for sale or use in California Products which fail to meet
24 Defendant's specifications for Metals content in finished Products, unless such Products meet all
25 terms of this Consent Judgment, including the warning obligations in Section 2 and Section 9.
26 Defendant may from time to time adjust specifications for raw materials or for finished Products.

2.2 Provision of Clear and Reasonable Warnings.

1 **2.2.1 On-Product Warnings.** On or before the date that is sixty (60) days
2 following the Effective Date, Defendant shall permanently cease and no longer ship for sale or
3 use in California any Products (as defined in Sections 1.2, 1.3 and 9.1) which require a warning
4 under the terms of this Consent Judgment, unless each individual Product (in the form intended
5 for sale to the end-user) bears one of the warning statements specified below on its individual unit
6 label or packaging:

7 (a) If use or consumption of the Product in accordance with Defendant's label
8 directions results in an exposure exceeding 10.0 micrograms/day of arsenic, but
9 otherwise would not require a warning under this Consent Judgment, then the
10 warning shall state:

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

13 (b) If use or consumption of the Product in accordance with Defendant's label
14 directions results in an exposure exceeding 10.0 micrograms/day of arsenic, and
15 exceeding any of the levels set for lead, mercury, or cadmium in this Consent
16 Judgment, then the warning shall state:

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

20 (c) If use or consumption of the Product in accordance with Defendant's label directions
21 results in an exposure that does not exceed 10.0 micrograms/day of arsenic, but
22 that does exceed any of the levels set for lead, mercury, or cadmium in this
23 Consent Judgment, then the warning shall state:

24 **WARNING: The use of this product will expose you to chemicals known to**
25 **the State of California to cause birth defects or other reproductive harm.**(d)
26

The warning statement shall be prominent and displayed on the label or packaging

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

2.2.2 Additional Warnings Concerning Mail Order & Internet Sales. If a Defendant sells a Product that requires a warning under this Consent Judgment, by mail order or over the Internet to a purchaser in the State of California on or after the date that is sixty (60) days after the Effective Date, the following additional requirements shall apply. For such mail order sales, the warning language required under this Consent Judgment shall be included in the mail order catalogue, either on the same page as any order form, or on the same page(s) upon which the Product's price is listed, in the same type size as the surrounding, non-heading text (this requirement shall be applicable only to all catalogues printed after the Effective Date). For such Internet sales, the warning language required under this Consent Judgment shall be displayed (in the same type size as the surrounding, non-heading text) either: (a) on the same page upon which the Product is displayed or referenced; (b) on the same page as any order form for any Product; or (c) on the same page as the price for the Product is displayed.

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

2.3.1 For Lead Warnings, Exposure Below "No Observable Effect Level." Use or consumption of a Product causes total daily exposure¹ to lead of less than 0.5 micrograms when consumed or used in accordance with the Defendant's label directions, excluding any naturally occurring lead, as defined for purposes of this Consent Judgment in Section 2.3.2 ("Naturally Occurring Lead"), in such Product. Prior to shipment for sale to California

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....").

1 consumers, Defendant shall provide consumer use instructions on the label or packaging of each
2 individual Product (in the form intended for sale to the end-user). If the consumer use
3 instructions include a range of consumption levels (e.g., "take 2 to 4 tablets daily"), then for
4 purposes of compliance with Sections 2.2, 2.4, 9 and otherwise under this Consent Judgment, the
5 highest dose instructed shall be the dose.

6 **2.3.2 "Naturally Occurring" Allowance For Lead for Products Shipped for**
7 **Sale After Sixty Days Following The Effective Date.**

8 (a) **Initial Naturally Occurring Lead Level.** Unless a Product contains a
9 warning in compliance with this Consent Judgment, the initiall Naturally Occurring Lead level in
10 any Product subject to this Consent Judgment Defendant ships for sale or use in California after
11 the date that is sixty (60) days following the Effective Date, shall not exceed a concentration that
12 will result in 3.5 micrograms lead ingested/day, assuming the Product is used or consumed in
13 accordance with the Defendant's consumer use instructions. Products where the concentration
14 results in lead levels that exceed (i) this initial 3.5 micrograms ingested level, or (ii) Products
15 which exceed any future Naturally Occurring Lead level subsequently established pursuant to this
16 Consent Judgment, (plus, in either the case of (i) or (ii) an additional 0.5 micrograms Lead as
17 allowed by regulation and under Section 2.3.1), shall be subject to the warning requirements set
18 forth in Sections 2.2.1, 2.2.2, and 9 herein, unless Defendant can show by a preponderance of the
19 evidence that all lead in such Products (except 0.5 micrograms ingested in a daily dose) is
20 naturally occurring per 22 Cal. Code Reg. § 12501. If Defendant in the future elects to make this
21 showing that more than 3.5 micrograms of lead is naturally occurring, Defendant agrees to
22 provide all evidence supporting such a showing to AYS in the context of the meet and confer
23 process concerning enforcement of this Consent Judgment contemplated under Section 8.1 herein.
24 Defendant's failure to produce this information or Defendant's failure to establish to the Court
25 that lead in excess of 0.5 micrograms in a daily dose, plus Naturally Occurring Lead, is naturally
26 occurring under the criteria in 22 Cal. Code Reg. § 12501 shall constitute a material breach of this

Consent Judgment and be subject to stipulated civil penalties as provided for herein if a Product

1 which requires a health hazard warning under this Consent Judgment was sold in California
2 without such warning. Nothing in this Section 2.3.2 constitutes a waiver of Defendant's right to
3 establish, in accordance with the procedures set forth in Sections 2.3.2 and 8.1, that levels of
4 Metals other than lead are naturally occurring under the criteria of 22 Cal. Code Reg. § 12501.
5 The Parties agree that the initial 3.5 micrograms Naturally Occurring Lead level is the result of
6 negotiations and a review of the available information and shall be applicable to the Products
7 subject to this Consent Judgment at this time and shall have no application to other products.

8 **(b) Evaluation of Future Naturally Occurring Lead Levels.** In recognition of
9 the possibility that the "lowest level feasible" of Lead may change over time, the Parties agree to
10 evaluate the Naturally Occurring Lead level annually for five (5) years as set forth below.
11 Commencing January 15, 2006 and ending January 15, 2011 for each year Defendant shall tender
12 a statement of determination whether an adjustment to the Naturally Occurring Lead level can be
13 supported by substantial evidence. Such a determination respecting the Naturally Occurring Lead
14 level shall be made by Defendant in good faith and be based on Representative Sampling and
15 "Feasibility." "Feasibility" for purposes of this Consent Judgment shall mean consideration of
16 the following: (1) the availability and reliability of a supply to Defendant of raw materials in
17 question; (2) the reasonable cost to Defendant of Products or raw materials therein; (3) any
18 resulting unreasonable increase in cost to a Defendant to procure a Product or raw materials with
19 lower levels of lead; (4) performance characteristics, including formulation, performance, safety,
20 taste, efficacy and stability, of any raw materials or finished Product; (5) the lawfulness of
21 alternatives (no alternative shall result in a violation of law, or a breach of a standard of identity);
22 and (6) other relevant and reasonable considerations. If upon determination of either Party a
23 change is warranted, then that Party within sixty (60) days of the statement date shall proceed to
24 modify this Consent Judgment in accordance with Section 8 herein. Defendant's obligations
25 under this Section 2.3.2(b) are without prejudice to any rights of Plaintiff under Section 8 or
26 otherwise herein. If either Party seeks to modify the initial or any subsequently established
Naturally Occurring Lead level as defined herein, such modification shall only be effective upon

1 an order by the Court, after a noticed motion, notice of which motion shall be served on the
2 Office of the Attorney General at least forty-five (45) days prior to the hearing date, and which
3 motion shall include the information supporting the request for modification.

4 **2.3.3 Conditions Under Which “Naturally Occurring” Allowance For Lead**
5 **Applies.** For purposes of compliance with Section 2.2, Defendant shall exclude that amount of
6 lead specified in Section 2.3.2, provided Defendant has not intentionally or unintentionally added
7 any lead to a Product and Defendant has done or caused to be done all of the following: (a) used,
8 or required the manufacturer of the Product to use, “Good Manufacturing Practices,” as defined in
9 Exhibit C hereto in connection with each ingredient in the Product and with the Product; (b) used
10 or, if Defendant is purchasing an ingredient used in a Product directly from the grower of that
11 ingredient, required the grower to use, in those instances where Defendant has the commercially
12 reasonable ability to do so, Good Agricultural Practices; (c) used, at all times relevant to the
13 production of the Product, quality control measures that reduce natural chemical contaminants to
14 the “lowest level currently feasible,” as that phrase is used in Title 21 Code of Federal
15 Regulations, Section 110.110(c) (2001). If the United States Food & Drug Administration adopts
16 Good Manufacturing Practices (“GMPs”) regulations applicable to Defendant’s dietary
17 supplement manufacturing, then Defendant, as of the effective date of those federal regulations,
18 shall proceed under such new regulatory GMPs (or require the manufacturer of the Products to
19 proceed under same) in lieu of the obligations set forth on Exhibit C within thirty (30) days of
20 such adoption.

21 **2.3.4 Stipulated Exposure Levels Triggering Warning Requirements For**
22 **Arsenic, Cadmium and Mercury.** Prior to shipment for sale to California consumers,
23 Defendant shall provide consumer use instructions on the label or packaging of each individual
24 Product (in the form intended for sale to the end-user). If the consumer use instructions include a
25 range of consumption levels (e.g., “take 2 to 4 tablets daily”), then for purposes of compliance
26 with Sections 2.2 and 9 and otherwise under this Consent Judgment, the highest dose instructed
shall be the dose. For arsenic, cadmium and mercury, the health hazard warnings set forth in

1 Section 2.2.1 shall be required if use or consumption of a Product in accordance with Defendant's
2 label directions results in an exposure exceeding any of the following levels: (a) (1) mercury and
3 mercury compounds, except inorganic mercury, 0.30 micrograms/day; (2) inorganic mercury, 3.0
4 micrograms/day; (b) cadmium, 4.10 micrograms/day; (c) arsenic, 10.0 micrograms/day. For
5 purposes of this Consent Judgment, and in the absence of knowledge to the contrary on the part of
6 Defendant, Defendant shall presume that all mercury in a Product is not inorganic mercury and
7 therefore is subject to the standard in 2.3.4(a)(1) unless Defendant, through laboratory testing and,
8 if applicable, other relevant information, establishes that a Product contains only inorganic
9 mercury, in which case that Product shall be subject to the standard in 2.3.4(a)(2). Records
10 supporting Defendant's determination respecting inorganic mercury content in a Product shall be
11 provided to Plaintiff in accordance with Defendant's obligations under Section 2.1.7, Section 8
12 and Section 9.1.

13 **2.4 Ban on Sales of Products Causing Exposures to Lead in Excess of 14**
14 **Micrograms Per Day.** No Product may be shipped by Defendant for sale in the State of
15 California after sixty (60) days following the Effective Date if, when used or consumed in
16 accordance with the Defendant's label directions, it causes an exposure to lead in excess of 14
17 micrograms/day.

18 **3. CIVIL PENALTIES**

19 **3.1 Stipulated Civil Penalties For Future Violations of This Agreement.**
20 Proposition 65 provides for civil penalties of up to \$2500 per violation per day, pursuant to
21 California Health & Safety Code § 25249.7. In the event that after sixty (60) days following the
22 Effective Date, Defendant violates Sections 2 or 9 herein, the Parties stipulate that Defendant
23 shall be liable for a stipulated civil penalty in the amount of \$5.00 per unit item sold in violation
24 of this Consent Judgment, unless the Defendant's actual per unit sale price to the buyer was less
25 than \$5.00, in which case the stipulated penalty shall be fifty percent (50%) of the sale price
26 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 \$70,000 for

1 such violations in any calendar year. Plaintiff may establish such violation(s) hereunder by a
2 preponderance of the evidence upon a duly noticed motion in the San Francisco Superior Court
3 and subject to the provisions of Section 8 herein. AYS shall remit 75% of this amount to the
4 State of California pursuant to Health & Safety Code § 25249.12(b).

5 **3.2 Civil Penalty Assessment.** Defendant shall pay a civil penalty in the amount of
6 \$5,000 to AYS, pursuant to Health & Safety Code § 25249.7(b). AYS shall remit 75% of this
7 amount to the State of California pursuant to Health & Safety Code § 25249.12(b).

8 **3.3 Payment in Lieu of Additional Civil Penalties.** Defendant shall make a payment
9 in lieu of additional penalties in the amount of \$55,300 to AYS. AYS shall forward at least one
10 half of these funds to California non-profit groups to reduce exposures to toxic chemicals, and to
11 increase consumer, worker and community awareness of the health hazards posed by toxic
12 chemicals. Any remaining funds shall be deposited in the AYS Environmental Enforcement
13 Fund and shall be used to reduce exposures to toxic chemicals, and to increase consumer, worker
14 and community awareness of the health hazards posed by toxic chemicals. In deciding among the
15 grantee proposals, the As You Sow Board of Directors ("Board") takes into consideration a
16 number of important factors, including: (1) the nexus between the harm done in the underlying
17 case(s), and the grant program work; (2) the potential for toxics reduction, prevention,
18 remediation or education benefits to California citizens from the proposal; (3) the budget
19 requirements of the proposed grantee and the alternate funding sources available to it for its
20 project; and (4) the Board's assessment of the grantee's chances for success in its program work.
21 AYS shall ensure that all funds will be disbursed and used in accordance with AYS' mission
22 statement, articles of incorporation, and bylaws and applicable state and federal laws and
23 regulations.

24 **3.4 Penalties are not a credit.** No penalties paid herein shall be construed as a
25 credit against future claims against Defendant.
26

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

2 **4.1 Reimbursement of Plaintiff's Investigative, Expert and Legal Fees and Costs.**

3 Each Defendant shall reimburse AYS in the amount of \$59,700 for AYS' reasonable
4 investigative, expert, and legal fees and costs incurred as a result of investigating and negotiating
5 a settlement in the public interest.

6 **5. PAYMENT OBLIGATIONS**

7 **5.1** Pursuant to Sections 3.2, 3.3 and 4.1 herein, Defendant agrees to remit the total
8 amount of \$120,000 to AYS, payable to "As You Sow" (Employer Identification Number 94-
9 3169008) within fifteen (15) days of the Parties' execution of this Consent Judgment, with the
10 last signature date triggering the fifteen (15) day period (if AYS is the last signatory, this fifteen
11 (15) day period shall run from the date of transmission of facsimile notice of AYS' signature to
12 Defendant and Defendant's counsel).

13 **6. RELEASE OF LIABILITY**

14 **6.1 Release of Liability.** AYS, on its own behalf, and on behalf of the general public,
15 waives all rights to institute or participate in, directly or indirectly, any claim or form of legal
16 action against Defendant, its officers, directors, employees, agents, attorneys, representatives,
17 shareholders, parents, subsidiaries, affiliates, divisions, predecessors, successors, subdivisions,
18 downstream distributors, downstream retailers, downstream customers, and upstream suppliers
19 (including manufacturers of the Products and manufacturers of the raw materials of the Products)
20 whether under Proposition 65, Business & Professions Code §§17200 or 17500, based upon
21 Defendant's alleged failure to warn, within the meaning of Proposition 65, about exposure to
22 lead, lead compounds, arsenic, cadmium, cadmium compounds, mercury or mercury compounds
23 contained in any of the Products sold in California on or before sixty (60) days after the Effective
24 Date or based on any other legal claim or theory that was or could have been alleged in the Action
25 based on the facts alleged in the Complaint.

26 **6.2 Release of Liability of AYS.** Defendant waives all of its rights to institute any
claim, or form of legal action against AYS, its officers, directors, employees, agents, attorneys

1 and representatives (the "AYS Releasees") for all actions or statements made or undertaken by
2 the AYS Releasees in the course of seeking enforcement of Proposition 65 or Business &
3 Professions Code §§ 17200 and 17500 et seq. in the Action.

4 7. CONSENT JUDGMENT

5 7.1 **Consent Judgment.** Upon execution of this [Proposed] Consent Judgment by all
6 Parties, AYS noticed a Motion for Approval & Entry of Consent Judgment in the San Francisco
7 Superior Court pursuant to Title 11, Cal. Code of Regs. §3000, *et seq.* This Motion was served
8 and any future Motions shall be served upon all of the Parties to the Action and upon the
9 California Attorney General's Office. In the event that the Court fails to approve and order entry
10 of the judgment, this Consent Judgment shall become null and void upon the election of any Party
11 as to them and upon written notice to all of the Parties to the Action pursuant to the notice
12 provisions herein. If this Consent Judgment becomes null and void, or is not approved by the
13 Court within one hundred and eighty (180) days of its execution by all Parties, AYS shall refund
14 all sums paid by Defendant pursuant to Sections 3.2, 3.3 and 4.1 within fifteen (15) days of
15 written notice to AYS by Defendant that a refund is due. Defendant and AYS shall use best
16 efforts to support entry of this Consent Judgment in the form submitted to the Office of the
17 Attorney General. If the Attorney General objects in writing to any term in this Consent
18 Judgment, the Parties shall use best efforts to resolve the concern in a timely manner and prior to
19 the hearing on the motion to approve this Consent Judgment. If the Parties cannot resolve an
20 objection of the Attorney General, then Plaintiff and Defendant shall proceed with seeking entry
21 of an order by the court approving this Consent Judgment in the form originally submitted to the
22 Office of the Attorney General, or in such other form as the Parties shall mutually agree upon
23 after consideration of any comments of the Attorney General. If the Attorney General elects to
24 file a notice or motion with the Court stating that the People shall appear at the hearing for entry
25 of this Consent Judgment so as to oppose entry of the Consent Judgment, then a party may
26 withdraw from this Consent Judgment prior to the date of the hearing, with notice to all parties
and the Attorney General, and upon such notice this Consent Judgment shall be null and void and

1 any sums paid hereunder shall be returned to Defendant within fifteen (15) days of the date of the
2 notice.

3 **7.2 Amendment To Complaint.** Upon the expiration of the 60-Day Notice issued on
4 or about March 25, 2005, the Complaint herein shall be deemed amended to include all violations
5 described in that 60-Day Notice.

6 **7.3 Dismissals.** Upon approval by the Court of the settlement agreement pursuant to
7 Section 7.1 herein, and before entry of judgment, AYS shall dismiss with prejudice its claims
8 against Defendants GENERAL RESEARCH LABORATORIES, INC., and ROBINSON
9 PHARMA, INC. that are based upon the Products (as set forth in Exhibit A hereto).

10 **8. ENFORCEMENT AND MODIFICATION**

11 **8.1 Enforcement and Stipulated Civil Penalties.** In the event that a dispute arises
12 with respect to any of the provisions of this Consent Judgment, the Parties shall meet and confer
13 within twenty (20) days after any party receives written notice of an alleged violation of this
14 Consent Judgment from another Party. In the event the affected Parties cannot resolve the
15 dispute, this Consent Judgment may be enforced pursuant to Code of Civil Procedure § 664.6 or
16 any other valid provision of law. The prevailing party in any dispute regarding compliance with
17 the terms of this Consent Judgment shall be awarded its reasonable fees and costs incurred, in
18 addition to any other relief otherwise ordered by the Court, including but not limited to civil
19 penalties assessed pursuant to Section 3 herein.

20 **8.2 Modification of Judgment - Grounds.** This Consent Judgment shall not
21 obligate Defendant to provide a health hazard warning (as described in Section 2 herein) for a
22 Product if that Product causes an exposure below the "No Significant Risk Level" or "Maximum
23 Allowable Daily Level," as those terms are defined in Proposition 65 and its implementing
24 regulations. Any such levels adopted in a final regulation or law pursuant to Proposition 65 after
25 the Effective Date shall become the standard under this Consent Judgment on the date they
26 become effective without need for formal modification of this Consent Judgment, but Defendant
retains its rights and obligations under Section 2.3.2. to establish naturally occurring levels of

1 Metals. The Parties acknowledge that new toxicological information or exposure assessments
2 concerning hazardous substances and testing methodologies are continuously becoming available,
3 and that statutory and regulatory standards applicable to the Products may evolve in the future.
4 Accordingly, the Parties agree that any Party may file a motion pursuant to § 664.6 of the
5 California Code of Civil Procedure, and under the conditions set forth below, move the Court for
6 modification of the warning requirement or any other term set forth in Section 2 herein on the
7 grounds that (a) they conflict with the applicable legal standards concerning the Products or any
8 ingredient therein, or (b) the warning requirement or any other term set forth in Section 2 herein
9 are more stringent than the warning requirements Plaintiff after the Effective Date in an order,
10 judgment or settlement under Proposition 65 agrees to with respect to any dietary supplements
11 that are substantially similar to the Products herein. Absent good cause shown by Plaintiff,
12 Plaintiff shall allow modification of this Consent Judgment to permit Defendant to adhere to such
13 less stringent warning requirements. Any disputes regarding the issues set forth in this subsection
14 shall be resolved in accordance with the procedures set forth in Section 8.3 below.

15 **8.3 Modification of Judgment – Procedure.** In the spirit of cooperation and in the
16 interests of minimizing the investigative, expert and attorneys’ fees and costs associated with
17 such a motion, the Parties agree to meet and confer in good faith as follows. Prior to filing a
18 motion pursuant to Section 8.2 herein, the Party seeking to modify the judgment shall first
19 provide the non-moving Party and the California Attorney General’s Office with any legal or
20 scientific data upon which the motion would rely. The non-moving Party and the California
21 Attorney General’s Office shall be allowed a period of forty-five (45) days to review that data and
22 to provide the moving Party with its formal written response (the Attorney General’s Office’s
23 failure to respond to this submission shall not be construed in any manner to reflect any particular
24 view, on the part of the Attorney General’s Office, of this Consent Judgment or of the applicable
25 law or science). The Parties shall then meet and confer within twenty (20) days of the non-
26 moving Party’s written response. If, after meeting and conferring, the moving Party elects to
proceed with a motion to amend this judgment, it may do so with proper notice to the other Party

1 and the Attorney General's Office as required under the California Code of Civil Procedure.
2 Such a motion may be accompanied by scientific data, studies, written declarations, and live
3 testimony or discovery responses. In the event that the Court determines that a Party seeking or
4 opposing a motion to modify this Consent Judgment did so without justification or failed to meet
5 and confer in good faith prior to moving for or opposing such modification, the other Party shall
6 be awarded reasonable fees and costs incurred.

7 **9. NEW PRODUCTS.**

8 **9.1 New Product Testing Prior To Sale In California.** If, after the date that is sixty
9 (60) days after the Effective Date, Defendant elects to ship for sale in California any new
10 product(s) of the type set forth in Section 1.2 hereinabove (herbs, herbal products, traditional
11 patent medicines, bulk herbs, infusions, extracted powders, tea pills, traditional pills, patent
12 formulas, teas, bulk teas, liquid herbal extracts, and capsules) but not identified on Exhibit A
13 hereto, Defendant shall, before shipping the new product(s) for sale in California, conduct the
14 testing set forth in Section 2.1 and adhere to the requirements of this Consent Judgment with
15 respect to such new product(s). If the Product requires a warning under the standards in Sections
16 2.2 and 2.3, Defendant shall, prior to shipment for sale in California of such new product(s)
17 provide AYS with a test result, using the testing methods set forth in Section 2.1 above, and a
18 notice that all of the warning requirements set forth in Section 2.2 hereinabove are complied with
19 as to such new product(s). Failure to provide the warning if required under Section 2.2 shall be a
20 violation of this Consent Judgment subject to stipulated penalties in accordance with Section 3.1.
21 Such new product(s) shall then be deemed Product(s) subject to all of the terms of this Consent
22 Judgment. Before the date that is sixty (60) days after the Effective Date, Defendant may ship for
23 sale to California customers new or reformulated products of the type set forth in Section 1.2 that
24 are not listed on Exhibit A, and the sales of such products shall not be deemed in violation of any
25 term of this Consent Judgment.

26 **9.2 Annual New Product Update List.** Commencing January 15, 2006 and through
and including January 15, 2011, Defendant shall provide AYS with an annual updated list of new

Products Defendant shipped for sale or use in California in the preceding calendar year for which Defendant has ascertained that warnings are not required under this Consent Judgment. If Plaintiff cannot ascertain and in good faith inquires in writing as to whether a specific Product is a new Product in a given year (for the period commencing January 15, 2006 and through and including January 15, 2011) Defendant shall promptly (and in any event within thirty-five (35) days of the date of Plaintiff's request) reply to advise whether the Product is a new Product for that year or is an existing Product.

10. GOVERNING LAW

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

11. NOTICES

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

All correspondence to AYS shall be mailed to:

Attn: Lawrence E. Fahn, Executive Director
As You Sow
311 California Street, Suite 510
San Francisco, CA 94104

With a copy to:

Andrew L. Packard, Esq.
Law Offices of Andrew L. Packard
294 Page Street
San Francisco, CA 94102

All correspondence to Defendant shall be mailed to:

Attn: Klee Irwin
Irwin Naturals
10549 W. Jefferson Blvd
Culver City, CA 90232

With a copy to:

Trenton H. Norris, Esq.
Bingham McCutchen LLP
Three Embarcadero Center
San Francisco, CA 94111-4067

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

1 in Section 8, this Consent Judgment may be modified only upon the written agreement of the
2 Parties to be bound. If any term of this Consent Judgment is found by the court to be invalid,
3 then such term shall be stricken and the remaining terms shall not be affected thereby. In the
4 interpretation hereof, references to general "Sections" (e.g., "Section 8") shall include all
5 subsections within said section (e.g., Sections 8.1, 8.2 and 8.3), but references to specific
6 subsections (e.g., "Section 2.2.1") shall refer only to that specific subsection.

7 **13. COUNTERPARTS**

8 **13.1 Counterparts.** This Consent Judgment may be executed in counterparts, each of
9 which shall be deemed an original, and all of which, when taken together, shall constitute one and
10 the same document.

11 **14. AUTHORIZATION**

12 **14.1 Authorization.** The undersigned are authorized to execute this Agreement on
13 behalf of their respective parties and have read, understood, and agree to all of the terms and
14 conditions of this Agreement.

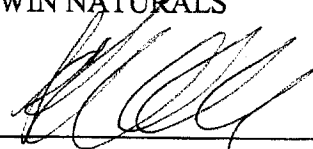
15 **IT IS SO STIPULATED:**

16 DATED: _____ AS YOU SOW

17
18 _____
19 By: Lawrence E. Fahn
Executive Director

20 DATED: 6-15-05

21 IRWIN NATURALS

22 
23 _____
By: Klee Irwin, President

24 **IT IS SO ORDERED:**

25 DATED: _____

26 _____
27 Judge of the Superior Court

28 **INDEX OF ATTACHED EXHIBITS**

[PROPOSED] CONSENT JUDGMENT

LAW OFFICES
ANDREW L. PACKARD
294 PAGE STREET SAN FRANCISCO CALIFORNIA 94102
TEL 415-431-2970 FAX 415-431-0410

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: 6-24-05

AS YOU SOW


By: Lawrence E. Fahn
Executive Director

DATED: _____

IRWIN NATURALS

By: Klee Irwin, President

IT IS SO ORDERED:

DATED: JUN 30 2005

AMES L WARREN

Judge of the Superior Court

[PROPOSED] CONSENT JUDGMENT

LAW OFFICES
ANDREW L. PACKARD
294 PAGE STREET SAN FRANCISCO CALIFORNIA 94102
TEL 415-431-2970 FAX 415-431-0410

- 1 EXHIBIT A - Product List
- 2 EXHIBIT B - Notices of Proposition 65 Violations
- 3 EXHIBIT C - GMPs In Place until Federal GMPs Apply to Defendant
- 4
- 5
- 6
- 7
- 8
- 9
- 10
- 11
- 12
- 13
- 14
- 15
- 16
- 17
- 18
- 19
- 20
- 21
- 22
- 23
- 24
- 25
- 26

EXHIBIT A

Exhibit A
Irwin Naturals, Inc. Products

Ultimate B
Ultimate Green
Ultimate Fiber
Ultimate Oil
Ultimate Cleanse
Supercleanse
Multi Herb, Economy
Multi Fiber, Economy
Fulfill Chocolate
Fulfill Vanilla
Burnmore, Ultimate Weight Loss
Craveless, Ultimate Weight Loss
Ultimate Weight Loss Combo
Ultimate Multi Plus
Candistroy, Candida, Part I & II
Rezyme, Enzyme, Parts I & II
Economy Supercleanse
Ultimate Energy
Doctor's Choice Diet & Cleanse
Parastroy Combo
Ultimate Liver Cleanse
Ultimate Respiratory Cleanse
Ultimate Urinary Cleanse
Estrogenesis
Veroxin 7
Ultimate Fasting Cleanse Kit
Adv. Ginkgo Smart
Steel Libido
Adv. Ginza Plus
Adv. Yohimbe Plus
Immuno-Shield
3-IN-1 Joint Form
Triple Boost
EstroPause
Prosta- Strong
Sys-Six w/Xen
Sys-Six w/Xen
Sys-Six Ripped Man

Female Steel Libido
Green Tea
Inholtra Lubri Joint
Grapefruit Diet
Carb block max strength
Cortisol Appetite Control
Multi Vitamin Herbal
Vitamin C
Calcium Complex
Antioxidant
Ester-C
Six-Way Cleanse Combo
Diet System 6 for Men
Grapefruit Diet
Bars (various flavors)
Adv. Diet System 6 (Xenedrol)
Green Tea Diet, Ephedra Free
Carbo Blocker
Libido Max
Cortisol Hunger Control
Cortisol Appetite Control
Carbo Blocker
Dual Action Cleanse
Perfect Fiber
Energy Burst
Dual Action Cortisol
Essential Oil Health
8 in 1 Multi
Pain Relief Roll on
Triple Action Joint Formula
Liquid Gel Carb interceptor
Cosmeceutical Wrinkle Cure
Super II
B Formula
Super Green Formula
Fiber Formula
Essential Oil Formula
Multi Cleanse Formula
Colon Formula
Para-Control
Urinary Cleanse
Hepatic Cleanse
Respiratory Cleanse

Joint Support Formula
Male Potency Formula
Multi Herb Formula, Economy
Multi Fiber Formula, Economy
Cholesterol Support
Full Formula Chocolate
Multi Plus Formula
Candida Program
Digestive Rebuilding Program
Weight control
Probiotic Formula

EXHIBIT B



As You Sow

Tel: (415) 391-3212

A Foundation Planting Seeds for Social Change

Fax: (415) 391-3245

A NON-PROFIT CORPORATION

311 California Street, Suite 510

San Francisco, California 94104

www.asyousow.org

December 23, 2003

NOTICE OF VIOLATION OF CALIFORNIA HEALTH & SAFETY CODE §25249.5 ET SEQ.

Dear Public Enforcement Agencies:

As You Sow ("AYS") is a non-profit foundation organized under California's Non-Profit Public Benefit Corporation Law. AYS is dedicated to, among other causes, the protection of the environment, the promotion of human health, the improvement of worker and consumer safety, and environmental education.

AYS has documented violations of California's Safe Drinking Water & Toxic Enforcement Act of 1986 ("Proposition 65"), codified at Health & Safety Code §25249.5 *et seq.* This letter serves to provide AYS' notification of these violations to the public enforcement agencies and to the violator. Pursuant to §25249.7(d) of the statute, AYS 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.

Alleged violator. The name of the violator covered by this notice is **IRWIN NATURALS doing business as NATURE'S SECRET** ("Nature's Secret").

Chemicals. These violations involve exposures to lead, lead compounds, mercury and mercury compounds from the products listed below. On February 27, 1987, the State of California officially listed lead as a chemical known to cause reproductive toxicity. On October 1, 1992, the State of California officially listed lead and lead compounds as chemicals known to cause cancer. On July 1, 1990, the State of California officially listed mercury and mercury compounds as chemicals known to cause reproductive toxicity.

Consumer products. The products that are the subject of this notice are herbs and herbal products, traditional patent medicines, bulk herbs, infusions, extracted powders, tea pills, traditional pills, patent formulas, bulk teas, liquid extracts and/or capsules that are imported, exported, manufactured, packaged, distributed, marketed and/or sold by Nature's Secret. The



phrase "traditional patent medicines" above is used herein as defined by the California Department of Health Services: "herbal and patent medicines consisting of single or multiple herbal ingredients, including botanical, mineral and animal products, formulated into tablets, pills, powders and liquids." The products that are the subject of this notice include but are not limited to the following:

Product

CraveLess
Ultimate Respiratory Cleanse
Ultimate Energy

Dr. Duncan's Diet & Cleanse
Super Cleanse
Multi-Herb

Chemical

lead and lead compounds
lead and lead compounds
lead and lead compounds
mercury and mercury compounds
lead and lead compounds
lead and lead compounds
lead and lead compounds
mercury and mercury compounds

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

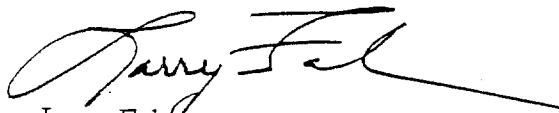
Duration of violations. Each of these ongoing violations has occurred on every day since December 23, 1999, and will continue every day until clear and reasonable warnings are provided or until these known toxic chemicals are removed from the products.

Pursuant to Title 11, C.C.R. § 3100, a certificate of merit is attached hereto.

In keeping with its public interest mission and to expeditiously rectify these ongoing violations of California law, AYS is interested in seeking a constructive resolution of this matter without engaging in costly and protracted litigation. Please direct all communications regarding this notice to AYS' counsel in this matter:

Andrew L. Packard, Esq.
Law Offices of Andrew L. Packard
294 Page Street
San Francisco, CA 94102
Tel. (415) 431-2970 Fax (415) 431-0410

Very truly yours,



Larry Fahn
Executive Director

Enclosure

CERTIFICATE OF MERIT
(for As You Sow's Notice of Proposition 65 Violation
on IRWIN NATURALS doing business as NATURE'S SECRET)

I, Andrew L. Packard, declare:

1. This Certificate of Merit accompanies the attached sixty-day notice in which it is alleged that **IRWIN NATURALS doing business as NATURE'S SECRET** has violated Health & Safety Code §25249.6 by failing to provide clear and reasonable warnings.
2. I am the 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 plaintiffs' 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: December 22, 2003


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, and not a party to the within action; my business address is: 311 California Street, Suite 510, San Francisco, California 94104.

On December 23, 2003, I served the following documents:

- Notice of Violation of California Health & Safety Code § 25249.5 et seq.
- Certificate of Merit
- "The Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): A Summary"

on the following party by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below, and depositing it at a United States Postal Service Office for delivery by Certified Mail:

Irwin Naturals doing business as Nature's Secret
Klee Irwin, CEO
5310 Beethoven Street
Los Angeles, CA 90066

On December 23, 2003, I served the following document(s):

- Notice of Violation of California Health & Safety Code § 25249.5 et seq.
- Certificate of Merit, including Supporting Documentation Required by Title 11, C.C.R. § 3102

on the following party by placing a true and correct copy thereof in a sealed envelope, addressed to the party listed below, and depositing it at a United States Postal Service Office for delivery by Certified Mail:

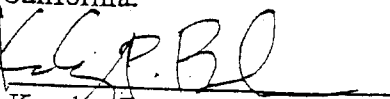
Attn: Craig Thompson, Deputy Attorney General
California Department of Justice
P.O. Box 944255
Sacramento, CA 94244-2550

On December 23, 2003, I served the following document(s):

- Notice of Violation of 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 at United States Postal Service mail box for delivery by First Class Mail.

Executed on December 23, 2003, at San Francisco, California.


Karak P. Buchner

PUBLIC ENFORCEMENT AGENCIES SERVICE LIST (updated 04/18/03)

THE HONORABLE THOMAS J ORLOFF
ALAMEDA COUNTY DISTRICT ATTORNEY
1225 FALLON ST RM 900
OAKLAND CA 94612

THE HONORABLE WILLIAM RICHMOND
ALPINE COUNTY DISTRICT ATTORNEY
PO BOX 248
MARKLEEVILLE CA 96120

THE HONORABLE TODD D RIEBE
AMADOR COUNTY DISTRICT ATTORNEY
708 COURT ST STE 202
JACKSON CA 95642

THE HONORABLE MICHAEL RAMSEY
BUTTE COUNTY DISTRICT ATTORNEY
25 COUNTY CTR DR
OROVILLE CA 95965

THE HONORABLE JEFFREY TUTTLE
CALAVERAS COUNTY DISTRICT ATTORNEY
891 MTN RANCH RD
SAN ANDREAS CA 95249

THE HONORABLE JOHN POYNER
COLUSA COUNTY DISTRICT ATTORNEY
547 MARKET ST
COLUSA CA 95932

THE HONORABLE ROBERT KOCHLY
CONTRA COSTA COUNTY DISTRICT ATTORNEY
PO BOX 670
MARTINEZ CA 94553

THE HONORABLE MICHAEL RIESE
DEL NORTE COUNTY DISTRICT ATTORNEY
450 H ST
CRESCENT CITY CA 95531

THE HONORABLE GARY LLACY
EL DORADO COUNTY DISTRICT ATTORNEY
515 MAIN ST
PLACERVILLE CA 95667

THE HONORABLE ELIZABETH EGAN
FRESNO COUNTY DISTRICT ATTORNEY
2220 TULARE ST STE 1000
FRESNO CA 93721

THE HONORABLE ROBERT HOLZAPFEL
GLENN COUNTY DISTRICT ATTORNEY
PO BOX 430
WILLOWS CA 95988

THE HONORABLE PAUL GALLEGOS
HUMBOLDT COUNTY DISTRICT ATTORNEY
825 FIFTH ST
EUREKA CA 95501

THE HONORABLE GILBERT OTERO
IMPERIAL COUNTY DISTRICT ATTORNEY
939 W MAIN ST
EL CENTRO CA 92243

THE HONORABLE ARTHUR MAILLET
INYO COUNTY DISTRICT ATTORNEY
PO DRAWER D
INDEPENDENCE CA 93526

THE HONORABLE EDWARD R JAGELS
KERN COUNTY DISTRICT ATTORNEY
1215 TRUXTUN AVE
BAKERSFIELD CA 93301

THE HONORABLE RON CALHOUN
KINGS COUNTY DISTRICT ATTORNEY
1400 W LACEY BLVD
HANFORD CA 93230

THE HONORABLE GERHARD LUCK
LAKE COUNTY DISTRICT ATTORNEY
255 N FORBES ST
LAKEPORT CA 95453

THE HONORABLE ROBERT BURNS
LASSEN COUNTY DISTRICT ATTORNEY
220 S LASSEN ST STE 8
SUSANVILLE CA 96130

THE HONORABLE STEVE COOLEY
LA COUNTY DISTRICT ATTORNEY
210 W TEMPLE ST STE 18000
LOS ANGELES CA 90012-3210

THE HONORABLE ERNEST LICALSI
MADERA COUNTY DISTRICT ATTORNEY
209 W YOSEMITE AVE
MADERA CA 93637

THE HONORABLE PAULA FRESCHI KAMENA
MARIN COUNTY DISTRICT ATTORNEY
3501 CIVIC CTR DR RM 130
SAN RAFAEL CA 94903

THE HONORABLE ROBERT BROWN
MARIPOSA COUNTY DISTRICT ATTORNEY
PO BOX 748
MARIPOSA CA 95338

THE HONORABLE NORMAN VROMAN
MENDOCINO COUNTY DISTRICT ATTORNEY
PO BOX 1000
UKIAH CA 95482

THE HONORABLE GORDON SPENCER
MERCED COUNTY DISTRICT ATTORNEY
2222 M ST
MERCED CA 95340

THE HONORABLE JORDAN FUNK
MODOC COUNTY DISTRICT ATTORNEY
PO BOX 1171
ALTURAS CA 96101

THE HONORABLE GEORGE BOOTH
MONO COUNTY DISTRICT ATTORNEY
PO BOX 617
BRIDGEPORT CA 93517

THE HONORABLE DEAN FLIPPO
MONTEREY COUNTY DISTRICT ATTORNEY
240 CHURCH ST #101
SALINAS CA 93902

THE HONORABLE GARY LIEBERSTEIN
NAPA COUNTY DISTRICT ATTORNEY
931 PARKWAY MALL
NAPA CA 94559

THE HONORABLE MICHAEL FERGUSON
NEVADA COUNTY DISTRICT ATTORNEY
201 CHURCH ST STE 8
NEVADA CITY CA 95959

THE HONORABLE TONY RACKAUCKAS
ORANGE COUNTY DISTRICT ATTORNEY
401 CIVIC CTR DR WEST
SANTA ANA CA 92701

THE HONORABLE BRAD FENOCCHIO
PLACER COUNTY DISTRICT ATTORNEY
11562 B AVE
AUBURN CA 95603

THE HONORABLE JEFF CUNAN
PLUMAS COUNTY DISTRICT ATTORNEY
520 MAIN ST RM 404
QUINCY CA 95971

THE HONORABLE GROVER C TRASK II
RIVERSIDE COUNTY DISTRICT ATTORNEY
4075 MAIN ST
RIVERSIDE CA 92501

THE HONORABLE JAN SCULLY
SACRAMENTO COUNTY DISTRICT ATTORNEY
901 G ST
SACRAMENTO CA 95814

THE HONORABLE JOHN SANSFIELD
SAN BENITO COUNTY DISTRICT ATTORNEY
419 FOURTH ST, FL 2
HOLLISTER CA 95023

THE HONORABLE MICHAEL RAMOS
SAN BERNARDINO COUNTY DISTRICT ATTORNEY
316 N MTN VIEW AVE
SAN BERNARDINO CA 92415-0004

THE HONORABLE BONNIE DUMANIS
SAN DIEGO COUNTY DISTRICT ATTORNEY
330 W BROADWAY STE 1320
SAN DIEGO CA 92101

THE HONORABLE TERENCE HALLINAN
SAN FRANCISCO COUNTY DISTRICT ATTORNEY
880 BRYANT ST STE 325
SAN FRANCISCO CA 94103

THE HONORABLE JOHN D PHILLIPS
SAN JOAQUIN COUNTY DISTRICT ATTORNEY
PO BOX 990
STOCKTON CA 95201-0990

THE HONORABLE GERALD T SHEA
SAN LUIS OBISPO COUNTY DISTRICT ATTORNEY
COUNTY GOVERNMENT CTR RM 450
SAN LUIS OBISPO CA 93408

THE HONORABLE DAVID L CROSS
TRINITY COUNTY DISTRICT ATTORNEY
PO BOX 310
WEAVERVILLE CA 96093

THE HONORABLE JAMES P FOX
SAN MATEO COUNTY DISTRICT ATTORNEY
400 COUNTY CTR FL 3
REDWOOD CITY CA 94063

THE HONORABLE PHILLIP J CLINE
TULARE COUNTY DISTRICT ATTORNEY
221 S MOONEY BLVD # 224
VISALIA CA 93291

THE HONORABLE THOMAS W SNEDDON JR
SANTA BARBARA COUNTY DISTRICT ATTORNEY
1105 SANTA BARBARA ST
SANTA BARBARA CA 93101

THE HONORABLE DONALD I SEGERSTROM
TUOLUMNE COUNTY DISTRICT ATTORNEY
423 N WASHINGTON ST
SONORA CA 95370

THE HONORABLE GEORGE KENNEDY
SANTA CLARA COUNTY DISTRICT ATTORNEY
70 W HEDDING ST
SAN JOSE CA 95110

THE HONORABLE GREG TOTTEN
VENTURA COUNTY DISTRICT ATTORNEY
800 S VICTORIA AVE
VENTURA CA 93009

THE HONORABLE BOB LEE
SANTA CRUZ COUNTY DISTRICT ATTORNEY
701 OCEAN ST STE 200
SANTA CRUZ CA 95060

THE HONORABLE DAVID C HENDERSON
YOLO COUNTY DISTRICT ATTORNEY
301 SECOND ST
WOODLAND CA 95695

THE HONORABLE MCGREGOR SCOTT
SHASTA COUNTY DISTRICT ATTORNEY
1525 COURT ST FL 3
REDDING CA 96001

THE HONORABLE PATRICK MCGRATH
YUBA COUNTY DISTRICT ATTORNEY
215 FIFTH ST
MARYSVILLE CA 95901

THE HONORABLE LAWRENCE ALLEN
SIERRA COUNTY DISTRICT ATTORNEY
PO BOX 457
DOWNIEVILLE CA 95936

LOS ANGELES CITY ATTORNEY'S OFFICE
200 N MAIN ST RM 1800
LOS ANGELES CA 90012

THE HONORABLE PETER F KNOLL
SISKIYOU COUNTY DISTRICT ATTORNEY
PO BOX 986
YREKA CA 96097

SAN DIEGO CITY ATTORNEY'S OFFICE
CIVIC CENTER PLAZA
1200 THIRD AVE STE 1620
SAN DIEGO CA 92101

THE HONORABLE DAVID W PAULSON
SOLANO COUNTY DISTRICT ATTORNEY
600 UNION AVE
FAIRFIELD CA 94533

SAN JOSE CITY ATTORNEY'S OFFICE
151 W MISSION ST
SAN JOSE CA 95110

THE HONORABLE STEPHEN PASSALACQUA
SONOMA COUNTY DISTRICT ATTORNEY
600 ADMINISTRATION DR RM 212-J
SANTA ROSA CA 95403

SAN FRANCISCO CITY ATTORNEY'S OFFICE
CITY HALL, ROOM 234
SAN FRANCISCO, CA 94102

THE HONORABLE JAMES C BRAZELTON
STANISLAUS COUNTY DISTRICT ATTORNEY
PO BOX 442
MODESTO CA 95353

THE HONORABLE CARL V ADAMS
SUTTER COUNTY DISTRICT ATTORNEY
446 SECOND ST
YUBA CITY CA 95991

THE HONORABLE GREGG COHEN
TEHAMA COUNTY DISTRICT ATTORNEY
PO BOX 519
RED BLUFF CA 96080

EXHIBIT C

EXHIBIT C
Irwin Naturals, Inc.

The following are the Good Manufacturing Practices that Irwin will utilize for the products listed on Exhibit A:

- Use 3rd party contract manufacturers which are independently audited for food GMP compliance for the manufacture of dietary supplements by a reputable auditing organization or are audited by Irwin.
- Irwin Vendor audit program includes food GMP audit processes and forms consistent with Irwin standard operating procedures.
- Manufacturers will maintain facilities consistent with food GMPs including grounds, facility and manufacturing environment.
- Manufacturers will be required to use water meeting municipal standards for foods and drinking water use.
- Manufacturers will be required to utilize equipment and processes which have product contact surfaces made of stainless steel or equally non-additive materials and which are designed to perform processes which will not intentionally add heavy metals to the materials being processed.
- Manufacturers will obtain raw materials from vendors accompanied by a COA.
- All equipment product contact surfaces will be cleaned between each different product.
- Irwin will supply the specific heavy metal specifications for each product.
- Irwin will select or approve the testing laboratory and methodology for heavy metal testing.
- Irwin will review all testing results for conformance to established requirements.
- Manufacturers will provide a COA for each product production lot.
- All manufacturing, testing and audit records will be maintained for not less than one year past the expiration date of the product.