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FILED
ALAMEDA COUNTY

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CLERK OF THE SUPERIOR COURT
By Rml Chilton Deputy

8 SUPERIOR COURT OF CALIFORNIA
9 COUNTY OF ALAMEDA

11 **PEOPLE OF THE STATE OF CALIFORNIA,**
12 Plaintiff,
13 v.
14 **NUTRACEUTICALS, INC., MK HEALTH FOOD**
THE PEOPLE OF THE STATE OF CALIFORNIA,
15 Plaintiff,
16 v.
17 **NUTRACEUTICALS, INC., MK HEALTH FOOD**
18 **DISTRIBUTORS, INC., NATURAL BALANCE,**
19 **INC., SOLARAY, INC., NBTY, INC., GOOD &**
20 **NATURAL MANUFACTURING CORPORATION,**
21 **NATURE'S BOUNTY, INC., SUNDOWN, INC.,**
22 **NATURAL ORGANICS LABORATORIES, INC.,**
NATURE'S ANSWER, INC., NATURE'S
SUNSHINE, INC., NATURE'S WAY PRODUCTS,
INC., NOW HEALTH GROUP, INC., VITAMINE
SHOPPE, INC.,
23 Defendants.

CASE NO: ^{R6} 07329561

COMPLAINT FOR
INJUNCTIVE RELIEF AND
CIVIL PENALTY
(42. Other Civil Complaint)

25 I. INTRODUCTION

26 1. This complaint seeks an injunction to remedy defendants' failure to warn consumers that
27 certain "red yeast rice" nutritional supplements contain lovastatin, a chemical known to the State of
28 California to cause birth defects or other reproductive harm. Under the Safe Drinking Water and

1 Toxic Enforcement Act of 1986, Health and Safety Code section 25249.6, also known as
2 "Proposition 65," businesses must provide persons with a "clear and reasonable warning" before
3 exposing them to such chemicals.

4 II. PARTIES

5 2. Plaintiffs are the People of the State of California, by and through the Attorney General
6 of California, Edmund G. Brown Jr. Health and Safety Code section 25249.7, subdivision (c),
7 provides that actions to enforce Proposition 65 may be brought by the Attorney General in the name
8 of the People of the State of California. Government Code section 12607 authorizes the Attorney
9 General to bring an action for equitable relief in the name of the People of the State of California
10 against any person to protect the natural resources of the State from pollution, impairment, or
11 destruction. Business and Professions Code section 17200 provides that actions to prohibit unfair
12 and unlawful business practices may be brought by the Attorney General in the name of the People
13 of the State of California.

14 3. Defendant Nutraceuticals, Inc., is a business entity that sells nutritional supplements
15 containing red yeast rice, which contains lovastatin ("Red Yeast Rice Supplements") to consumers
16 within the State of California, and is the parent of defendants MK Health Food Distributors, Inc.,
17 Natural Balance, Inc., and Solaray, Inc.

18 4. Defendant MK Health Food Distributors, Inc., (dba Nature's Life), is a business entity that
19 sells Red Yeast Rice Supplements to consumers within the State of California, and is the subsidiary
20 of defendant Nutraceuticals, Inc.

21 5. Defendant Natural Balance, Inc., is a business entity that sells Red Yeast Rice Supplements
22 to consumers within the State of California, and is a subsidiary of defendant Nutraceuticals, Inc.

23 6. Defendant Solaray, Inc., is a business entity that sells Red Yeast Rice Supplements to
24 consumers within the State of California, and is a subsidiary of defendant Nutraceuticals, Inc.

25 7. Defendant NBTY, Inc., is a business entity that sells Red Yeast Rice Supplements to
26 consumers within the State of California, and is the parent corporation of defendants Good & natural
27 Manufacturing Corporation, Nature's Bounty, Inc., and Sundown, Inc.

28 8. Defendant Good & Natural Manufacturing Corporation, is a business entity that sells Red

1 Yeast Rice Supplements to consumers within the State of California, and is a subsidiary of defendant
2 NBTY, Inc.

3 9. Defendant Nature's Bounty, Inc., is a business entity that sells Red Yeast Rice
4 Supplements to consumers within the State of California, and is a subsidiary of defendant NBTY,
5 Inc.

6 10. Defendant Sundown, Inc., is a business entity that sells Red Yeast Rice Supplements to
7 consumers within the State of California, and is a subsidiary of defendant NBTY, Inc.

8 11. Defendant Natural Organics Laboratories, Inc., (dba Nature's Plus), is a business entity
9 that sells Red Yeast Rice Supplements to consumers within the State of California.

10 12. Defendant Nature's Answer, Inc., is a business entity that sells supplements containing to
11 consumers within the State of California.

12 13. Defendant Nature's Sunshine, Inc., is a business entity that sells Red Yeast Rice
13 Supplements to consumers within the State of California.

14 14. Defendant Nature's Way Products, Inc., is a business entity that sells Red Yeast Rice
15 Supplements to consumers within the State of California.

16 15. Defendant Now Health Group, Inc., is a business entity that sells Red Yeast Rice
17 Supplements to consumers within the State of California.

18 16. Defendant Vitamin Shoppe, Inc., is a business entity that sells Red Yeast Rice
19 Supplements to consumers within the State of California.

20 17. The true names and capacities of the defendants sued herein as Does 1 through 100 are
21 unknown to plaintiff, who therefore sues them by such fictitious names. Plaintiff will amend this
22 complaint to allege the true names and capacities of these defendants when they have been
23 determined. Each of the fictitiously named defendants is responsible in some manner for the conduct
24 alleged herein.

25 **III. JURISDICTION AND VENUE**

26 18. This Court has jurisdiction pursuant to California Constitution Article VI, section 10,
27 because this case is a cause not given by statute to other trial courts.

28 19. This Court has jurisdiction over the defendants named above because they do sufficient

1 business in California, or otherwise have sufficient minimum contacts in California to render the
2 exercise of jurisdiction over them by the California courts consistent with traditional notions of fair
3 play and substantial justice.

4 20. Venue is proper in this Court because the cause arises in the County of Alameda, where
5 some of the violations of law have occurred.

6 IV. STATUTORY BACKGROUND

7 A. Proposition 65

8 21. The Safe Drinking Water and Toxic Enforcement Act of 1986 is an initiative statute passed
9 as "Proposition 65" by a vote of the People in November of 1986.

10 22. The warning requirement of Proposition 65 is contained in Health and Safety Code section
11 25249.6, which provides:

12 No person in the course of doing business shall knowingly and intentionally expose
13 any individual to a chemical known to the state to cause cancer or reproductive
14 toxicity without first giving clear and reasonable warning to such individual, except
as provided in Section 25249.10

15 23. Proposition 65 also establishes a procedure by which the state is to develop a list of
16 chemicals "known to the State to cause cancer or reproductive toxicity." (Health & Saf. Code §
17 25249.8.) No warning need be given concerning a listed chemical until one year after the chemical
18 first appears on the list. (Id., § 25249.10, subd. (b).)

19 24. Proposition 65 provides that any person "violating or threatening to violate" the statute
20 may be enjoined in any court of competent jurisdiction. (Health & Saf. Code, § 25249.7.) To
21 "threaten to violate" is defined to mean "to create a condition in which there is a substantial
22 probability that a violation will occur." (Id., § 25249.11, subd. (e).) In addition, violators are liable
23 for civil penalties of up to \$2,500 per day for each violation, recoverable in a civil action. (Id., §
24 25249.7, subd. (b).) Actions to enforce the law "may be brought by the Attorney General in the
25 name of the People of the State of California or by any district attorney". (Id., § 25249.7, subd. (c).)

26 25. Implementing regulations promulgated by the Health and Welfare Agency provide that the
27 warning method "must be reasonably calculated, considering the alternative methods available under
28 the circumstances, to make the warning message available to the individual prior to exposure." (Cal.
Code Regs., tit. 22, § 12601(a).)

1 26. The regulations prescribe certain types of warnings that are considered valid, including:
2 (A) warnings on labels, (B) identification at the retail outlet through "shelf labeling, signs, menus,
3 or a combination thereof," and (C) " a system of signs, public advertising identifying the system and
4 toll-free information services, that provides clear and reasonable warnings." (Cal. Code Regs., tit.
5 22, §§ 12601(b)(1)(A)-(C).)

6 **B. The Unfair Competition Act**

7 27. California Business and Professions Code section 17200 provides that "unfair competition
8 shall mean and include unlawful, unfair or fraudulent business practice." Section 17203 of the
9 Business and Professions Code provides that "(a)ny person performing or proposing to perform an
10 act of unfair competition within this state may be enjoined in any court of competent jurisdiction."

11 28. Section 17206(a) provides that any person violating Section 17200 "shall be liable for a
12 civil penalty not to exceed two thousand five hundred dollars (\$2,500) for each violation, which shall
13 be assessed and recovered in a civil action brought in the name of the people of the State of
14 California by the Attorney General or by any district attorney." Under section 17205,
15 these penalties are "cumulative to each other and to the remedies or penalties available under all
16 other laws of this state."

17 **V. FACTS**

18 29. Lovastatin was listed under Proposition 65 as a chemical known to the State of California
19 to cause reproductive toxicity, under the sub-category "developmental toxicity," which means that
20 the chemical harms the developing fetus, on October 1, 1992. (Cal. Code Regs., tit. 22, § 12000,
21 subd. (c).) "Lovastatin" is a chemical used in anti-cholesterol medications given by prescription only.
22 When drugs containing lovastatin are given by prescription, the U.S. Food and Drug Administration
23 requires that "it should be administered to women of childbearing age only when such patients are
24 highly unlikely to conceive. If the patient become pregnant while taking this drug [it] should be
25 discontinued immediately and the patient should be apprised of the potential hazard to the fetus."
26 (Mevacor Product Description, Merck & Co., Inc., pp. 8, 13, November 2005.)

27 30. Red Yeast Rice Supplements contain lovastatin, which is created by the deliberate use of
28 a fermentation process in the manufacturing of the product.

1 31. The lovastatin in Red Yeast Rice Supplements is ingested by persons who consume those
2 products in their intended manner. Plaintiffs are informed and believe, and based on that information
3 and belief allege, that each defendant has known since at least June 7, 2003 that the Red Yeast Rice
4 Supplements that it sells, distributes, or manufactures, contain lovastatin and cause consumers of the
5 of the Red Yeast Rice Supplements to be exposed to lovastatin.

6 32. Each defendant has failed to provide consumers of the Red Yeast Rice Supplements with
7 a clear and reasonable warning in compliance with Proposition 65 and its implementing regulations
8 that they are being exposed to a chemical known to the State of California to cause reproductive
9 toxicity.

10 **VI. FIRST CAUSE OF ACTION**

11 (For Violation of Proposition 65)

12 33. Paragraphs 1 through 32 are realleged as if fully set forth herein.

13 34. Plaintiffs are informed and believe, and based on such information and belief allege, that
14 each defendant employs ten or more persons.

15 35. By committing the acts alleged above, each defendant has, in the course of doing business,
16 knowingly and intentionally exposed individuals to lovastatin, a chemical known to the state of
17 California to cause reproductive toxicity, without first giving clear and reasonable warning to such
18 individuals, within the meaning of Health and Safety Code section 25249.6.

19 36. Said violations render each defendant liable to plaintiff for civil penalties of up to \$2,500
20 per day for each violation.

21 **VII. SECOND CAUSE OF ACTION**

22 (For Unlawful Business Practices)

23 37. Paragraphs 1 through 36 are re-alleged as if fully set forth herein.

24 38. By committing the acts alleged above, each defendant has engaged in unlawful business
25 practices which constitute unfair competition within the meaning of Business and Professions Code
26 section 17200.

27 39. Said violations render each defendant liable to plaintiff for civil penalties of up to \$2,500
28 for each violation.

1 **PRAYER FOR RELIEF**

2 WHEREFORE, plaintiffs pray that the Court:

- 3 1. Pursuant to the First and Second Causes of Action, grant civil penalties according to proof;
- 4 2. Pursuant to Health and Safety Code section 25249.7, and Business and Professions Code
- 5 sections 17203, enter such preliminary injunctions, permanent injunctions, or other orders
- 6 prohibiting each defendant from exposing persons within the State of California to lovastatin without
- 7 providing clear and reasonable warnings, as plaintiffs shall specify in further application to the court;
- 8 3. Award plaintiffs their costs of suit;
- 9 4. Grant such other and further relief as the court deems just and proper.

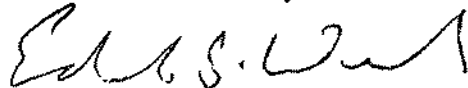
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11 Dated: June 6, 2007

12 Respectfully submitted,

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