

Richard Jaffe, Esq.  
3200 Southwest Frwy, Suite 3200  
Houston, Texas 77027  
Telephone: (713) 626-3550  
Fax (713) 626-9420  
E-mail: rickjaffeesq@aol.com

Judith A. Rosenstein, P.C.,  
PO Box 25622,  
Albuquerque, NM 87125-5622  
Telephone: 505-379-1289  
Fax: 505-797-8086  
Email: jrosenstein7@cybermesa.com

*Attorneys for Plaintiff*

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW MEXICO

MARK HERSHISER, MARIANNE	)	
HERSHISER AND NATIVE ESSENCE	)	
HERB COMPANY,	)	
	)	Civil Action No.:
Plaintiffs,	)	
vs.	)	COMPLAINT
FEDERAL TRADE COMMISSION	)	
	)	
Defendant.	)	
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Plaintiffs, by their counsel, hereby allege against the Defendant as follows:

1. Plaintiffs Mark Hershiser, Marianne Hershiser and their company Native Essence Herb Company, bring this action against the Federal Trade Commission ( the "FTC" or the "Commission") for declaratory relief that:

- a. The FTC's dietary supplement advertising guidelines with respect to claims concerning the historical use of herbs violate the First Amendment and;
  - b. Plaintiffs can accurately and completely quote or provide a link to information contained on any informational federal government website concerning herbs or herbal remedies.
2. Plaintiffs also seek a preliminary and permanent injunction barring the FTC from enforcing its policies prohibiting truthful statements concerning the historical use of herbs against the Plaintiffs and all other persons or companies.

#### **Jurisdiction and Venue**

3. This Court has subject matter jurisdiction under 28 USC §1331 and §1337
  - (a). Venue is proper in this district based on 28 USC §1391 (b).

#### **The Parties**

4. Plaintiffs Mark and Marianne Hershiser are married and jointly own and operate Plaintiff Native Essence Herb Company. Plaintiffs reside and work in Taos County, New Mexico
5. The Federal Trade Commission is the federal government agency which oversees, among other things, advertising of products.

## Factual Background

6. Plaintiffs own and operate a small business which manufactures and sells herbs and herbal remedies, almost all of which have been used in traditional folk medicine around the world for hundreds if not thousands of years
7. Plaintiffs sell their products to retail customers and to health food stores and distributors for resale. Most of the retail sales are online and are generated through Plaintiffs' website [www.allherbs.com](http://www.allherbs.com).
8. Plaintiffs have been in business for approximately fifteen years. During that time, Plaintiffs have never received a complaint. No customer has ever told them that any information contained in their website was false, misleading or deceptive.
9. Their website lists the herb and herb compounds that they sell. Until April, 2008, for each such listing, Plaintiffs posted information about the product. Plaintiffs did not create any of the information contained on their website.
10. All of the information on their website came from federal government websites, from private not-for-profit websites which are recognized as having fair and accurate information about herbal products, such as, NaturalStandard.com (which is where federal government websites such as [www.nccam.nih.gov](http://www.nccam.nih.gov) obtain their information), the Herb Research Foundation at [www.herbs.org](http://www.herbs.org), [www.herbmed.org](http://www.herbmed.org), Natural Medicines Comprehensive Database at [www.NaturalDatabase.com](http://www.NaturalDatabase.com), as well as from industry respected reference books such as *Herbal Drugs and Phytopharmaceuticals* by Max Wichtl, *British Herbal Pharmacopeia*, *The Scientific Validation of Herbal*

*Medicine* by Daniel B. Mowrey Ph.D., and *Remington's Pharmaceutical Sciences*.

11. Plaintiffs have always endeavored to provide truthful, accurate and complete information about their products.
12. In or about early April, 2008, Plaintiffs received a letter from the FTC which informed them that their website contained false, misleading or unsubstantiated information with respect to several herbs or herbal products. There was no indication that the FTC had received any consumer complaints, nor did the communication claim that the FTC had contacted any of their customers.
13. Upon information and belief, the FTC did not have any complaints from customers, and had no information that any of Plaintiffs' customers were damaged, injured or thought that they had been defrauded or misled.
14. The FTC had conducted no trial or hearing and it was unclear who or how this decision concerning Plaintiffs' website was made.
15. Attached to the FTC's letter was a copy of a federal civil complaint which the FTC threatened to file. The complaint contained a request for preliminary and permanent injunctive relief, and also requested monetary damages equal to the amount of sales for the products alleged to have been advertised in a false, misleading or unsubstantiated manner.
16. Also attached to the FTC's letter was a stipulated consent agreement, which contained an agreed preliminary and permanent injunction and extensive provisions for monitoring, reporting and compliance.

17. The consent agreement also contained a provision for an undetermined amount of monetary damages. However, the FTC's covering letter stated that it wanted all of the proceeds from the sale of these herbs, unless Plaintiffs could demonstrate that they did not have the funds to pay the entire amount.
18. In an abundance of caution, after receiving the FTC's communication, Plaintiffs removed from their website all substantive information concerning all of its products (not only the few products mentioned in the FTC's communication).
19. Plaintiffs have decided not to execute the consent agreement. They wish to put back on their website what they believe is truthful, accurate and non-misleading information concerning the products they sell. Based on the FTC's Guidelines, prudence dictates that Plaintiffs seek judicial intervention to establish their right to publish what they believe to be truthful, accurate and non-misleading information.
20. Specifically, the FTC takes the position that it is illegal to make a truthful statement that an herb has a documented historical use for the treatment of a serious disease like cancer. Plaintiffs believe they have the right to disseminate information about the historical use of an herb, without qualification, limitation or restriction. Plaintiffs seek declaratory and injunctive relief prohibiting the FTC from enforcing what Plaintiffs believe to be unconstitutional advertising rules.

21. In addition, Plaintiffs hope to demonstrate that the standards used by the FTC to judge whether an herb product has adequate "substantiation" is fatally flawed and should be rejected by the Court.

### **First Cause of Action**

22. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 21 above.

23. The FTC oversees the truth and accuracy of advertising to consumers. As part of its duties, the FTC has published "Dietary Supplements: An Advertising Guide for Industry"( the "Guideline"). The purpose of the Guideline is to state the FTC's position regarding permissible and impermissible advertising.

24. Section II C 2 of the Guideline entitled "Claims Based on Traditional Uses" states that "Claims based on historical or traditional use should be substantiated by confirming scientific evidence, or should be presented in such a way that consumers understand that the sole basis for the claim is a history of use of the product for a particular purpose. "

25. The above language suggests that properly qualified historical use claims are permissible. However the Guideline goes on to state that:

"There are some situations, however, where traditional use evidence alone will be inadequate to substantiate a claim, even if that claim is carefully qualified to convey the limited nature of the support. In determining the level of substantiation necessary to substantiate the claim, the FTC assesses, among other things, the consequences of a false claim. Claims that if unfounded, could present a substantial risk of injury to consumer health or safety will be held to a higher level of scientific proof. For that reason, an advertiser should not suggest, either directly or indirectly, that a supplement product will provide a disease benefit unless there is competent and reliable scientific evidence to substantiate that

benefit. The FTC will closely scrutinize the scientific support for such claims, particularly where the claim could lead consumers to forgo other treatments that have been validated by scientific evidence, or to self-medicate for potentially serious conditions without medical supervision.” (“Dietary Supplements: An Advertising Guide for Industry, part II C 2, pages 10-11.)

26. Based on the above language and other information, the FTC takes the position that it is never permissible for a company to truthfully advise consumers that an herb has a documented historical use for a serious disease like cancer.
27. Plaintiffs believe that this FTC Guideline, and/or its application in this and other enforcement proceedings is unconstitutional. Consumers have a First Amendment right to this information, and companies like Native Essence Herb Company have a First Amendment right to provide such information to consumers. The FTC’s position, which restricts consumers’ right to this information, may also violate the privacy rights of citizens.
28. The fact that a documented historical use of an herb is for cancer or some other serious or life-threatening disease does not lessen the constitutional protection afforded to consumers to have such information, nor does it make an otherwise truthful statement, untruthful or misleading. The fact that a consumer may utilize the information in a manner which FTC officials think might be harmful does not make a true statement untrue or misleading. The FTC’s position which in effect prohibits sellers of herbs from disseminating information about the historical use of herbs for serious illnesses is constitutionally defective.

29. Accordingly, Plaintiffs seek a declaratory judgment under 28 U.S.C. § 2201, holding that FTC Guideline II C 2 is unconstitutional on its face and/or as it has been applied to the Plaintiffs and in all other enforcement actions.

### **Second Cause of Action**

30. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 21 above.

31. Based on the allegations set forth in paragraphs 21 through 28 above, Plaintiffs seek a permanent injunction barring the FTC from prohibiting them or any other company from making statements that an herb has a documented historical use, even if that use is for a serious or life-threatening medical condition, so long as the information relayed to the consumer is truthful, accurate and complete.

### **Third Cause of Action**

32. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 21 above.

33. Most of the information in Plaintiffs' website is and will be taken from federal government websites such as the National Center for Complementary and Alternative Medicine ([www.nccam.nih.gov](http://www.nccam.nih.gov)), the National Institute of Health ([www.nih.gov](http://www.nih.gov)), or the National Academy of Sciences ([www.nationalacademies.org](http://www.nationalacademies.org)).

34. Plaintiffs seek a declaratory judgment under 28 U.S.C. § 2201 that they may use the information contained in these and other government websites, so

long as the content taken from these websites is truthful, accurate and complete.

#### **Fourth Cause of Action**

35. Plaintiffs repeat and reallege the allegations contained in paragraphs 1 through 21 above.
36. According to the FTC, a disease claim can be made for a nutritional supplement or herb only if there is adequate "substantiation." The FTC takes the position that it is misleading for a company to provide consumers with information about clinical studies which has not been approved by the FDA or which has not been reported in American mainstream medical journals, or which otherwise the FTC or FDA considers problematic, flawed or unreliable.
37. Plaintiffs assert that the testing process for herbs in the United States is biased and flawed. Plaintiffs further assert that consumers have a First Amendment right to know about any testing done on supplements or herbs, whether or not the testing meets the standards established by the FTC or the FDA.
38. Different countries have different standards for what constitutes scientific evidence. In some developed countries like Germany, there are dozens if not hundreds of herbs for which health and disease claims can be made.
39. Plaintiffs assert that American consumers have the First Amendment right to obtain all information concerning the efficacy of supplements and herbs, not just information which meets the federal government's standard of proof.

40. If American consumers have such a right, then companies marketing these products have the First Amendment right to provide this information.
41. Plaintiffs seek a declaratory judgment under 28 U.S.C. § 2201 that they and other companies which sell herbs are permitted to provide information regarding any study conducted about herbal products, at least so long as there is an adequate disclosure as to whether the study was conducted under a protocol approved by the FDA.
42. Plaintiffs further seek a declaration that the FTC's "substantiation" requirement is based on a biased and flawed methodology.

WHEREFORE Plaintiffs respectfully request that after a trial in this action judgment be awarded the Plaintiffs as follows:

- a. A declaratory judgment that FTC advertising guideline II C 2 is unconstitutional on its face and/or as applied to the Plaintiffs and all other sellers of herbs;
- b. An injunction prohibiting the FTC from enforcing this advertising guideline against Plaintiffs or any other seller of herbs;
- c. A declaratory judgment declaring that Plaintiffs and any other company are entitled to utilize information about herbs contained in any federal government website, so long as the information is truthful, complete and not misleading.
- d. A declaratory judgment that Plaintiffs and other sellers of herbs are permitted to provide information regarding any study conducted about herbal products, as long as there is an adequate disclosure

as to whether the study was conducted under a protocol approved by the FDA; and

- e. A declaratory judgment that the FTC's substantiation standard is based on flawed and biased testing procedures, together with costs and attorneys fees, and for such other and further relief as this Court deems just and proper.

Houston Texas,  
June 25, 2008

Respectfully Submitted

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Richard Jaffe, Esq.  
3200 Southwest Frwy, Suite 3200  
Houston, Texas 77027  
Telephone: (713) 626-3550  
Fax (713) 626-9420  
E-mail: rickjaffeesq@aol.com

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Judith A. Rosenstein, P.C.,  
PO Box 25622,  
Albuquerque, NM 87125-5622  
Telephone: 505-379-1289  
Fax: 505-797-8086  
Email: jrosenstein7@cybermesa.com

*Attorneys for Plaintiffs*