Richard A. Jaffe, Esq.

October 8, 2008

Office of the Secretary Federal Trade Commission, Room H-135 600 Pennsylvania Avenue, NW Washington, D.C. 20580. TRADE COMBIGINA

EDER RECEIVED DOCUMENTS SO DE LA COMBINA DE LA COMBINA

Re: Docket No: D09328/Native Essence Herb Company/Answer

To whom it may concern:

Enclosed for filing is an original and one copy of Respondent's Answer in the above referenced case, together with my notice of appearance.

Very truly yours,

Richard Jaffe

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UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

NATIVE ESSENCE HERB COMPANY, a corporation,

MARK J. HERSHISER, individually, d/b/a Native Essence Herb Company, and as an officer of the corporation, and

MARIANNE HERSHISER, individually, d/b/a Native Essence Herb Company, and as an officer of the corporation.

DOCKET NO. 9328

ANSWER

Respondents Native Essence Herb Company, a corporation, Mark J. Hershiser, individually, d/b/a Native Essence Herb Company, and as an officer of the corporation, and Marianne Hershiser, individually, d/b/a Native Essence Herb Company, and as an officer of the corporation ("Respondents"), submit this answer in response to the FTC's complaint and state as follows:

- 1. Respondents admit the allegations in paragraph 1 of the complaint.
- 2. Respondents admit the allegations in paragraph 2 of the complaint

- 3. Respondents admit the allegations in paragraph 3 of the complaint.
- 4. Respondents admit the allegations in paragraph 4 of the complaint.
- 5. Respondents admit the allegations in paragraph 5 of the complaint.
- 6. Respondents deny that they promote their products as a treatment of cancer and the other diseases alleged in paragraph 6 of the complaint. Respondents maintain that they provide truthful, accurate information about the historical use of such products, and other information including past experience with their products from their customers. Respondents maintain that they have a First Amendment right to provide such information to the public and that such activity does not constitute the promotion of these products for the treatment of cancer or other diseases as alleged in paragraph 6 of the complaint.
- 7. Respondents admit that they have disseminated or caused to be disseminated the advertisement which in part is set forth in paragraph 7 of the complaint. However, the excerpt of in the complaint fails to include the following disclaimer at the end of this advertisement:

"The information presented here is not presented with the intention of diagnosing any disease or condition or prescribing any treatment and is offered as information only, for use in the maintenance and promotion of good health, in cooperation with a licensed medical practitioner. In the event that any individual should use the information presented on this website without a licensed medical practitioner's approval, that individual will be diagnosing for him or herself. No responsibility is assumed by the author, publisher or distributors of this information should the information be used in place of a licensed medical practitioner's services. No guarantees of any kind are made for the performance or effectiveness of the preparations mentioned on this website.

Furthermore, this information is to be used for educational purposes only and has been based solely on the traditional and historic use of a given herb, or in clinical trials that are generally not recognized by any US government agency or medical organization. This information has not been evaluated by the US Food and Drug Administration, nor has it gone through the rigorous double-blind studies required before a particular product can be

deemed truly beneficial or potentially dangerous and prescribed in the treatment of any condition or disease."

In addition to failing to specifically mention the foregoing disclaimer, the FTC also omits referring to the other information provided by Respondents about this product and its components. The net effect or net impression of all the information about this product is that the content is neither false nor misleading to the reasonable consumer.

- 8. Respondents deny that have made the unqualified representations of cure or treatment of cancer as alleged in paragraph 8 of the complaint. Respondents maintain that they have truthfully related the historical use of these products or components, have accurately related past experience and therefore deny the allegations in paragraph 8 of the complaint.
- 9. Respondents deny that they have expressly stated or implied that there is adequate scientific substantiation justifying the use of these products as alleged or implied in paragraph 9 of the complaint. In truth and in fact, Respondents specifically stated after each description of a product, *inter alia*, that there is no or limited scientific substantiation for the use of these products and the information contained on the website is based solely on historical use, individual testimonials or scientific studies which are not accepted by the federal government, as set forth in paragraph 7 *supra*, a copy of which disclaimer is attached to the complaint as Exhibit "A," pages 2-3.
- 10. Respondents admit that they did not possess, rely on and that they did not claim to possess or rely on scientific studies which substantiated or proved that these products are effective to treat cancer. Respondents deny that the statements made on their website were false and misleading as alleged in paragraph 10 of the complaint. Respondents

maintain that the statements set forth in the advertisement were truthful, not misleading or inherently misleading and were qualified by the disclaimers set for in paragraph 7 above.

- 11. Respondents deny that they have represented or implied that:
 - A. Scientific research proves that Native Essence Plus prevents breast cancer; and
 - B. Scientific studies prove that Native Essence with Cat's Claw is effective in the treatment of cancer.

as alleged in paragraph 11 of the complaint.

- 12. Respondents admit that:
 - A. Scientific research does not prove that Native Essence Plus prevents breast cancer; and
 - B. Scientific studies do not prove that Native Essence with Cat's Claw is effective in the treatment of cancer,

as alleged in paragraph 12 of the complaint, but deny that they stated or implied that there was such scientific research supporting these products.

- 13. Respondents admit that they disseminated or caused to be disseminated advertisements for their Chaparral herb extract as set forth in paragraph 13 of the complaint. However, the complaint fails to relate that Respondents provided a disclaimer concerning this product (the same disclaimer set forth in paragraph 7 above) a copy of which disclaimer is attached to the complaint as Exhibit "B," page 2.
- 14. Respondents deny that they have represented, expressly or by implication, an unqualified claim that:

- A. Chaparral herb is effective in treating and curing cancer;
- B. Chaparral herb is effective in causing people with cancer to go into complete remission, without the need for any other form of treatment; and
- C. Chaparral herb is effective in shrinking or eliminating cancerous tumors, as alleged in paragraph 14 of the complaint. Respondent provided truthful and accurate information about the product and related actual experience from their customers.
- 15. Respondents deny that they have represented, expressly or by implication, that they had adequate scientific evidence demonstrating that the products were proven to be effective in the treatment of cancer as alleged in paragraph 15 of the complaint. In truth and in fact, Respondents specifically stated after each description of a product, *inter alia*, that the is limited or no scientific substantiation for the use of these products and the information contained on the website is based solely on historical use, individual testimonials or scientific studies that are not accepted by the federal government, a copy of which disclaimer is attached as Exhibit "B" to the complaint at page 2.
- 16. Respondents admit that they did not possess, rely on and that they did not claim to possess or rely on scientific studies which substantiated or proved that these products are effective to treat cancer. Respondents deny that the statements made on their website was false and misleading as alleged in paragraph16 of the complaint.
- 17. Respondents admit that they have disseminated or caused to be disseminated the advertisements set forth in paragraph 17 of the complaint. However, the excerpt of the advertisement set forth in paragraph 17 is not complete and fails to state that Respondents made a disclaimer at the end of this advertisement as set forth Exhibit "C," page 4 attached to the complaint.

- 18. Respondents deny that they stated or implied Mai-T Mushroom Plus is effective in preventing, treating and curing cancer, including but not limited to lung cancer, stomach cancer, hepatocellular cancer, leukemia, and Kaposi's sarcoma as alleged in paragraph 18 of the complaint and or that Mai-T Mushroom Plus has been scientifically proven to be effective in inhibiting the growth of cancerous tumors.
- 19. Respondents deny that that they have represented, expressly or by implication that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 18, at the time the representations were made as alleged in paragraph 19 of the complaint.
- 20. Respondents admit that they did not possess, rely on or claim that there was adequate scientific substantiation in connection with the statements made with the products which are the subject of paragraph 20 of the complaint. Respondents deny that the representations set forth with respect to these products were false and misleading.
- 21. Respondents deny that they have represented, expressly or by implication that clinical studies prove that Maitake mushrooms and Mai-T Mushroom Plus prevent and treat lung cancer, stomach cancer, hepatocellular cancer, leukemia, and Karposi's sarcoma, and inhibit tumor growth as alleged in paragraph 21 of the complaint. In truth and in fact, Respondents disclosed on their website just the opposite, namely, that there are no government approved studies which show that these products are proven to be safe or effective for any medical condition. (See complaint, Exhibit "C," page 4)
- 22. Respondents admit that there are no clinical studies which prove that Maitake mushrooms and Mai-T Mushroom Plus prevent or treat lung cancer, stomach cancer,

hepatocellular cancer, leukemia, and Karposi's sarcoma, and inhibit tumor growth.

Respondents deny that the statements made on their website were false and misleading as alleged in paragraph 22 of the complaint.

23. Respondents deny that the acts and practices alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act as alleged in paragraph 23 of the complaint.

ADDITIONAL FACTS AND FACTUAL BASIS OF RESPONDENT'S DEFENSES

- 24. Respondents 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
- Respondents 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.
- 26. Respondents 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.
- 27. Respondents' website lists the herb and herb compounds that they sell. Until April, 2008, for each such listing, Respondents posted information about the product. Plaintiffs did not create any of the information contained on their website.
- 28. All of the information on their website (except for the patient testimonials) 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 obtain their information), the Herb Research Foundation at www.herbs.org, www.herbmed.org, Natural Medicines

Comprehensive Database at 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.

- 29. Respondents have always endeavored to provide truthful, accurate and complete information about their products.
- 30. In or about early April, 2008, Respondents 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.
- 31. Upon information and belief, the FTC did not have any complaints from customers, and had no information that any of Respondents customers were damaged, injured or thought that they had been defrauded or misled.
- 32. In an abundance of caution, after receiving the FTC's communication, Respondents removed from their website all substantive information concerning all of its products (not only the few products mentioned in the FTC's communication which products are the subject of this administrative action). Since that time, Respondent's website has not contained any substantive information about any of its herbal products.

DEFENSES

FIRST DEFENSE

All of the relief requested in the complaint should be denied because the information which had been posted on Respondent's website, including historical use statements, information about studies performed and/or published in other countries, testimonials and the general information about these products is protected by the commercial speech doctrine of the First Amendment.

SECOND DEFENSE

The FTC's request for a cease and desist order should be denied. To justify a prohibition of commercial speech, the FTC has the burden of proof that the statements contained on Respondent's website were inherently misleading and incapable of being rendered non-misleading by way of a disclaimer. *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002). The FTC cannot meet its burden because there is no evidence that the disclaimers contained in Respondent's website are insufficient to adequately warn consumers about the scientific status of these products, nor can the FTC demonstrate that the information on the website is inherently misleading and/or not capable of becoming non-misleading (assuming arguendo it is potentially misleading) by way of a disclaimer. Alternatively, there is no evidence that a different, stronger or more prominent disclosure and disclaimer would not adequately warn consumers.

THIRD DEFENSE

To the extent the information contained on Respondent's website is found on federal government websites or other non-commercial websites, the FTC cannot prohibit Respondent

from posting such information under established commercial speech jurisprudence of the First

Amendment. City of Cincinnati v. Discovery Network, 507 U.S. 410 (1993).

FOURTH DEFENSE

To the extent that the FTC seeks a cease and desist order prohibiting Respondents from

posting information on its website about studies which the FTC does not believe constitutes

"adequate substantiation," such request should be denied because Respondent has a First

Amendment right to post such information on its website. Pearson v. Shalala, 164 F.3d 650 (D.C.

Cir. 1999).

COUNTERCLAIM

Respondent seeks a declaration that they have the right to post on their website truthful,

complete and non-misleading information (or a hyperlink to such information) contained in the

National Center for Complementary and Alternative Medicine or any other federal government

website which contains information about herbs and herbal remedies.

Houston Texas,

October 8, 2008

RESPECTFULLY SUBMITTED

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CERTIFICATE OF SERVICE

Richard Jaffe, Esq. affirms as follows:

On October 8, 2008, I served the within Answer via USPS first class mail on:

Office of the Secretary Federal Trade Commission Room H-135 600 Pennsylvania Avenue, NW Washington, D.C. 20580.

Erika Wodinsky, Esq. Federal Trade Commission 901 Market St, Suite 570 San Francisco, CA 94103

Regional Director Federal Trade Commission 901 Market St, Suite 570 San Francisco, CA 94103

Hon. D. Michael Chappell Federal Trade Commission 600 Pennsylvania Avenue, NW Washington, D.C. 20580

Richard Jaffe, Esq

