Analysis of Proposed Consent Order to Aid Public Comment In the Matter of Native Essence Herb Company, et al., Docket No. 9328

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from 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").

The proposed consent order has been placed on the public record for thirty days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter concerns the respondents' advertising and promotion of Native Essense (Rene Caisse) Formula tea and extract, Native Essense Plus tea and extract, Native Essense with Cat's Claw tea and extract, chaparral herb, Maitake mushroom extract, and Mai-T Mushroom Plus Formula extract. The complaint alleges that respondents have made a number of deceptive claims regarding the efficacy of these products in the prevention, treatment or cure of cancer.

Specifically, the Commission's complaint alleges that respondents have claimed that their Native Essense Original Formula, Native Essense Plus, and Native Essense with Cat's Claw products are effective in treating and curing cancer, including but not limited to lymphoma, colon cancer, rectal cancer, and prostate cancer. The complaint also alleges that respondents have claimed that these products are effective in reducing the size of, or eliminating, cancerous tumors. The complaint further alleges that respondents have claimed that Native Essense Plus is effective in preventing breast cancer. The complaint alleges that respondents did not have a reasonable basis for these claims. The complaint also alleges that respondents falsely claimed that scientific research proves that Native Essense Plus prevents breast cancer, and that scientific studies prove that Native Essense with Cat's Claw is effective in the treatment of cancer.

Regarding chaparral herb, the Commission's complaint alleges that respondents claimed that chaparral herb is effective in treating and curing cancer, is effective in causing people with cancer to go into complete remission without the need for any other form of treatment, and is effective in shrinking or eliminating cancerous tumors. The complaint alleges that respondents lacked a reasonable basis for these claims.

The complaint also alleges that respondents lacked a reasonable basis for the claims that 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; and that Mai-T Mushroom Plus is effective in inhibiting the growth of cancerous tumors. Finally, the complaint alleges that respondents falsely claimed 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.

The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future. Part I requires respondents to have competent and reliable scientific evidence substantiating any claim that Native Essense (Rene Caisse) Formula tea or extract, Native Essense Plus tea or extract, Native Essense with Cat's Claw tea or extract, chaparral herb (or any product containing chaparral herb), Maitake mushroom extract, or Mai-T Mushroom Plus Formula extract, or any other covered product or service, is effective in the treatment or cure of cancer; prevents or lowers the risk of cancer; is effective in reducing the size of, or eliminating, cancerous tumors; or is safe or non-toxic or has no side effects. A "covered product or service" is defined as any food, dietary supplement, or drug, including, but not limited to any of the above products, or any other health-related product, service, or program.

Part II requires that any future claim about the efficacy, performance, or health-related benefits of any covered product or service be truthful and supported by competent and reliable scientific evidence. Part III requires that respondents, in connection with the advertising of any product, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part IV of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA, and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Part V of the proposed order requires respondents to compile a list of all consumers who purchased Native Essense (Rene Caisse) Formula tea or extract, Native Essense Plus tea or extract, Native Essense with Cat's Claw tea or extract, chaparral herb (or any product containing chaparral herb), Maitake mushroom extract, or Mai-T Mushroom Plus Formula extract from respondents since July 1, 2005, and to mail a letter (attached to the proposed order as Attachment A) to each such purchaser describing the scientific evidence related to these products. Part V also prohibits respondents from providing any identifying information about these purchasers to anyone other than the Commission, another law enforcement agency, or as required by law.

Part VI of the proposed order requires respondents to keep copies of relevant advertisements and materials that substantiate claims made in the advertisements. Part VII requires respondents to provide copies of the order to certain of their employees. Part VIII requires the corporate respondent to notify the Commission at least thirty days prior to any change in the corporation that may affect compliance obligations arising under this order. Part IX requires the individual respondents to notify the Commission of their affiliation with any new business or employment. Part X requires respondents to file compliance reports with the Commission. Part XI of the proposed order is a "sunset" provision, dictating that the order will terminate twenty years from the date it is issued or twenty years after a complaint is filed in federal court, by either the United States or the FTC, alleging any violation of the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.