

Appendix "A"

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished with a copy of a draft of complaint which the San Francisco Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Body Wise International, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office, principal place of business and mailing address at 6350 Palomar Oaks Court, Suite A, Carlsbad, California.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent and the proceeding is in the public interest.

ORDER

DEFINITIONS

For the purposes of this order, the following definitions shall apply:

A. "*Distributor*" means any person, other than direct employees of Body Wise, who has sold nutritional supplements on behalf of Body Wise or who has received any compensation in connection with the sale of nutritional supplements on behalf of Body Wise, whether such person is characterized as a consultant, associate, distributor or otherwise.

B. "*Competent and reliable scientific evidence*" means tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I.

It is ordered, That Body Wise International, Inc., a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting or assisting others in misrepresenting, in any manner, directly or by implication, that the nutritional supplement, food or drug:

a. Can cause, aid, facilitate or contribute to achieving or maintaining weight loss without a reduction in total caloric intake or an increase in exercise; or

b. Contains any ingredient that, individually or in connection with other ingredients, can cause, aid, facilitate or contribute to achieving

or maintaining weight loss without a reduction in total caloric intake or an increase in exercise.

II.

It is further ordered, That Body Wise International, Inc., a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing or assisting others in representing, in any manner, directly or by implication, that the nutritional supplement, food or drug:

- a. Can cause, aid, facilitate or contribute to achieving or maintaining weight loss;
- b. Contains any ingredient that, individually or in connection with other ingredients, can cause, aid, facilitate or contribute to achieving or maintaining weight loss;
- c. Reduces, can reduce or helps reduce serum cholesterol levels;
- d. Contains any ingredient that, individually or in connection with other ingredients, reduces, can reduce or helps reduce serum cholesterol levels; or
- e. Provides, can provide, or helps provide any other health benefit;

unless, at the time of making any such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

It is further ordered, That Body Wise International, Inc., a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with

the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

It is further ordered, That Body Wise International, Inc., a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing or assisting others in representing, in any manner, directly or by implication, that any endorsement (as "endorsement" is defined in 16 CFR 255.0(b)) of such nutritional supplement, food or drug represents the typical or ordinary experience of members of the public who use the nutritional supplement, food or drug, unless such representation is true and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates such representation.

Provided, however, respondent may use such endorsements if the statements or depictions that comprise the endorsements are true and accurate, and if respondent discloses clearly, prominently, and in close proximity to the endorsement:

- a. What the generally expected performance would be in the depicted circumstances; or
- b. The limited applicability of the endorser's experience to what consumers may generally expect to achieve; *i.e.*, that consumers should not expect to experience similar results.

V.

It is further ordered a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from failing to disclose, clearly and prominently, a material connection, when one exists, between a person providing an endorsement for any such product, as "endorsement" is defined in 16 C.F.R. 255.0(b), and respondent or any other individual or entity manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product. For purposes of this order, "material connection" shall mean any relationship that might materially affect the weight or credibility of the endorsement and would not reasonably be expected by consumers.

VI.

It is further ordered, That Body Wise International, Inc., a corporation, its successors and assigns, and its officers, directors, representatives, agents, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of nutritional supplements, food or drugs, as "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. 52 and 55, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from disseminating or assisting others in disseminating any advertisement which contains any reference to physicians or other health care professionals unless respondent discloses clearly and conspicuously that physicians and other health care professionals who endorse Body Wise products may be Body Wise distributors and have a financial interest in promoting the sale of Body Wise products.

VII.

Nothing in this order shall prohibit respondent from making any representation that is specifically permitted in labeling for any product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VIII.

Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IX.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation, such as dissolution, assignment, sale resulting in the emergence of a successor corporation or association, or the creation or dissolution of subsidiaries or affiliates, or any other change in the corporation that may affect compliance obligations arising under this order.

X.

It is further ordered, That for three (3) years following the dissemination of any representation covered by this order, respondent, or its successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying, copies of:

A. All materials that were relied upon in disseminating such advertisement; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in its possession or control that contradict, qualify, or call

into question such representation, including complaints from consumers.

XI.

It is further ordered, That respondent shall distribute a copy of this order to each of its operating divisions and to each of its officers, agents, representatives, and employees engaged in the preparation or placement of advertisements or other materials covered by this order.

XII.

It is further ordered, respondent shall distribute a copy of this order to each of its current distributors; provided that respondent may satisfy the requirements of this section with respect to current distributors by publishing the full text of this order clearly and prominently in any periodical which is published by respondent and which is distributed to all of its distributors.

XIII.

It is further ordered, That this order will terminate on September 25, 2015, or twenty years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any paragraph in this order that terminates in less than twenty years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this paragraph as though the complaint was never filed, except that the order will not terminate

between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

XIV.

It is further ordered, That respondent shall, within sixty (60) days after service of this order, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this order.

Appendix "B"

Appendix “B”

Dear Body Wise Consultant:

In 1995 Body Wise International, Inc. (BW) consented to the issuance of a cease and desist order (Order) by the Federal Trade Commission (FTC) to resolve allegations that it violated the FTC Act by making unsubstantiated claims for weight loss products. The FTC now alleges that BW violated the Order by failing to possess competent and reliable evidence to substantiate its claims that AG-Immune:

- prevents, mitigates, treats, cures or improves the symptoms of Allergies; AIDS; Asthma; Cancer; Candida; Canker Sores; Chronic Fatigue Syndrome; Cold; Colon Disease; Crohn’s Disease; Epstein Barr; Fibromyalgia; Flu; Heart Disease; Hepatitis B; Hepatitis C; HIV; Hyperactive Thyroid; Infection, Irritable Bowel Syndrome; Lupus; Mononucleosis; Poison Ivy; Rheumatoid Arthritis; Shingles; Sinusitis; Toenail Fungus; and Ulcerative Colitis;
- triggers or activates the immune system to prevent or treat diseases or conditions;
- increases the activity and/or the production of natural killer (NK) cells to prevent or treat diseases or conditions;
- gives the immune system specific, coded information on how to respond to diseases or conditions; and
- improves immune system function to prevent or treat diseases or conditions.

The FTC also alleges that BW violated the Order by falsely claiming that AG Immune has been shown by scientific research to prevent, mitigate, treat, cure or improve the symptoms of the above-listed diseases or conditions. Finally, the FTC alleges that BW advertising contained expert endorsements by Dr. Jesse A. Stoff without disclosing, clearly and conspicuously, that Dr. Stoff derived financial compensation from the sale of BW products containing the ingredient Ai/E¹⁰, in violation of the Order.

As a result of discussions with the FTC, BW has agreed to the entry of a consent decree (Decree) in the United States District Court for the Central District of California to resolve the FTC’s allegations that it violated the Order. The Decree is for settlement purposes only and does not constitute an admission of violations of the Order by BW. Pursuant to the Decree, BW has agreed to the payment of a \$2 million civil penalty and an injunction prohibiting future violations of the Order. The Decree enjoins BW from making any of the above listed claims, or making any claim with respect to the health benefits of any product or service for the immune system or weight control, any health-related service or therapy, or any dietary supplement, food, drug, or device, unless, at the time of making the claim, BW possesses competent and reliable scientific evidence substantiating the claim. The injunction applies to BW, its officers, agents, representatives, and employees, and all persons in participation with any of them who receive actual notice of the Decree. Accordingly, BW has withdrawn and destroyed all prior materials containing the contested claims. We suggest that you do the same.

The Decree requires that BW provide a copy of this notice to each of its current and future consultants.

If you have any questions or would like a copy of the Decree, you may contact BW at (phone number or e-mail address). Thank you for your cooperation.

Sincerely yours,

BW