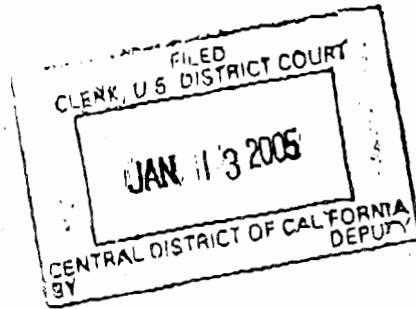


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8 Attorneys for Plaintiff  
 9 United States of America

10 UNITED STATES DISTRICT COURT  
 11 CENTRAL DISTRICT OF CALIFORNIA  
 SOUTHERN DIVISION

12 UNITED STATES OF AMERICA,

13 Plaintiff,

CIVIL ACTION

14 v.

15 BODY WISE INTERNATIONAL, INC., and  
 16 JESSE A. STOFF, M.D.,

SACV 05-43 DOC (ANx)

17 Defendants.

18  
 19 **COMPLAINT FOR CIVIL PENALTIES,**  
 20 **INJUNCTIVE AND OTHER RELIEF**

21 Plaintiff, United States of America, acting upon the notification and  
 22 authorization to the Attorney General by the Federal Trade Commission  
 23 ("Commission"), for its Complaint alleges that:

24 1. Plaintiff brings this action under Sections 5(a), 5(l), 12, 13(b) and 16(a) of the  
 25 Federal Trade Commission Act ("FTC Act"), 15 U.S.C. §§ 45(a), 45(l), 52, 53(b)  
 26 and 56(a), to obtain monetary civil penalties, consumer redress and/or  
 27 disgorgement, injunctive and other relief for Defendants' violations of the Federal  
 28

1 Trade Commission Act and a final cease and desist order issued by the  
2 Commission.

3 **JURISDICTION AND VENUE**

4 2. This Court has jurisdiction over this matter under 28 U.S.C. §§ 1331, 1337(a),  
5 1345 and, 1355 and under 15 U.S.C. §§ 45(a), 45(l), 52, 53(b) and 56(a).

6 3. Venue in the United States District Court for the Central District of California  
7 is proper under 15 U.S.C. § 53(b) and under 28 U.S.C. §§ 1391(b-c) and 1395(a).

8 **THE DEFENDANTS**

9 4. Defendant **Body Wise International, Inc.** (“Body Wise”) is a Nevada  
10 corporation with its principal office and place of business located at 2802 Dow  
11 Avenue, Tustin, California 92789.

12 5. Defendant **Jesse A. Stoff, M.D.** (“Stoff”) does business within the Central  
13 District of California. His business address is Immune Consultants, LLC, 2507  
14 North 1<sup>st</sup> Avenue, Tucson, Arizona 85719. Defendant Stoff is a consultant to Body  
15 Wise and derives financial compensation from the sale of Body Wise products.  
16 Individually and in concert with others, Stoff has formulated, directed, controlled  
17 or participated in the acts and practices set forth herein.

18 6. At all times mentioned herein, Defendants have been engaged in the labeling,  
19 advertising, promotion, offering for sale, sale or distribution of nutritional  
20 supplements that purportedly prevent, mitigate or treat certain diseases and/or  
21 medical conditions. Each of Defendants’ nutritional supplements is a “food” or  
22 “drug,” within the meaning of sections 12 and 15 of the Federal Trade Commission  
23 Act, 15 U.S.C. §§ 52, 55.

24 7. Defendants maintain, and at all times mentioned herein have maintained, a  
25 course of trade in or affecting commerce, as “commerce” is defined in Section 4 of  
26 the FTC Act, 15 U.S.C. § 44.



1 II.

2 IT IS FURTHER ORDERED that Body Wise International,  
3 Inc., a corporation, its successors and assigns, and its officers,  
4 directors, representatives, agents, and employees, directly or  
5 through any corporation, subsidiary, division or other device, in  
6 connection with the advertising, packaging, labeling,  
7 promotion, offering for sale, sale or distribution of nutritional  
8 supplements, food or drugs, as “food” and “drug” are defined in  
9 sections 12 and 15 of the Federal Trade Commission Act, 15  
10 U.S.C. §§ 52 and 55, in or affecting commerce, as “commerce”  
11 is defined in the Federal Trade Commission Act, do forthwith  
12 cease and desist from representing or assisting others in  
13 representing, in any manner, directly or by implication, that the  
14 nutritional supplement, food or drug:

15 \* \* \*

16 e. provides, can provide, or helps provide any other health  
17 benefit;

18 unless, at the time of making such representation, respondent  
19 possesses and relies upon competent evidence that substantiates the  
20 representation.

21 III.

22 IT IS FURTHER ORDERED that Body Wise International,  
23 Inc., a corporation, its successors and assigns, and its officers,  
24 directors, representatives, agents and employees, directly or  
25 through any corporation, subsidiary, division or other device, in  
26 connection with the advertising, packaging, labeling,  
27 promotion, offering for sale, sale or distribution of nutritional  
28 supplements, food or drugs, as “food” and “drug” are defined in

1 sections 12 and 15 of the Federal Trade Commission Act, 15  
2 U.S.C. §§ 52 and 55, in or affecting commerce, as “commerce”  
3 is defined in the Federal Trade Commission Act, do forthwith  
4 cease and desist from misrepresenting, in any manner, directly  
5 or by implication, the existence, contents, validity, results,  
6 conclusions, or interpretations of any test or study.

7 \* \* \*

8 V.

9 IT IS FURTHER ORDERED that Body Wise International,  
10 Inc., a corporation, its successors and assigns, and its officers,  
11 directors, representatives, agents and employees, directly or  
12 through any corporation, subsidiary, division or other device, in  
13 connection with the advertising, packaging, labeling,  
14 promotion, offering for sale, sale or distribution of nutritional  
15 supplements, food or drugs, as “food” and “drug” are defined in  
16 sections 12 and 15 of the Federal Trade Commission Act, 15  
17 U.S.C. §§ 52 and 55, in or affecting commerce, as “commerce”  
18 is defined in the Federal Trade Commission Act, do forthwith  
19 cease and desist from failing to disclose, clearly and  
20 prominently, a material connection, when one exists, between a  
21 person providing an endorsement for any such product, as  
22 “endorsement” is defined in 16 C.F.R. § 255.0(b), and  
23 respondent or any other individual or entity manufacturing,  
24 labeling, advertising, promoting, offering for sale, selling, or  
25 distributing such product. For the purposes of this Order,  
26 “material connection” shall mean any relationship that might  
27 materially affect the weight or credibility of the endorsement  
28 and would not reasonably be expected by consumers.”

## DEFENDANTS' COURSE OF CONDUCT

10. Defendant Body Wise promotes, offers for sale, sells or distributes numerous Body Wise-branded nutritional supplements directly to consumers and through a network of "consultants." The consultants, who are often independent health care providers, agree to retail Body Wise products from their homes or as a part of their ongoing businesses.

11. Since April 2000, Defendant Body Wise has labeled, advertised, promoted, offered for sale, sold, or distributed, throughout the United States and parts of Canada, AG-Immune, a product for human consumption containing an ingredient referred to as "antigen infused dialyzable bovine colostrum/whey" or "AI/E-10."

The active ingredients in each dose of AG-Immune are as follows:

100 milligrams (mg.) AI/E-10

300 mg. arabinogalactin

50 mg. maitake mushroom

50 mg. astragalus.

12. Since Defendant Body Wise introduced AG-Immune in April 2000, Defendant's sales of AG-Immune have exceeded \$14 million.

13. Defendant Body Wise markets AG-Immune as a product that triggers the immune system and prevents or treats numerous diseases or conditions or their symptoms in human beings, including cancer.

14. In April 2000, Defendant Body Wise contracted with Defendant Stoff to consult, explain the benefits, describe his personal clinical observations, endorse, and popularize the Body Wise products containing AI/E-10, including AG-Immune.

15. Body Wise pays Defendant Stoff 50¢ per unit of AI/E-10 products sold. Body Wise has paid Stoff over \$250,000 for his services.

16. Defendants Body Wise and Stoff promote AG-Immune to consumers via a publication and an audiotape:

1 A. "The Ultimate Nutrient: Clinically Proven Benefit for Anyone  
2 Suffering Weakened Immune Function, Irritable Bowel Syndrome, Chronic  
3 Fatigue Syndrome, Candida Albicans, Arthritis and Rheumatism, Infection,  
4 Hepatitis C, Colds and Flu, Sinusitis, HIV/AIDS, Heart Disease, Lupus,  
5 Cancer," a publication authored by Defendant Jesse A. Stoff, and

6 B. "The Killer Within," an audiotope authored by and featuring Defendant  
7 Jesse A. Stoff.

8 Defendant Body Wise and its consultants recommend that consumers seeking  
9 specific information about the use and benefits of AG-Immune in the treatment,  
10 cure or mitigation of a wide variety of serious diseases or conditions, including  
11 weakened immune function, irritable bowel syndrome, chronic fatigue syndrome,  
12 candida albicans, arthritis and rheumatism, infection, hepatitis C, colds and flu,  
13 sinusitis, HIV/AIDS, heart disease, lupus, and cancer, purchase these materials  
14 from defendant Body Wise or its consultants. Information on how to order these  
15 materials is also available on Defendant Body Wise's Internet web site,  
16 [www.bodywise.com](http://www.bodywise.com).

17 17. "The Ultimate Nutrient" and "The Killer Within" were used to generate  
18 public interest in AI/E-10 products and promote their use.

19 18. Since April 2000, Defendants have made unsubstantiated claims in  
20 advertising and other promotional materials that AG-Immune is effective for use in  
21 the cure, mitigation or prevention of disease in human beings; and have falsely  
22 claimed that these claims are substantiated. Defendants' false and unsubstantiated  
23 advertising is set forth in greater detail below.

#### 24 **DEFENDANTS' ADVERTISING OF AG-IMMUNE**

25 19. Since April 2000, Defendants have disseminated or caused to be  
26 disseminated advertisements and promotional materials for AG-Immune including,  
27 but not necessarily limited to, the attached Exhibits A-I. These advertisements  
28 and promotional materials contain the following statements:

1 a. “Nothing compares to the immune supporting power of Ai/E<sup>10</sup>.™ . . .  
2 A double-blind clinical study shows that antigen infused bovine  
3 colostrum/whey extract improves the immune system function in  
4 healthy people. (Exhibit A-1).

5 b. Your immune system is a complicated network of cells and bio-  
6 chemicals that act as a defense system for your body. Its job is  
7 to seek-and-destroy all foreign invaders. If your immune  
8 system is weakened, it won’t be able to fend off the destructive  
9 effects of invasive organisms or poisons. If your immune  
10 system is overworking, it can result in autoimmune disorders,  
11 such as chronic fatigue syndrome, ulcerative colitis, rheumatoid  
12 arthritis, Crohn’s disease and lupus. Autoimmune illness  
13 results when the immune system reacts to normal components  
14 of the body as if they were foreign substances and produces  
15 antibodies against them.

16 A strong immune system will include active natural killer (NK)  
17 cell function, an important component in maintaining good  
18 health. They are the body’s primary defense against developing  
19 virally-infected cells and cancer cells. However, these cells  
20 must be “activated” in order to be effective and this is achieved  
21 through a complex communication network within the body. If  
22 this communication network is compromised, however, there  
23 will be a reduction in NK cell activity. AG-Immune can help  
24 your body reverse this process. (Exhibit A-2).

25 Body Wise International explicitly makes no claims for nutrient  
26 efficacy, or the treatment, mitigation, prevention or cure of disease. If  
27 you are ill, we recommend you see a qualified physician. Individuals  
28 providing their Body Wise testimonials or endorsements, including



1 physicians and other health care professionals, have a financial  
2 interest in promoting the sale of Body Wise products. This statement  
3 has not been evaluated by the U.S. Food and Drug Administration.

- 4 c. **AG-Immune** includes an immune system ‘trigger’ which gives your  
5 immune system specific, coded information on how to respond.  
6 When used in clinical studies, Ai/E<sup>10</sup>™, the patented proprietary  
7 ingredient in **AG-Immune**, supports and ‘triggers’ large increases in  
8 the production of natural killer (NK) cell activity without the risk of  
9 overstimulating or otherwise confusing the immune function, as other  
10 products do.\* (Exhibit A-2).

11 \*Refer to the book ‘The Ultimate Nutrient,’ by Jesse Stoff, M.D.,  
12 Insight Consulting, AZ 2000.

13 Body Wise International explicitly makes no claims for nutrient  
14 efficacy, or the treatment, mitigation, prevention or cure of disease. If  
15 you are ill, we recommend you see a qualified physician. Individuals  
16 providing their Body Wise testimonials or endorsements, including  
17 physicians and other health care professionals, have a financial  
18 interest in promoting the sale of Body Wise products. This statement  
19 has not been evaluated by the U.S. Food and Drug Administration.

- 20 d. When compromised, your immune system forgets what and when to  
21 attack. AG-Immune includes an immune system trigger which gives  
22 your immune system specific, coded information on how to respond.

23 – Jesse Stoff, M.D.

24 One of the nation’s top immunologists (Exhibit A-2).

25 Body Wise International explicitly makes no claims for nutrient  
26 efficacy, or the treatment, mitigation, prevention or cure of disease. If  
27 you are ill, we recommend you see a qualified physician. Individuals  
28 providing their Body Wise testimonials or endorsements, including

1 physicians and other health care professionals, have a financial  
2 interest in promoting the sale of Body Wise products. This statement  
3 has not been evaluated by the U.S. Food and Drug Administration.

4 e. **A Unique Immune System Trigger**

5 Think of your immune system as the engine that keeps your body  
6 running smoothly; Ai/E<sup>10</sup>™ acts as the trigger or spark which fires up  
7 the engine and helps it work properly without misfiring. (Exhibit A-  
8 3).

9 f. The **AG-Immune** formula combines the “triggering” activity of  
10 Ai/E<sup>10</sup>™ with nutritional “fuels” that feed and energize your immune  
11 system. References in the field of natural medicine show:

12 \* \* \*

13 ■Reduces risk of colon disease (decreases harmful bacteria  
14 entobacters)

15 \* \* \*

16 ■Used in cancer treatment in China

17 ■Increases Interferon production

18 ■Known to support and accelerate immunological reactions

19 \* \* \*

20 ■Stimulates cytokine production – interferon, interleukins,  
21 natural killer cells (NK) and tumor necrosis factors (Exhibit A-  
22 3).

23 g. ‘With antigen infused dialyzable bovine colostrun/whey extract  
24 (Ai/E<sup>10</sup>™), in conjunction with nutritional fuels, I have been able to  
25 activate the immune systems of hundreds and hundreds of people. I  
26 believe this is the most powerful nutrient ever created for immune  
27 modulation.’ – *Jesse Stoff, M.D.*” (Exhibit A-4).

28

1 Body Wise International explicitly makes no claims for nutrient  
2 efficacy, or the treatment, mitigation, prevention or cure of disease. If  
3 you are ill, we recommend you see a qualified physician. Individuals  
4 providing their Body Wise testimonials or endorsements, including  
5 physicians and other health care professionals, have a financial  
6 interest in promoting the sale of Body Wise products. This statement  
7 has not been evaluated by the U.S. Food and Drug Administration.

8 **h. Scientific Validation for AG-Immune™ Ingredient**

9 Body Wise® International is pleased to announce the first double-blind  
10 placebo-controlled study of the effects on immune function created by  
11 the oral intake of antigen infused bovine colostrum/whey extract. A  
12 proprietary form of this extract, designated Ai/E<sup>10</sup>™ is an integral part  
13 of the formulation in the exclusive Body Wise products AG-  
14 Immune™ and Relief™. . . .

15 In this recent double-blind-placebo-controlled study,\* 20 healthy  
16 people took 100 mg of antigen infused bovine colostrum/whey extract  
17 (a main ingredient in the AG-Immune and Relief products) or a  
18 placebo three times a day for 15 days. At the end of the 15-day trial,  
19 there was a significant increase in natural killer (NK) cells, tumor  
20 necrosis factor (TNF), and macrophage activity – important immune  
21 system components – in the people taking the antigen infused bovine  
22 colostrum/whey extract. There was no significant improvement in  
23 immune system function in the people taking the placebo. This study  
24 shows that antigen infused bovine colostrum/whey extract helps to  
25 support the protective functions of the immune system.

26 [graphic photograph of cells]

27 NK Cells Killing a Cancer Cell

1 \*Stoff, JA. 'The Examination of Immune Response Modulation in  
2 Humans by Antigen Infused Dialyzable Bovine Colostrum/Whey  
3 Extract Utilizing a Double Blind Study.' Tucson, AZ: Immune  
4 Consultants: 2001.

5 These statements have not been evaluated by the Food and Drug  
6 Administration. These products are not intended to diagnose, treat,  
7 cure or prevent any disease. (Exhibit B).

8 i. **Confronting the Cold and Flu Season Head on with AG-  
9 Immune™ and Relief™**

10 **Isn't It About Time You Protected Your Immune System?**

11 **Q. What do you get when you add AG-Immune™ and a bottle of  
12 Relief™ to the medicine cabinet for every member of your  
13 family?**

14 **A. A strong healthy, and happy family ready to take on the cold  
15 and flu season.**

16 These statements have not been evaluated by the Food and Drug  
17 Administration. These products are not intended to diagnose, treat,  
18 cure or prevent any disease. (Exhibit C).

19 j. Our son Austin, who has asthma, started taking **AG-Immune** and the  
20 **Body Wise** products in February 2001. We noticed a difference  
21 within 4 days of him taking the products. Within five days all of our  
22 son's symptoms were completely gone. His congestion and cough  
23 have cleared up and he is able to sleep through the night. (Exhibit D).

24 Individuals providing their **Body Wise** testimonials or endorsements,  
25 including physicians and other healthcare professionals have a  
26 financial interest in promoting the sale of **Body Wise** products.

27 k. I have lupus. After starting the **Body Wise** products in September  
28 2000, I have been living my life everyday without pain. I no longer

1 have to spend my life in doctors' offices or in the hospital. I also  
2 sleep regularly. I attend outings with my friends, golf, and play with  
3 my dogs on the beach. This is all possible with **AG-Immune** and  
4 **Body Wise**. (Exhibit D).

5 Individuals providing their **Body Wise** testimonials or endorsements,  
6 including physicians and other healthcare professionals have a  
7 financial interest in promoting the sale of **Body Wise** products.

- 8 1. **Every Day Your Body Is Under Attack And The Results Can Be**  
9 **Deadly.**

10 *The best thing you can do is to bolster your immune system so it can*  
11 *defend itself from infection and foreign invaders. We believe **Body***  
12 *Wise International's all natural **AG-Immune**<sup>TM</sup> formula is **the most***  
13 ***powerful product ever created to promote a healthy immune system .***  
14 *. . . and a healthier future. And while it's [sic] primary ingredient,*  
15 ***Ai/E**<sup>10</sup>**TM** , has proven to be clinically effective for use with both*  
16 *immune and autoimmune disorders, **\* you don't have to be immune***  
17 ***system challenged to enjoy the amazing benefits of this exciting new***  
18 ***supplement.** Think of it as a prudent preventative measure that*  
19 *promotes optimal health by increasing the activity of natural killer*  
20 *(NK) cells – your body's last line of defense against illness and*  
21 *disease.*

22 \*Refer to the book *The Ultimate Nutrient*, by Jesse Stoff, M.D.,  
23 Insight, Consulting, AZ 2000. (Exhibit E-1).

- 24 m. **AG-Immune** has already changed the lives of thousands of people  
25 across North America. **Imagine what it could do for you . . .**  
26 **Candida**

27 . . .one day I happened to notice that, on the cover of *The Ultimate*  
28 *Nutrient* booklet\*, candida was listed as one of the areas **Ai/E**<sup>10</sup> was

1 clinically successful in treating. I began taking two a day and literally  
2 – within 36 hours – the pain began to dissipate. After only three  
3 weeks, my symptoms were completely gone! I have been on Body  
4 Wise for almost eight years and at the risk of sounding over-dramatic.  
5 I have to say, the products have **definitely changed my quality of**  
6 **life.**

7 *Shingles*

8 In late February, I was diagnosed with shingles on my face, scalp and  
9 throat. It's been extremely painful. I tried vitamins and subscription  
10 [sic] medicines, but without relief. However, after one week of  
11 adding **AG-Immune** to my nutritional program the pain started  
12 diminishing. Four weeks later, I'm pleased to report that **my pain has**  
13 **disappeared** and so have the symptoms.

14 Consumer Notice: Personal testimonials are the reflections of  
15 individual experiences and are not typical of the results that you will  
16 obtain. If you have a medical condition, we recommend that you  
17 consult a health-care professional. Individuals providing their Body  
18 Wise testimonials or endorsements, including physicians and other  
19 health care professionals, are Body Wise Independent Consultants and  
20 have a financial interest in promoting the sale of Body Wise products.  
21 The statements herein have not been evaluated or approved by the  
22 Food and Drug Administration or the Federal Trade Commission.  
23 Body Wise makes no claim that its products are meant to treat,  
24 diagnose, cure or prevent disease. All Body Wise consultants are  
25 independent contractors.

26 \*Refer to the book *The Ultimate Nutrient*, by Jesse Stoff, M.D.,  
27 Insight, Consulting, AZ 2000. (Exhibit E-1).

1 n. *Allergies*

2 I couldn't be more excited about **AG-Immune**<sup>TM</sup>! My daughter has  
3 had severe allergies since she was six months old. . . . I often had to  
4 miss work to care for her. Then Body Wise introduced **AG-Immune**  
5 and I began adding two capsules a day to her applesauce. I couldn't  
6 believe the difference in her! No more sneezing, no more runny nose,  
7 and now she can play outside almost all day."

8 (A "Consumer Notice" identical to that set forth in Paragraph 12(m)  
9 appears in small print at the bottom of the page). (Exhibit E-2).

10 o. *"Poison Ivy*

11 I became exposed to poison ivy and my dermatologist said it would  
12 take two weeks to clear up. He gave me a prescription for some  
13 topical cream. After I added **AG-Immune** to my nutritional program,  
14 I experience absolutely no itching or discomfort whatsoever, and the  
15 rash only lasted about ten days. **Quite amazing!**"

16 (A "Consumer Notice" identical to that set forth in Paragraph 12(m)  
17 appears in small print at the bottom of the page). (Exhibit E-2).

18 p. *"Asthma*

19 For several years, my athletic 16-year-old son has been an asthma  
20 sufferer and was subject to frequent respiratory infections. Since  
21 adding the nutritional support of four **AG-Immune** a day, he's needed  
22 no breathing treatments, had no upper respiratory infections and has  
23 only occasionally used an inhaler. As a concerned parent, **I'm**  
24 **thrilled.**"

25 (A "Consumer Notice" identical to that set forth in Paragraph 12(m)  
26 appears in small print at the bottom of the page). (Exhibit E-2).

1 q. ***“Fibromyalgia***

2 My 28-year-old daughter has suffered with fibromyalgia for three  
3 years now. She added six **AG-Immune** capsules a day to her  
4 nutritional regimen and after ten days, **her symptoms subsided**. She  
5 has been feeling some healing affects – mild cold-like symptoms – but  
6 her pain, numbness, fatigue, headaches, etc., have subsided. **Thank**  
7 **you, Body Wise!”**

8 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
9 appears in small print at the bottom of the page). (Exhibit E-2).

10 r. ***“Hyperactive Thyroid***

11 For the past seven weeks, I’ve been fighting a health problem that  
12 totally depleted my energy. . . . Finally, the doctors determined that I  
13 had a virus or infection which caused me to have a hyperactive  
14 thyroid. I was told no medication would resolve this problem and that  
15 recovery time was four to five months. Ironically, my **AG-Immune**  
16 arrived that evening. After two weeks of adding it to my nutritional  
17 regimen, **I felt 100 percent recovered**. Now I’m able to **work a full**  
18 **day and have great energy!”**

19 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
20 appears in small print at the bottom of the page). (Exhibit E-2)

21 s. ***“Toenail Fungus***

22 I originally began adding **AG-Immune** to my nutritional regimen for  
23 my allergies and soon discovered it was helping a secondary problem  
24 I hadn’t considered. I have had a fungus under my big toenail for  
25 over 15 years. I have even had it surgically removed to try to correct  
26 the problem. . . . I have been on **AG-Immune** for two months now  
27 and **I now have a healthy toenail. . . .”**



1 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
2 appears in small print at the bottom of the page). (Exhibit E-3).

3 t. **“Rheumatoid Arthritis**

4 About six months ago, rheumatoid arthritis struck my hands and feet  
5 with pain and swelling. After hearing Jesse Stoff at the ELC, I started  
6 adding the nutritional support of six **AG-Immune** daily. Within a  
7 week, the pain and swelling has subsided. When I write, I don’t have  
8 pain and there’s very little swelling.”

9 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
10 appears in small print at the bottom of the page). (Exhibit E-3).

11 u. **“Stamina**

12 When my fit, athletic wife added two **AG-Immune** to her Body Wise  
13 nutritional program, she started experiencing **incredible results**.

14 Within her first week, she started a running program. . . . Six weeks  
15 into her **AG-Immune** regimen, she now runs a mile for speed one  
16 day, then two miles for endurance the next. . . . She’s noticed a  
17 **significant increase in energy and overall tone** as well as an  
18 **improved positive attitude.**”

19 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
20 appears in small print at the bottom of the page). (Exhibit E-3).

21 v. **“Hepatitis B**

22 Unfortunately, when [my mother] had her hip replacement done two  
23 years ago, she apparently contracted Hepatitis B. Over the past year,  
24 she has become increasingly fatigued and developed a badly swollen,  
25 inflamed liver. Unfortunately, her doctor was unable to help her with  
26 this condition. . . . [W]e added the nutritional support of four **AG-**  
27 **Immune** a day. This week her doctor told her that the liver was  
28 normal and that she need not return for three months.”

1 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
2 appears in small print at the bottom of the page). (Exhibit E-3).

3 w. ***“Sinusitis and Chronic Fatigue***

4 For the past ten years I’ve been a chronic sinus infection sufferer. . . .  
5 [T]he years of infection and antibiotics left me with a lack of stamina  
6 and symptoms of chronic fatigue. I started **AG-Immune** – six a day –  
7 and felt **completely revitalized** after the second day.”

8 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
9 appears in small print at the bottom of the page). (Exhibit E-3).

10 x. ***“Canker Sores***

11 “Two weeks ago, my three-year-old daughter got her first bout of  
12 canker sores. . . . [S]he complained that it hurt to swallow. . . . [S]he  
13 would not eat. . . . I decided to mix a half a capsule of **AG-Immune** in  
14 her rice milk at breakfast, then the other half at lunchtime in her  
15 chamomile tea. At dinnertime, I mixed another half capsule in her  
16 evening water. To my amazement, the next morning she woke me up  
17 saying how hungry she was. . . . She ate [breakfast] without a  
18 complaint. . . .”

19 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
20 appears in small print at the bottom of the page). (Exhibit E-4).

21 y. ***“Mononucleosis***

22 My 13-year-old niece Paige had been in bed for three weeks with  
23 mononucleosis and wasn’t getting better. My sister-in-law started her  
24 on the nutritional support of two **AG-Immune** capsules the first day  
25 and then four capsules for the next three days. She was back to school  
26 the following day!”

27 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
28 appears in small print at the bottom of the page). (Exhibit E-4).

1 z. ***“Chronic Fatigue and Epstein Barr***

2 I’ve had Chronic Fatigue and the Epstein-Barr Virus for years which  
3 has resulted in many challenges. I added **AG-Immune** to my  
4 nutritional supplement program in April when it first came out and  
5 also followed the Dr. Jesse Stoff regimen of reducing stress and  
6 getting more rest. I feel better than I ever have in my life.”

7 (A “Consumer Notice” identical to that set forth in Paragraph 12(m)  
8 appears in small print at the bottom of the page). (Exhibit E-4).

9 aa. **“Announcing new AG-Immune!**

10 . . . Ai/E<sup>10</sup> is an amazing nutrient found in AG-Immune. . . . Some of  
11 the conditions which are highly resistant to cure, but for which **Ai/E<sup>10</sup>**  
12 **in clinical use has proven to be very effective are:**

- 13 • **Cancer**
- 14 • **Irritable Bowel Syndrome**
- 15 • **Colds and flu**
- 16 • **Chronic Fatigue Syndrome**
- 17 • **Sinusitis**
- 18 • **Candida Albicans**
- 19 • **Arthritis and Rheumatism**
- 20 • **Heart Disease**
- 21 • **Infection**
- 22 • **Lupus**
- 23 • **Hepatitis C**

24 (Exhibit F).

25 bb. If you’re like me, you know there are killers, biological killers,  
26 waiting in the shadows to claim your life, and you know it’s not only  
27 celebrities, you have friends and relatives recently diagnosed with  
28

1 breast cancer, prostate cancer, maybe even lupus, chronic fatigue  
2 syndrome or hepatitis C. (Exhibit G-1).

3 \* \* \*

4 On this audio, you're going to hear about the most powerful break-  
5 through in human nutrition in the last 100 years. It is now possible to  
6 modulate your immune system, to make yourself more resistant to  
7 these ravaging, chronic and infectious diseases that are the result of  
8 modern life and a suppressed immune system. (Exhibit G-3).

9 \* \* \*

10 Let's join Dr. Jesse Stoff in a recent interview. (Exhibit G-6)

11 \* \* \*

12 MALE INTERVIEWER: You and Tom Tierney recently  
13 collaborated to formulate an immune modulation product, using a  
14 component, which has been referred to as the ultimate nutrient. What  
15 is it about this product that modulates the immune system so quickly  
16 and effectively?

17 DR. STOFF: The most effective immune modulator that has yet  
18 to be discovered is this wonderful compound of communication  
19 molecules referred to as Ai/E<sup>10</sup>. Ai/E<sup>10</sup>, of course, is the most potent  
20 component of AG-Immune. Ai/E<sup>10</sup> is a unique combination of  
21 molecules that enables the immune system to turn back on its  
22 identification process to identify things that are potential risks to our  
23 body. Then Ai/E<sup>10</sup> goes further to turn on the modulating effect of  
24 restoring the ability of the immune system to create an effective  
25 counter attack to search for and destroy abnormal cells, to search for  
26 and destroy virally infected cells, to help our body in the  
27 detoxification process. (Exhibit G-13).

28 \* \* \*

1 DR. STOFF: In my practice, I have specialized in working with  
2 people with severe and chronic diseases. Now, I specialize in doing  
3 research and in consulting with physicians who are continuing to work  
4 with these patients. I have seen many, many cases of patients where  
5 cancers can be reversed and put into a state of long-term remission,  
6 where severe and chronic infectious diseases, hepatitis C, Epstein-  
7 Barr virus can also be stopped and reversed through a process of  
8 immune support, detoxification, and critically immune modulation.  
9 (Exhibit G-16-17).

10 \* \* \*

11 I [DR. STOFF] recently completed a double blind study on 20 people  
12 where half of them were given a placebo and half were given the pure  
13 Ai/E<sup>10</sup> complex. The results were astounding to see in how quickly  
14 the immune system was able to restore its modulating function and its  
15 protective function in helping to reduce our risk of getting future  
16 illness. (Exhibit G-18).

17 \* \* \*

18 MALE INTERVIEWER: Dr. Stoff, we recognize that individual cases  
19 cannot predict the experience of our listeners, but. . . . One patient, age  
20 77 with prostate cancer, saw his NK level rise from seven to 757 over  
21 21 months and cancer in remission. Another, 56-year-old, in 16  
22 months experiences an NK level increase from 26 to 399 and chronic  
23 fatigue syndrome is resolved. A 38-year-old with chronic infection  
24 went from four to 368 in 31 months and was normalized. Others had  
25 significant results in three to six months.” (Exhibit G-20-21).  
26  
27  
28

1 cc.

2 **“Antigen Infused Dialyzable**  
3 **Bovine Colostrum/Whey Extract**

4 **The**  
5 **Ultimate**  
6 **Nutrient**

7 **Clinically Proven Benefit**  
8 **for Anyone Suffering**  
9 *Weakened Immune Function*

10 *Irritable Bowel Syndrome*

11 *Chronic Fatigue Syndrome*

12 *Candida Albicans*

13 *Arthritis & Rheumatism*

14 *Infection*

15 *Hepatitis C*

16 *Colds and Flu*

17 *Sinusitis*

18 *HIV/AIDS*

19 *Heart Disease*

20 *Lupus*

21 *Cancer*

22 **Jesse A. Stoff, M.D.**

23 (Exhibit H).

24 dd. BIG BEAR SEMINAR

25 MARSHA: My name is MARSHA HART and I'm really glad to have  
26 all you here this evening . . . to hear about the immune wellness  
27 seminar that TOM TIERNEY'S gonna do. (Exhibit I-10).

1 \* \* \*

2 TOM: . . . And allow me to just read this in case it's hard to read this  
3 from where you're sitting. If your [sic] like me, I would say, oh come  
4 on, are you kidding? The Ultimate Nutrient clinically proven benefit  
5 for anybody suffering from... Anybody? Weakened immune function,  
6 Irritable Bowl [sic] Syndrome, Chronic Fatigue Syndrome, Candida,  
7 Arthritis, Rheumatism, Infection, Hepatitis C, Colds, Flu, Sinusitis,  
8 HIV, Lupus, Cancer and the like. Show me, and why doesn't my  
9 doctor know? Okay, so the book gives you the results of 107 human  
10 clinicals. (Exhibit I-28).

11 So what does it take to move you up here, which is good. A healthy  
12 population. Well, intervention with an antigen infused therapy.  
13 Every single day. Just like taking a Centrum vitamin or something  
14 like that. So, when you are down here with a depressed immune  
15 system, really depressed. Wow, deep trouble. So let's look at some  
16 of those clinical cases that doctor STOFF has shared with us. And I  
17 want to reinforce, I'm not here as a physician because I'm not.

18 \*\*\*Now why don't you take that patient? That happens to be a 48-  
19 year-old male with Chronic Fatigue Syndrome, Psoriasis, an NK level  
20 21 which we can all tell is poor, on that chart. JESSE'S treated that  
21 man for 20 months to put a \*\*\* an NK count of 780, and things look  
22 good. (Exhibit I-29).

23 The number one preventable cancer is colon cancer. Number one  
24 preventable cancer. Slow growing easy to detect, and the first thing  
25 you do is you start to notice uh, \*\*\* colon \*\*\* get polyps. Well, and  
26 this is a guy problem, this particular case is a beer drinker. Beer  
27 predisposes you to colon cancer \*\*\*. Now this guy had a lot of colon  
28 polyps. He was a polyp factory. No wonder. He had an NK count of

1 one. You might as well say nothing. You talk about sneezing and  
2 saying goodbye to him. JESSE treated him, 26 months, brought his  
3 NK level to an acceptable range. Polyps are gone. (Exhibit I-29-30).  
4 Now let's go and talk about that woman, case number eleven. 42  
5 years old, Ovarian Cancer, JESSE treated her for 15 months.  
6 Complete remission. She started out with an NK count of 23.  
7 Brought it up to \*\*\*. You know this goes on and on. (Exhibit I-30).  
8 By the way, in the statistics, he tells you about the cases that don't.  
9 And he told me personally that these 107 cases, he lost an additional  
10 three people, but they presented themselves with him, when all other  
11 treatments have failed. So what we advocate is a prevention strategy,  
12 it's called know this stuff. Buy it for yourself \*\*\* I want to be  
13 proactive and I can do something about it, cause you can. This is the  
14 trade name for the antigen infused extract it's called AIE-10."  
15 (Exhibit I-30).

## 16 **VIOLATIONS OF THE COMMISSION'S ORDER**

### 17 **FIRST CAUSE OF ACTION**

18 20. Through the means described in Paragraph 19, Defendant Body Wise  
19 International, Inc., in connection with the labeling, advertising, promotion, offering  
20 for sale, sale, or distribution of AG-Immune, has represented, expressly or by  
21 implication, including through the use of expert endorsements and consumer  
22 testimonials, that:

23 A. AG-Immune prevents, mitigates, treats, cures or improves the  
24 symptoms of the following diseases or conditions: Allergies; AIDS; Asthma;  
25 Cancer; Candida; Canker Sores; Chronic Fatigue Syndrome; Cold; Colon  
26 Disease; Crohn's Disease; Epstein Barr; Fibromyalgia; Flu; Heart Disease;  
27 Hepatitis B; Hepatitis C; HIV; Hyperactive Thyroid; Infection; Irritable  
28



1 Bowel Syndrome; Lupus; Mononucleosis; Poison Ivy; Rheumatoid Arthritis;  
2 Shingles; Sinusitis; Toenail Fungus; and Ulcerative Colitis; and,

3 B. AG-Immune:

- 4 1. triggers or activates the immune system to prevent or treat diseases  
5 or conditions;
- 6 2. increases the activity and/or the production of natural killer (NK)  
7 cells to prevent or treat diseases or conditions;
- 8 3. gives the immune system specific, coded information on how to  
9 respond to diseases or conditions; and
- 10 4. improves immune system function to prevent or treat diseases or  
11 conditions.

12 21. Defendant Body Wise International, Inc. has made the representations set  
13 forth in Paragraph 20 without possessing and relying upon competent and reliable  
14 scientific evidence that substantiates the representations, thereby violating Part II  
15 of the Commission's order.

16 **SECOND CAUSE OF ACTION**

17 22. Through the means described in Paragraph 19, Defendant Body Wise  
18 International, Inc., in connection with the labeling, advertising, promotion, offering  
19 for sale, sale, or distribution of AG-Immune, has represented, expressly or by  
20 implication, that scientific research demonstrates that AG-Immune prevents,  
21 mitigates, treats, cures or improves the symptoms of Irritable Bowel Syndrome;  
22 Chronic Fatigue Syndrome; Candida Albicans; Arthritis and Rheumatism;  
23 Infection; Hepatitis C; Colds and Flu; Sinusitis; HIV/AIDS; Heart Disease; Lupus  
24 and Cancer.

25 23. In truth and in fact, scientific research does not demonstrate that the use of  
26 AG-Immune prevents, mitigates, treats, cures or improves the symptoms of  
27 Irritable Bowel Syndrome; Chronic Fatigue Syndrome; Candida Albicans; Arthritis  
28 and Rheumatism; Infection; Hepatitis C; Colds and Flu; Sinusitis; HIV/AIDS;

1 Heart Disease; Lupus and Cancer. Defendant Body Wise International, Inc. has  
2 therefore misrepresented the existence, contents, validity, results, conclusions or  
3 interpretations of tests, studies or research, thereby violating Part III of the  
4 Commission's order.

### 5 **THIRD CAUSE OF ACTION**

6 24. The advertisements and promotional materials described in Paragraph 19(d),  
7 (g), (bb), and (cc) contain endorsements by Dr. Jesse A. Stoff. A material  
8 connection exists between Defendant Jesse A. Stoff and Defendant Body Wise  
9 International, Inc., in that he is a consultant to the company and derives financial  
10 compensation from the sale of Body Wise products containing the ingredient  
11 Ai/E<sup>10</sup>.

12 25. Defendant Body Wise International, Inc. has failed to disclose, clearly and  
13 prominently, the material connection between Defendant Stoff and Body Wise  
14 International, Inc., in violation of Part V of the Commission's order.

### 15 **VIOLATIONS OF SECTIONS 5 AND 12 OF THE FTC ACT**

16 26. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive  
17 acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15  
18 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or  
19 affecting commerce for the purpose of inducing, or which is likely to induce, the  
20 purchase of food, drugs, devices, cosmetics or services. For the purposes of  
21 Section 12 of the FTC Act, 15 U.S.C. § 52, AG-Immune is either a "food" or  
22 "drug" pursuant to Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b) and (c).  
23 As set forth below, Defendants have engaged in such unlawful practices in  
24 connection with the labeling, advertising, promotion, offering for sale, sale or  
25 distribution of AG-Immune.

### 26 **FOURTH CAUSE OF ACTION**

27 27. Through the means described in Paragraph 19(d), (g), (bb), and (cc),  
28 Defendant Jesse A. Stoff, in connection with the labeling, advertising, promotion,

1 offering for sale, sale, or distribution of AG-Immune, has represented, expressly or  
2 by implication, including through the use of expert endorsements, that:

3 A. AG-Immune prevents, mitigates, treats, cures or improves the  
4 symptoms of Irritable Bowel Syndrome; Chronic Fatigue Syndrome;  
5 Candida Albicans; Arthritis and Rheumatism; Infection; Hepatitis C; Colds  
6 and Flu; Sinusitis; HIV/AIDS; Heart Disease; Lupus and Cancer; and

7 B. AG-Immune:

8 1. triggers or activates the immune system to prevent or treat diseases  
9 or conditions;

10 2. increases the activity and/or the production of natural killer (NK)  
11 cells to prevent or treat diseases or conditions;

12 3. gives the immune system specific, coded information on how to  
13 respond to diseases and conditions; and

14 4. improves immune system function to prevent or treat diseases or  
15 conditions.

16 28. Through the means described in Paragraph 19(d), (g), (bb), and (cc),  
17 Defendant Jesse A. Stoff has represented, expressly or by implication, that he  
18 possessed and relied upon a reasonable basis that substantiated the representations  
19 set forth in Paragraph 27, at the time the representations were made.

20 29. In truth and in fact, Defendant Jesse A. Stoff did not possess and rely upon a  
21 reasonable basis that substantiated the representations set forth in Paragraph 27 at  
22 the time the representations were made. Therefore, the representations set forth in  
23 Paragraph 28 constitute deceptive practices, and the making of false  
24 advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of  
25 the FTC Act, 15 U.S.C. §§ 45(a) and 52.

26 **FIFTH CAUSE OF ACTION**

27 30. Through the means described in Paragraph 19(d), (g), (bb), and (cc),  
28 Defendant Jesse A. Stoff has represented, directly or by implication, that, at the

1 time he made the representations set forth in Paragraph 27, he possessed and relied  
2 upon a reasonable basis for such representations, consisting of an actual exercise of  
3 his represented expertise in the causes and treatments of the diseases and  
4 conditions identified in Paragraph 27 at least as extensive as an expert in their  
5 treatment would normally conduct in order to support the conclusions represented  
6 in the endorsement.

7 31. In truth and in fact, at the time he made the representations set forth in  
8 Paragraph 27, Defendant Jesse A. Stoff did not possess and rely upon such a  
9 reasonable basis for such representations. Therefore, Defendant Jesse A. Stoff's  
10 representations set forth in Paragraph 30 constitute deceptive practices, and the  
11 making of false advertisements, in or affecting commerce, in violation of Sections  
12 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

### 13 **SIXTH CAUSE OF ACTION**

14 32. Through the means described in Paragraph 19(d), (g), (bb), and (cc),  
15 Defendant Jesse A. Stoff has represented, expressly or by implication, that  
16 scientific research demonstrates that AG-Immune prevents, mitigates, treats, cures  
17 or improves the symptoms of Irritable Bowel Syndrome; Chronic Fatigue  
18 Syndrome; Candida Albicans; Arthritis and Rheumatism; Infection; Hepatitis C;  
19 Colds and Flu; Sinusitis; HIV/AIDS; Heart Disease; Lupus and Cancer.

20 33. In truth and in fact, scientific research does not demonstrate that AG-  
21 Immune prevents, mitigates, treats, cures or improves the symptoms of Irritable  
22 Bowel Syndrome; Chronic Fatigue Syndrome; Candida Albicans; Arthritis and  
23 Rheumatism; Infection; Hepatitis C; Colds and Flu; Sinusitis; HIV/AIDS; Heart  
24 Disease; Lupus and Cancer. Therefore, Defendant Jesse A. Stoff's representations  
25 set forth in Paragraph 32 constitute deceptive practices, and the making of false  
26 advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of  
27 the FTC Act, 15 U.S.C. §§ 45(a) and 52.

1 **CONSUMER INJURY**

2 34. Consumers throughout the United States have suffered and continue to  
3 suffer substantial monetary loss as a result of Defendants’ unlawful acts and  
4 practices. In addition, the Defendants have been unjustly enriched as a result of  
5 their unlawful practices. Absent injunctive relief by this Court, the Defendants are  
6 likely to continue to injure consumers, reap unjust enrichment, and harm the public  
7 interest.

8 **CIVIL PENALTIES, REDRESS, INJUNCTIVE**  
9 **AND OTHER EQUITABLE RELIEF**

10 35. Each dissemination of an advertisement containing any representation in  
11 violation of the Commission’s order in one or more of the ways described above  
12 constitutes a separate violation for which plaintiff seeks monetary civil penalties.

13 36. Section 5(1) of the FTC Act, 15 U.S.C. § 45(1), as modified by Section 4 of  
14 the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. § 2461, as  
15 amended, and Section 1.98(c) of the Commission’s Rules of Practice, 16 C.F.R.  
16 § 1.98(c), authorizes the Court to award monetary civil penalties of not more than  
17 \$11,000 for each violation of the Commission’s order.

18 37. Under Sections 5(1) and 13(b) of the FTC Act, 15 U.S.C. §§ 45(1) and 53(b),  
19 this Court is authorized to issue a permanent injunction against Defendants’  
20 violations of the Commission’s order and the FTC Act, and to grant ancillary  
21 relief, including consumer redress, disgorgement, and restitution to prevent and  
22 remedy any violations of any provision of law enforced by the Commission.

23 38. This Court, in the exercise of its equitable jurisdiction, may award other  
24 ancillary relief to remedy the injury caused by Defendants’ violations of the law.

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Plaintiff requests this Court, pursuant to 15 U.S.C. §§ 45(1) and  
27 53(b), and pursuant to the Court’s own equitable powers, to:

1 (1) Enter judgment against Defendants and in favor of Plaintiff for each  
2 violation alleged in this Complaint;

3 (2) Award Plaintiff monetary civil penalties from Defendant Body Wise  
4 International, Inc. for each violation of the Commission's order alleged in  
5 this Complaint;

6 (3) Enjoin Defendant Body Wise International from violating the  
7 Commission's order issued in FTC Docket No. C-3617;

8 (4) Enjoin Defendants from engaging in, or assisting others engaged in,  
9 violations of the FTC Act;

10 (5) Award such relief as the Court finds necessary to redress injury to  
11 consumers resulting from Defendants' violations of the FTC Order and the  
12 FTC Act; including, but not limited to, rescission of contracts, the refund of  
13 monies paid, and the disgorgement of ill-gotten monies;

14 (6) Order Defendants to pay the costs of this action; and

15 ///

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1 (7) Award Plaintiff such additional relief as the Court may deem just and  
2 proper.

3 Dated: \_\_\_\_\_, 2005

4  
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