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Please have this [redacted] and place it in the United States Attorney's box. Thank you.

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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION

LODGED

UNITED STATES OF AMERICA,  
Plaintiff,

CIVIL ACTION

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

SACV 05-43 DOC (ANx)

Defendants.

CONSENT DECREE AS TO JESSE A. STOFF, M.D.

WHEREAS, Plaintiff, the United States of America, has commenced this action by filing the Complaint herein; Defendant Jesse A. Stoff, M.D., has waived service of the Summons and Complaint; the parties have been represented by the attorneys whose names appear hereafter; and the parties have agreed to settlement of this action upon the following terms and conditions, without adjudication of any issue of fact or law and without Defendant admitting liability for any of the matters alleged in the Complaint;

THEREFORE, on the joint motion of Plaintiff and Defendant Jesse A. Stoff, M.D., it is hereby ORDERED, ADJUDGED, and DECREED as follows:

1 1. This Court has jurisdiction over the subject matter and of the parties.

2 2. The Complaint states a claim upon which relief may be granted against Defendant  
3 under Sections 5(a), 12, 13(b) and 16(a) of the Federal Trade Commission Act, 15 U.S.C.  
4 §§ 45(a), 52, 53(b) and 56(a).

5 3. The activities of the Defendant were or are in or affecting commerce, as defined in  
6 Section 4 of the FTC Act, 15 U.S.C. § 44.

7 4. Plaintiff and Defendant hereby waive all rights to appeal or otherwise challenge or  
8 contest the validity of this Consent Decree.

9 5. Defendant has agreed that this Consent Decree does not entitle Defendant to seek  
10 or to obtain attorney's fees as a prevailing party under the Equal Access to Justice Act, 28  
11 U.S.C. § 2412, as amended by Pub. L. 104-121, 110 Stat. 847, 863-64 (1996), and  
12 Defendant further waives any rights to attorney's fees that may arise under said provision  
13 of law.

14 6. Each party to this Consent Decree hereby agrees to bear its own costs and  
15 attorney's fees incurred in connection with this action.

16 7. Entry of this Consent Decree is in the public interest.

17 8. Defendant does not admit any allegations set forth in the Complaint, other than  
18 jurisdictional facts. This Consent Decree does not constitute, nor shall it be interpreted to  
19 constitute, either an admission by Defendant of any wrongdoing or a finding by the Court  
20 that Defendant has engaged in any violation of law.

## 21 **DEFINITIONS**

22 The following definitions shall apply to this Consent Decree:

- 23 1. "Commerce" means as defined in Section 4 of the Federal Trade  
24 Commission Act, 15 U.S.C. § 44.
- 25 2. "Commission" means the Federal Trade Commission.
- 26 3. "Competent and reliable scientific evidence" means tests, analyses,  
27 research, studies, or other evidence based on the expertise of professionals  
28 in the relevant area, that has been conducted and evaluated in an objective

1 manner by persons qualified to do so, using procedures generally accepted  
2 in the profession to yield accurate and reliable results.

3 4. “Defendant” means Jesse A. Stoff, M.D.

4 5. “Endorsement” and “expert” mean as defined in 16 C.F.R. § 255.0.

5 6. “Food” and “drug” mean as defined in Sections 12 and 15 of the Federal  
6 Trade Commission Act, 15 U.S.C. §§ 52 and 55.

## 7 INJUNCTION

### 8 I. PROHIBITION AGAINST CERTAIN ADVERTISING CLAIMS FOR 9 CERTAIN PRODUCTS UNLESS TRUE AND SUBSTANTIATED

10 IT IS ORDERED that Defendant, his agents, representatives, employees and all  
11 other persons or entities within the scope of Fed R. Civ. P. 65, and all persons in active  
12 concert or participation with him who receive actual notice of this Consent Decree by  
13 personal service or otherwise, directly or through any corporation, subsidiary, division, or  
14 other device, in connection with the manufacturing, labeling, advertising, promotion,  
15 offering for sale, sale or distribution of AG Immune or any food, drug, or dietary  
16 supplement, in or affecting commerce, is hereby permanently enjoined from representing  
17 or assisting others in representing, in any manner, expressly or by implication, that any  
18 such product:

- 19 A. prevents, mitigates, treats, cures or improves the symptoms of any disease  
20 including but not limited to: Allergies; AIDS; Asthma; Cancer; Candida;  
21 Canker Sores; Chronic Fatigue Syndrome; Cold; Colon Disease; Crohn’s  
22 Disease; Epstein Barr; Fibromyalgia; Flu; Heart Disease; Hepatitis B;  
23 Hepatitis C; HIV; Hyperactive Thyroid; Infection; Irritable Bowel  
24 Syndrome; Lupus; Mononucleosis; Poison Ivy; Rheumatoid Arthritis;  
25 Shingles; Sinusitis; Toenail Fungus; and Ulcerative Colitis;
- 26 B. triggers or activates the immune system to prevent or treat diseases;
- 27 C. increases the activity and/or the production of natural killer (NK) or other  
28 immune blood cells to prevent or treat diseases;

- 1 D. gives the immune system specific, coded information on how to respond to  
2 prevent or treat diseases;  
3 E. improves immune system function to prevent or treat diseases; or  
4 F. provides any other health benefit;

5 unless the representation is true and, at the time of making such representation, Defendant  
6 possesses and relies upon competent and reliable scientific evidence that substantiates the  
7 representation. *Provided, however,* that for any representation made by Defendant as an  
8 expert endorser, he must possess and rely upon competent and reliable scientific evidence  
9 and an actual exercise of his represented expertise, in the form of an examination or  
10 testing of the product at least as extensive as an expert in the field would normally  
11 conduct in order to support the conclusions presented in the representation.

12 **II. PROHIBITION AGAINST MISREPRESENTING THE**  
13 **EXISTENCE OR RESULTS OF TESTS, STUDIES OR RESEARCH**

14 **IT IS FURTHER ORDERED** that Defendant, his agents, representatives,  
15 employees and all other persons or entities within the scope of Fed. R. Civ. P. 65, and all  
16 persons in active concert or participation with him who receive actual notice of this  
17 Consent Decree by personal service or otherwise, directly or through any corporation,  
18 subsidiary, division, or other device, in connection with the manufacturing, labeling,  
19 advertising, promotion, offering for sale, sale or distribution of AG Immune or any food,  
20 drug, or dietary supplement, in or affecting commerce, is hereby permanently enjoined  
21 from misrepresenting or assisting others in misrepresenting, in any manner, expressly or  
22 by implication, the existence, contents, validity, results, conclusions, or interpretations of  
23 any test, study or research.

24 **III. FOOD AND DRUG ADMINISTRATION**

25 **IT IS FURTHER ORDERED** that nothing in this Consent Decree prohibits  
26 Defendant from:

- 27 A. Making any representation for any drug that is permitted in labeling for  
28 such drug under any tentative final or final standard promulgated by the

1 Food and Drug Administration, or under any new drug application  
2 approved by the Food and Drug Administration; or

- 3 B. Making any representation for any product that is specifically permitted in  
4 labeling for such product by regulations promulgated by the Food and Drug  
5 Administration pursuant to the Nutrition Labeling and Education Act of  
6 1990.

7 **IV. SUSPENDED MONETARY RELIEF AND RIGHT TO REOPEN**

8 **IT IS FURTHER ORDERED** that judgment is hereby entered against Defendant  
9 Jesse A. Stoff in the amount of **THREE HUNDRED FIFTY-EIGHT THOUSAND**  
10 **DOLLARS (\$358,000)**; *provided, however*, that this judgment shall be suspended until  
11 further order of the Court, and *provided further* that this judgment shall be subject to the  
12 following conditions:

- 13 A. Plaintiff's agreement to this Consent Decree is expressly premised on the  
14 truthfulness, accuracy, and completeness of Defendant's sworn financial  
15 statements and supporting documents submitted to the Commission,  
16 including: Defendant's Financial Statement dated September 20, 2004;  
17 Defendant's 2001 amended federal tax return and his 2002 and 2003 federal  
18 tax returns; and the letters from Barry J. Cutler, Esq., dated November 5,  
19 2004 and November 18, 2004. Such financial statement and supporting  
20 documents contain material information upon which Plaintiff relied in  
21 negotiating and agreeing to this Consent Decree.

- 22 B. If Plaintiff should have evidence that Defendant has failed to disclose any  
23 material asset, or materially misrepresented the value of any asset, or made  
24 any other material misrepresentation or omission in the financial statement  
25 or supporting documents described above, the Plaintiff may move that the  
26 Court reopen this Order for the sole purpose of allowing it to modify the  
27 monetary liability of Defendant. If the Court finds that Defendant failed to  
28 disclose any material asset, materially misrepresented the value of any

1 asset, or made any other material misrepresentation or omission in the  
2 above-referenced financial statement or supporting documents, the Court  
3 shall reinstate the suspended judgment against Defendant in favor of  
4 Plaintiff, in the amount of THREE HUNDRED FIFTY-EIGHT  
5 THOUSAND DOLLARS (\$358,000) in U.S. currency, which amount  
6 would be rendered immediately due and payable. Interest computed at the  
7 rate prescribed in 28 U.S.C. § 1961 shall immediately begin to accrue on  
8 the balance. For the purposes of this Part and any subsequent proceedings  
9 to enforce payment, Defendant waives any right to contest any of the  
10 allegations in the Complaint filed in this action. *Provided, however*, that in  
11 all other respects this Consent Decree remains in full force and effect unless  
12 otherwise ordered by the Court; and *provided further*, that proceedings  
13 instituted under this Paragraph are in addition to, and not in lieu of, any  
14 other civil or criminal remedies that may be provided by law, including any  
15 other proceedings the Plaintiff may initiate to enforce this Order.

16 C. All funds paid pursuant to this Part shall be deposited into a fund  
17 administered by the Commission or its agent to be used for equitable relief,  
18 including but not limited to, consumer redress and any attendant expenses  
19 for the administration of any redress fund. The Commission shall have full  
20 and sole discretion to administer any redress program implemented pursuant  
21 to this Consent Decree. In the event that the Commission determines, in its  
22 sole discretion, that direct redress to consumers is wholly or partially  
23 impracticable or funds remain after redress is completed, the Commission  
24 may apply any remaining funds for such other equitable relief (including  
25 consumer information remedies) as it determines to be reasonably related to  
26 Defendant's practices alleged in the Complaint. Any funds not used for  
27 such equitable relief shall be deposited into the Treasury as disgorgement.  
28 Defendant acknowledges and agrees that all money paid pursuant to this

1 Part is irrevocably paid to the Commission. Defendant shall have no right  
2 to challenge the Commission's choice or administration of remedies under  
3 this Part. No portion of this judgment shall be deemed a fine, penalty or  
4 punitive assessment, or forfeiture.

5 **V. ACKNOWLEDGMENT OF RECEIPT OF CONSENT DECREE**

6 IT IS FURTHER ORDERED that Defendant, within five (5) business days of  
7 receipt of this Consent Decree as entered by the Court, shall submit to the Commission a  
8 truthful sworn statement acknowledging receipt of this Consent Decree.

9 **VI. DISTRIBUTION OF CONSENT DECREE**

10 **IT IS FURTHER ORDERED** that, for a period of three (3) years from the date of  
11 entry of this Consent Decree, Defendant shall deliver copies of the Consent Decree as  
12 directed below:

- 13 A. For any business that Defendant controls, directly or indirectly, or in which  
14 Defendant has a majority ownership interest, Defendant must deliver a copy  
15 of this Consent Decree to all principals, officers, directors, and managers of  
16 that business. Defendant must also deliver copies of this Consent Decree to  
17 all employees, agents, and representatives of that business who engage in  
18 conduct related to the subject matter of this Consent Decree. For current  
19 personnel, delivery shall be within thirty (30) days of service of this  
20 Consent Decree upon Defendant. For new personnel, delivery shall occur  
21 prior to them assuming their responsibilities.
- 22 B. For any business where Defendant is not a controlling person and he  
23 engages in the manufacturing, labeling, advertising, promotion, offering for  
24 sale, sale or distribution of any food, drug or dietary supplement, Defendant  
25 must deliver a copy of this Consent Decree to all principals and managers  
26 of such business before engaging in such conduct.
- 27  
28

1 C. Defendant must secure a signed and dated statement acknowledging receipt  
2 of the Consent Decree, within thirty (30) days of delivery, from all persons  
3 receiving a copy of the Consent Decree pursuant to this Part.

#### 4 **VII. RECORD KEEPING**

5 **IT IS FURTHER ORDERED** that for a period of six (6) years from the date of  
6 entry of this Consent Decree, Defendant, if he is engaged in the manufacturing, labeling,  
7 advertising, promotion, offering for sale, sale or distribution of any food, drug, or dietary  
8 supplement, and any business where (1) Defendant is the majority owner of the business  
9 or directly or indirectly manages or controls the business, and (2) the business is engaged  
10 in the manufacturing, labeling, advertising, promotion, offering for sale, sale or  
11 distribution of any food, drug, or dietary supplement, their agents, employees, and  
12 representatives, and those persons in active concert or participation with them who  
13 receive actual notice of this Consent Decree by personal service or otherwise, directly or  
14 through any corporation, subsidiary, division or other device, in connection with the  
15 dissemination of any representation covered by this Consent Decree, are hereby restrained  
16 and enjoined from failing to create and retain the following records:

- 17 A. Accounting records that reflect the cost of goods or services sold, revenues  
18 generated, and the disbursement of such revenues;
- 19 B. Personnel records accurately reflecting: the name, address, and telephone  
20 number of each person employed in any capacity by such business,  
21 including as an independent contractor; that person's job title or position;  
22 the date upon which the person commenced work; and the date and reason  
23 for the person's termination, if applicable;
- 24 C. Customer files containing the names, addresses, phone numbers, dollar  
25 amounts paid, quantity of items or services purchased, and description of  
26 items or services purchased, to the extent such information is obtained in  
27 the ordinary course of business;
- 28



- 1 D. Complaints and refund requests (whether received directly, indirectly or  
2 through any third party) and any responses to those complaints or requests;  
3 E. Copies of all sales scripts, training materials, advertisements, or other  
4 marketing materials;  
5 F. All materials that were relied upon to substantiate any representation made  
6 in the sales scripts, training materials, advertisements or other marketing  
7 materials;  
8 G. All tests, reports, studies, surveys, demonstrations, or other evidence in  
9 their possession or control that contradict, qualify, or call into question any  
10 representation made in the sales scripts, training materials, advertisements  
11 or other marketing materials; and  
12 H. All records and documents necessary to demonstrate full compliance with  
13 each provision of this Consent Decree, including but not limited to, copies  
14 of acknowledgments of receipt of this Consent Decree, required by Part VI,  
15 and all reports submitted to the FTC pursuant to Parts VIII and IX.

16 **VIII. COMPLIANCE REPORTING BY DEFENDANT**

17 **IT IS FURTHER ORDERED** that, in order that compliance with the provisions  
18 of this Consent Decree may be monitored:

- 19 A. For a period of three (3) years from the date of entry of this Consent  
20 Decree, Defendant shall notify the Commission of the following:  
21 (1) Any changes in residence, mailing addresses, and telephone numbers  
22 of Defendant, within thirty (30) days of the date of such change;  
23 (2) Any changes in employment status (including self-employment) of  
24 Defendant, and any change in the ownership of the Defendant in any  
25 business entity, within thirty (30) days of the date of such change.  
26 Such notice shall include the name and address of each business that  
27 the Defendant is affiliated with, employed by, creates or forms, or  
28 performs services for; a statement of the nature of the business, and a

1 statement of Defendant's duties and responsibilities in connection  
2 with the business or employment; and

3 (3) Any change in Defendant's name or use of any aliases or fictitious  
4 names.

5 B. Defendant shall notify the Commission of any changes in corporate  
6 structure or any business entity that Defendant directly or indirectly  
7 controls, or has an ownership interest in, that may affect compliance  
8 obligations arising under this Consent Decree, including but not limited to a  
9 dissolution, assignment, sale, merger, or other action that would result in  
10 the emergence of a successor entity; the creation or dissolution of a  
11 subsidiary, parent, or affiliate that engages in any acts or practices subject to  
12 this Consent Decree; the filing of a bankruptcy petition; or a change in the  
13 corporate name or address, at least thirty (30) days prior to such change,  
14 *provided* that, with respect to any proposed change in the corporation about  
15 which Defendant learns less than thirty (30) days prior to the date such  
16 action is to take place, Defendant shall notify the Commission as soon as is  
17 practicable after obtaining such knowledge.

18 C. One hundred eighty (180) days after the date of entry of this Consent  
19 Decree, Defendant shall provide a written report to the FTC, sworn to under  
20 penalty of perjury, setting forth in detail the manner and form in which he  
21 has complied and is complying with this Consent Decree. This report shall  
22 include, but not be limited to:

23 (1) The then-current residence address, mailing address and telephone  
24 numbers of Defendant;

25 (2) The then-current employment and business address and telephone  
26 numbers of Defendant, a description of the business activities of  
27 each such employer or business, and the title and responsibilities of  
28 Defendant for each such employer or business;

- 1 (3) A copy of each acknowledgment of receipt of this Consent Decree  
2 obtained pursuant to Part V.; and  
3 (4) Any other changes required to be reported under subparagraph A of  
4 this Part.

5 D. For purposes of this Consent Decree, Defendant shall, unless otherwise  
6 directed by the Commission's authorized representatives, mail all written  
7 notifications to the Commission to:

8 Associate Director for Enforcement  
9 Bureau of Consumer Protection  
10 Federal Trade Commission  
11 600 Pennsylvania Avenue, NW  
12 Washington, DC, 20580  
13 Re: *United States v. Jesse A. Stoff, M.D.*, Civil Action No. \_\_\_\_\_

### 14 IX. COMPLIANCE MONITORING

15 **IT IS FURTHER ORDERED** that, for the purpose of monitoring and  
16 investigating compliance with any provision of this Order,

- 17 A. Within thirty (30) days of receipt of written notice from a representative of  
18 the Commission, Defendant shall submit additional written reports, sworn  
19 to under penalty of perjury; produce documents for inspection and copying;  
20 appear for deposition; and/or provide entry during normal business hours to  
21 any business location in such defendant's possession or direct or indirect  
22 control to inspect the business operation;
- 23 B. In addition, the Commission is authorized to monitor compliance with this  
24 Order by all other lawful means, including but not limited to the following:
- 25 (1) obtaining discovery from any person, without further leave of court,  
26 using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36,  
27 and 45;
- 28 (2) posing as consumers and suppliers to Defendant's employees, or any  
other entity managed or controlled in whole or in part by Defendant,  
without the necessity of identification or prior notice; and

1 C. Defendant shall permit representatives of the Commission to interview any  
2 employer, consultant, independent contractor, representative, agent, or  
3 employee who has agreed to such an interview, relating in any way to any  
4 conduct subject to this Order. The person interviewed may have counsel  
5 present.

6 *Provided, however,* that nothing in this Order shall limit the Commission's lawful use of  
7 compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49,  
8 57b-1, to obtain any documentary material, tangible things, testimony, or information  
9 relevant to unfair or deceptive acts or practices in or affecting commerce (within the  
10 meaning of 15 U.S.C. § 45(a)(1)).

11 **X. RETENTION OF JURISDICTION**

12 **IT IS FURTHER ORDERED** that this Court shall retain jurisdiction of this  
13 matter for the purposes of enabling any of the parties to this Consent Decree to apply to  
14 the Court at any time for such further orders or directives as may be necessary or  
15 appropriate for the interpretation or modification of this Consent Decree, for enforcement  
16 of compliance therewith, or for the punishment of violations thereof.

17 **JUDGMENT IS THEREFORE ENTERED** in favor of Plaintiff and against  
18 Defendant pursuant to all the terms and conditions recited above.

19 This \_\_\_\_\_ day of \_\_\_\_\_, 2005 .

20  
21 \_\_\_\_\_  
22 United States District Judge

23 The parties, by their respective counsel, hereby consent to the terms and conditions of the  
24 Consent Decree as set forth above and consent to the entry thereof.

1 FOR THE UNITED STATES OF AMERICA:  
2 PETER D. KEISLER  
3 Assistant Attorney General  
4 Civil Division  
5 U.S. Department of Justice

6 DEBRA W. YANG  
7 United States Attorney

8 By: \_\_\_\_\_  
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18 Director  
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20 By: \_\_\_\_\_  
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FOR THE FEDERAL TRADE COMMISSION:

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FOR THE DEFENDANT:

\_\_\_\_\_  
JESSE A. STOFF, M.D.

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By: \_\_\_\_\_  
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