1 2 3 4 5 6 7 8 9 10 11 11	 WILLIAM E. KOVACIC General Counsel JANET M. EVANS LEMUEL DOWDY JOCK CHUNG FEDERAL TRADE COMMISSION JE 2404 600 Pennsylvania Ave., N.W. Mail Drop S-4002 Washington, D.C. 20580 Tel: (202) 326-2125 Fax: (202) 326-3259 LOCAL COUNSEL RAY MCKOWN FEDERAL TRADE COMMISSION California Bar # 150975 10877 Wilshire Boulevard, Suite 700 Los Angeles, CA 90024 Tel: (310) 824-4325 Fax: (310) 824-4380 Attorneys for Plaintiff, 							
	FEDERAL TRADE COMMISSION							
13	UNITED STATES DISTRICT COURT							
14	FOR THE CENTRAL DISTRICT OF CALIFORNIA WESTERN DIVISION							
15	FEDERAL TRADE COMMISSION,) Hon.							
16	Plaintiff, Civil Action No.							
17	v. {Proposed] STIPULATED FINAL ORDER							
18	J. MICHAEL ERNEST,) FOR PERMANENT INJUNCTION							
19	Defendant.) AND SETTLEMENT OF CLAIMS							
20)							
21	Plaintiff, the Federal Trade Commission ("FTC" or "Commission") filed a Complaint for							
22	permanent injunction and other relief against J. Michael Ernest, pursuant to Section 13(b) of the							
23	Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). Defendant denies the allegations							
24	in the Complaint, except jurisdictional facts, but is willing to agree to the entry of the following							
25	Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief							
26	("Order").							
27								
28	Page 1 of 10							
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The Commission and Defendant have stipulated to the entry of the following Order in settlement of the Commission's Complaint against Defendant. The Court, being advised in the premises, finds:

FINDINGS

5	FINDINGS	
6	1.	This Court has jurisdiction over the subject matter of this case and jurisdiction
7		over all parties. Venue in the Central District of California is proper.
8	2.	The Complaint states a claim upon which relief can be granted, and the
9		Commission has the authority to seek the relief it has requested.
10	3.	The activities of Defendant are in or affecting commerce, as defined in 15 U.S.C. §
11		44.
12	4.	Defendant waives all rights to seek judicial review or otherwise challenge or
13		contest the validity of this Order. Defendant also waives any claims that he may
14		have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the
15		prosecution of this action to the date of this Order.
16	5.	This action and the relief awarded herein are in addition to, and not in lieu of, other
17		remedies as may be provided by law.
18	6.	Each party shall bear its own costs and attorneys' fees.
19	7.	Entry of this Order is in the public interest.
20	8.	Pursuant to Federal Rule of Civil Procedure 65(d), the provisions of this Order are
21		binding upon Defendant, and his officers, agents, servants, employees and all other
22		persons or entities in active concern or participation with him, who receive actual
23		notice of this Order by personal service or otherwise.
24		
25	DEFINITION	IS
26	For pu	rposes of this Order, the following definitions shall apply:
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28		Page 2 of 10

1	1.	Unless otherwise specified, "Defendant" shall mean J. Michael Ernest, individually.
2	2.	"Isis product" shall mean the "Isis Breast Enhancement Herbal Supplement," the
3		"Isis Breast Enhancement Herbal Cream," and any substantially similar product
4		containing one or more of the ingredients in the current Isis products.
5	3.	"Competent and reliable scientific evidence" shall mean tests, analyses, research,
6		studies, or other evidence based on the expertise of professionals in the relevant
7		area, that has been conducted and evaluated in an objective manner by persons
8		qualified to do so, using procedures generally accepted in the profession to yield
9		accurate and reliable results.
10	. 4.	"Food," "drug," "device," and "cosmetic," shall have the meaning defined in
11		Section 15 of the FTC Act, 15 U.S.C. Section 55.
12	5.	"Covered product" means any dietary supplement, food, drug, cosmetic, or device.
13	6.	"Commerce" shall mean as defined in Section 4 of the Federal Trade Commission
14		Act, 15 U.S.C. Section 44.
15	7.	"Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
16	8.	"Employment" shall mean any affiliation with any business, non-profit, or
17		government entity, including the performance of services as an officer, owner,
18		manager, supervisor, employee, consultant, or independent contractor; and
19		"Employer" shall mean any and all individuals or entities for whom any Defendant
20		performs services as an employee, consultant, or independent contractor.
21	9.	A requirement that any Defendant "notify the Commission" shall mean that the
22		Defendant shall send the necessary information via first-class mail, costs prepaid,
23		to the Associate Director for Advertising Practices, Federal Trade Commission,
24		600 Pennsylvania Ave., N.W., Washington, D.C. 20580. Attn: FTC v. J.
25		Michael Ernest (C.D. Cal.).
26	10.	The term "including" in this Order shall mean "without limitation."
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- 11. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.
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PROHIBITED BUSINESS ACTIVITIES I.

IT IS HEREBY ORDERED that Defendant Ernest, directly or through any corporation, 6 7 subsidiary, division, trade name, or other device, and his officers, agents, servants, employees and 8 all persons or entities in active concert or participation with him who receive actual notice of this 9 Order, by personal service or otherwise, in connection with the manufacturing, labeling, 10 advertising, promotion, offering for sale, sale, or distribution of any covered product is hereby permanently restrained and enjoined from making any representation, in any manner, expressly or 11 by implication, about the benefits, performance, efficacy, safety, or side effects, of an Isis product 12 or any other covered product unless, at the time the representation is made, he possesses and 13 relies upon competent and reliable scientific evidence that substantiates the representation. 14 15 Provided, that for any representation made by Defendant Ernest as an expert endorser, he must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his 16 represented expertise, in the form of an examination or testing of the product at least as extensive 17 18 as an expert in that field would normally conduct in order to support the conclusions presented in 19 the representation.

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FDA APPROVED CLAIMS II.

IT IS FURTHER ORDERED that: 22

23 1. Nothing in this order shall prohibit Defendant from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard 24 promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and 26

Page 4 of 10

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- Nothing in this order shall prohibit Defendant from making any representation for any
 product that is specifically permitted in labeling for such product by regulations
 promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and
 Education Act of 1990.
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III. ACKNOWLEDGMENT OF RECEIPT OF ORDER

7 IT IS FURTHER STIPULATED AND ORDERED that, within five (5) business days
8 after receipt by Defendant of this Order as entered by the Court, the Defendant shall execute and
9 submit to the Commission a truthful sworn statement, in the form shown on Appendix A, that
10 shall acknowledge receipt of this Order.

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IV. COMMISSION'S AUTHORITY TO MONITOR COMPLIANCE

13 IT IS FURTHER ORDERED that the Commission is authorized to monitor Defendant's
14 compliance with this Order by all lawful means, including but not limited to the following:

The Commission is authorized, without further leave of court, to obtain discovery A. 15 from any person in the manner provided by Chapter V of the Federal Rules of Civil 16 17 Procedure, Fed. R. Civ. P. 26 - 37, including the use of compulsory process 18 pursuant to Fed. R. Civ. P. 45, for the purpose of monitoring and investigating Defendant's compliance with any provision of this Order; 19 B. The Commission is authorized to use representatives posing as consumers and 20 suppliers to Defendant, Defendant's employees, or any other entity managed or 21 22 controlled in whole or in part by Defendant, without the necessity of identification 23 or prior notice; A. Nothing in this Order shall limit the Commission's lawful use of compulsory 24 process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to 25 investigate whether Defendant has violated any provision of this Order or Section 26 27

Page 5 of 10

1		5 or 12 of the FTC Act, 15 U.S.C. §§ 45, 52.
2		
3	v. C	COMPLIANCE REPORTING
4	ľ	Γ IS FURTHER ORDERED that, in order that compliance with the provisions of this
5	Order ma	ay be monitored:
6	A	For a period of three (3) years from the date of entry of this Order, for Defendant
7		shall notify the Commission of the following:
8		1. Any changes in his residence, mailing addresses, and telephone numbers,
9		within ten (10) days of the date of such change; and
10		2. Any changes in his employment status (including self-employment) within
11		ten (10) days of such change. Such notice shall include the name and address of
12		each business that Defendant is affiliated with or employed by, a statement of the
13		nature of the business, and a statement of Defendant's duties and responsibilities in
14		connection with the business or employment; and
15	E	Sixty (60) days after the date of entry of this Order, Defendant shall provide a
16		written report to the FTC, sworn to under penalty of perjury, setting forth in detail
17		the manner and form in which he has complied and are complying with this Order.
18		This report shall include but not be limited to:
19		1. His then current residence addresses and telephone numbers;
20		2. His then current employment, business addresses, and telephone numbers, a
21		description of the business activities of each such employer, and the Defendant's
22		title and responsibilities for each employer;
23		3. A statement describing the manner in which Defendant has complied and
24		are complying with Paragraph I; and
25	C	Upon written request by a representative of the Commission, Defendant shall
26		submit additional written reports (under oath, if requested) and produce
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28		Page 6 of 10

1			documents on twenty (20) days' notice with respect to any conduct subject to this
2			Order.
3		D.	For purposes of the compliance reporting required by this Paragraph, the
4			Commission is authorized to communicate with the Defendant directly.
5			
6	VI.	RECO	ORD KEEPING PROVISIONS
7		IT IS	FURTHER ORDERED that, for a period of three (3) years from the date of entry of
8	this O	rder, D	efendant Ernest is enjoined from failing to retain, unless otherwise specified:
9		A.	Copies of all advertisements, promotional materials, sales scripts, training
10			materials, or other marketing materials, utilized in the advertising, marketing,
11			promotion, offering for sale, distribution or sale of any covered product, which he
12			prepares, approves, or disseminates, or in which he makes an endorsement;
13		B.	All materials that were relied upon in making any representation in any materials
14			identified in Subparagraph (A);
15		C.	All other documents evidencing or referring to the accuracy of any claim made in
16			any materials identified in Subparagraph (A), including, but not limited to, all tests,
17			reports, studies, demonstrations, or other evidence that confirm, contradict,
18			qualify, or call into question the accuracy or efficacy of such covered product.
19	//		
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26	VII.	RETE	ENTION OF JURISDICTION
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1	IT IS FURTHER ORDERED that this	Court shall retain jurisdiction of this matter for
2	purposes of construction, modification, and e	nforcement of this Order.
3		
4	SO STIPULATED:	
5	JANET M. EVANS	J. MICHAEL ERNEST, individually
6	Federal Trade Commission	J. MICHAEL EKNEST, IIUIVIUUUIIY
7	601 Pennsylvania Ave., N.W., Rm. S-4002 Washington, D.C. 20580	STEVEN ZWICK
8	(202) 326-2125/2263 (202) 326-3259 (facsimile)	Law Office of Seven Zwick 25909 Pala, #380
9	Attorneys for Plaintiff FEDERAL TRADE COMMISSION	Mission Viejo, CA 92671 (949) 699-4444
10		Attorney for Defendant
11		
12 13		
13	SO ORDERED	
15	DATED:	
16	UNITED STATES DISTRICT JUDGE	
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28	Pag	ge 8 of 10

1	APPENDIX A		
2	UNITED STATES DISTRICT COURT		
3	FOR THE CENTRAL DISTRICT OF CALIFORNIA WESTERN DIVISION		
4			
5	FEDERAL TRADE COMMISSION,		
6) Plaintiff,) Hon.		
7	v.) Civil Action No.		
8) AFFIDAVIT OF DEFENDANT		
9	Defendant.) [NAME]		
10)		
11	[Defendant], being duly sworn, hereby states and affirms:		
12	1. My name is I am a citizen of the United States and am		
13	over the age of eighteen. I have personal knowledge of the matters discussed in this declaration,		
14 15	and if called as a witness, I could and would competently testify as to the matters stated herein. I		
15	am a Defendant in the above captioned action.		
10	2. My current business address is My current business		
18	telephone number is My current residential address is		
19	My current residential telephone number is		
20	3. On (date), I received a copy of the Stipulated Final Order and		
21	Settlement of Claims for Monetary Relief, which was signed by the Honorable,		
22	United States District Court Judge for the Central District of California. A true and correct copy of the Order that I received is appended to this Affidavit.		
23	4. I reaffirm and attest to the truthfulness, accuracy and completeness of the financial		
24	statements that I submitted to the Federal Trade Commission on or about		
25	I hereby declare under penalty of perjury under the laws of the United States of America that the		
26	Thereby declare under penalty of perjury under the laws of the Onited States of America that the		
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	(Name of Defendar	nt)			
STATE OF					
COUNTY OF					
BEFORE ME this day personally appeared	d	, who being fi			
duly sworn, deposes and says that s/he has read and understands the foregoing statement and that					
s/he has executed the same for the purposes contained therein.					
SUBSCRIBED AND SWORN TO before me this	day of	,2001 by			
presented (state identification)					
	Print Name				
NOTARY PUBLIC,		,			
	STATE OF				
	Commission Numb	er			
	Affix Seal				
Page 10 of 10					