

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION

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In the Matter of )  
GLOBAL WORLD MEDIA CORPORATION, )  
a corporation, and ) FILE NO. 962-3210  
SEAN SHAYAN, ) AGREEMENT

- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of this proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

## ORDER

### DEFINITIONS

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

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has 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.

2. "Clearly and prominently" shall mean as follows:
  - A. In a television or video advertisement, the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it.
  - B. In a radio advertisement or in telephone conversations the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
  - C. In a print advertisement, the disclosure shall be in a type size and in a location that are sufficiently noticeable so that an ordinary consumer will see and read it, in print that contrasts with the background against which it appears. In multi-page documents, the disclosure shall appear on the cover or the first page.
  - D. In an advertisement on any electronic media received by consumers via computer, such as the Internet's World Wide Web or commercial online computer services, the disclosure shall be in a type size, and in a location, that are sufficiently noticeable so that an ordinary consumer will see it and read it, in print that contrasts with the background against which it appears. In multi-screen documents, the disclosure shall appear on the first screen and on any screen containing ordering information.
  - E. On a product label, the disclosure shall be in a type size, and in a location on the principal display panel, that are sufficiently noticeable so that an ordinary consumer will see and read it, in print that contrasts with the background against which it appears.

Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or on any label.

3. Unless otherwise specified, "respondents" shall mean Global World Media Corporation, its successors and assigns and its officers; Sean Shayan, individually and as an officer of the corporation; and each of the above's agents, representatives and employees.

4. "Ephedrine product(s)" shall mean foods, drugs, dietary supplements, or other products intended for internal use containing a source of any ephedrine alkaloid, including but not limited to ephedrine, pseudoephedrine, norephedrine, norpseudoephedrine, N-methylephedrine, and N-methylpseudoephedrine, either derived from natural sources such as Ephedra sinica (also called Ma-Huang or Chinese Ephedra) or synthetically produced.

5. "Purchaser for resale" shall mean any purchaser of any ephedrine product(s) sold by respondents (a) who is a distributor or operates a wholesale or retail business selling any such product(s) or (b) who orders one hundred (100) or more tablets, doses, or other units of any such product(s) in any three (3) month period.

6. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Ecstasy or Herbal Ecstasy tablets or any other food, drug, or dietary supplement in or affecting commerce, shall not:

- A. Represent in any manner, expressly or by implication, that the use of such product is safe or will cause no side effects; or
- B. Make any other representation, in any manner, expressly or by implication, about the safety or side effects of such product,

unless the representation is true and, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Ecstasy or Herbal Ecstasy tablets or any other ephedrine product that is not a "drug" as defined by the Federal Food, Drug and Cosmetic Act, 21

### III.

IT IS FURTHER ORDERED that respondents shall make the following disclosure, clearly and prominently, in any advertisement, promotional material, package label, and package insert for Ecstasy or Herbal Ecstasy tablets or any other ephedrine product, and in any discussion relating to dosage or use of any such product that results from a communication via electronic mail or from any call made by or on behalf of respondents or received on their toll-free, pay-per-call number, or other telephone lines.

**WARNING:** This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose.

Provided, however, if the product is subject to any FDA rule or regulation that requires a warning or a disclosure about safety or health effects for labeling, such warning or disclosure shall be required in lieu of the disclosure set forth above.

### IV.

IT IS FURTHER ORDERED that respondents shall not provide the means and instrumentalities to, or otherwise assist, any person who respondents know or have reason to know is making any false or misleading representation or deceptive material omission in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of

For purposes of this Part, "advertising, marketing, or other promotional activity directed to individuals under the age of twenty-one (21) years" shall include, but not be limited to:

- A. Advertisements appearing in publications whose readers younger than twenty-one (21) years of age constitute fifty percent (50%) or more of the total readership;
- B. Advertisements appearing during or immediately adjacent to television programs seen by audiences whose viewers younger than twenty-one (21) years of age constitute fifty percent (50%) or more of total viewers;
- C. Advertisements appearing on a television or radio station or channel at a time when its viewers or listeners younger than twenty-one (21) years of age constitute fifty percent (50%) or more of total viewers or listeners;
- D. Advertisements appearing on the same video as a commercially prepared video whose viewers younger than twenty-one (21) years of age constitute fifty percent (50%) or more of total viewers; or preceding a movie whose viewers younger than twenty-one (21) years of age constitute fifty percent (50%) or more of total viewers;
- E.

VIII.

Nothing in this order shall be construed as permitting respondents to market any ephedrine product:

- A. In a state where the sale of such products has been banned;
- B. In a manner that is inconsistent with any applicable state restrictions on their sale; or
- C. In a manner that is inconsistent with any applicable FDA rule or regulation.

IX.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for 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.

X.

Nothing in this order shall prohibit respondents 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.

XI.

IT IS FURTHER ORDERED that respondent Global World Media Corporation, and its successors and assigns, and respondent Sean Shayan shall:

- A. Send by first class certified mail or deliver in person, an exact copy of the notice attached hereto as Attachment A, without any other accompanying material, to each person who makes or answers calls on respondents' toll-free, pay-per-call number, or other telephone lines maintained for providing information about Ecstasy or Herbal Ecstasy or any other ephedrine product and each person who provides such information via electronic mail. Persons presently making or answering such calls and electronic mail shall be sent the notice within thirty (30) days after the date of service of this order. Persons retained in the future to make or answer such calls and electronic mail shall be given the notice prior to being permitted to make or answer any such calls;

- B. Notify any person who fails to return the signed statement included in Attachment A within seven (7) days of receipt that they will be terminated in the event that they fail to return the signed statement;
- C. Terminate any person who receives the notification required by subpart B and fails to return the signed statement within seven (7) days of receipt of the notification, and terminate immediately any person who fails to comply with the provisions of the notice attached hereto as Attachment A; and
- D. Institute a reasonable program of continuing surveillance adequate to reveal whether each person who makes or answers calls received on respondents' toll-free, pay-per-call number, or other telephone lines maintained for inquires about Ecstasy or Herbal Ecstasy or any other ephedrine product, and each person who provides information about such products via electronic mail, is conforming to the requirements of this order.

## XII.

IT IS FURTHER ORDERED that respondent Global World Media Corporation, and its successors and assigns, and respondent Sean Shayan shall for five (5) years after the receipt of the last correspondence required by Part XI above, maintain and upon request make available for the Federal Trade Commission for inspection and copying:

- A. Copies of all notices sent to any person pursuant to subpart A of Part XI of this order; and
- B. Copies of all communications with any person who receives the notification required by subpart B or is terminated pursuant to subpart C of Part XI of this order.

## XIII.

IT IS FURTHER ORDERED that respondent Global World Media Corporation, and its successors and assigns, and Sean Shayan shall:

- A. Send an exact copy of the notice attached hereto as Attachment B by first class certified mail, return receipt requested within thirty (30) days after the date of service of this order, to any purchaser for resale on or after January 1, 1993. The mailing shall include no other document;
- B. For a period of three (3) years following the date of service of this order, send an exact copy of the notice attached hereto as Attachment B by first class certified mail, return receipt requested, to any purchaser for resale. The mailing shall



include no document other than Attachment B with the exception of an invoice for the purchase of the product, and shall be made prior to or simultaneously with the first shipment of the product;

- C. In the event respondents receive any information that, subsequent to receipt of Attachment B, any purchaser for resale is using or disseminating advertisements or promotional materials that contain any representation prohibited by this order, respondents shall immediately notify such person that respondents will cease to sell ephedrine products to such person if the prohibited representations continue to be made; and
- D. Terminate any purchaser for resale about whom respondents receive any information that such person is continuing to use advertisements or promotional materials that contain any representation prohibited by this order after receipt of the notice required by subpart C of this Part.

#### XIV.

IT IS FURTHER ORDERED that respondent Global World Media Corporation, and its successors and assigns, and respondent Sean Shayan shall for five (5) years after the last correspondence to which they pertain, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Copies of all notification letters sent to persons pursuant to subpart A or B of Part XIII; and
- B. Copies of all communications received or sent pursuant to subpart C or D of Part XIII.

#### XV.

IT IS FURTHER ORDERED that respondents Global World Media Corporation, and its successors and assigns, and respondent Sean Shayan shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available for the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, including complaints and other communications with consumers or

with governmental or consumer protection organizations.

XVI.

IT IS FURTHER ORDERED that respondents Global World Media Corporation, and its successors and assigns, and respondent Sean Shayan shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

XVII.

IT IS FURTHER ORDERED that Global World Media Corporation and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XVIII.

IT IS FURTHER ORDERED that respondent Sean Shayan, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of (1) the discontinuance of his current business or employment and (2) his affiliation with any new business or employment where such business or employment relates to the manufacturing, advertising, promoting, offering for sale, sale, or distribution of any food, drug, or dietary supplement. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

IX.

IT IS FURTHER ORDERED that respondents Global World Media Corporation, and its

successors and assigns, and respondent Sean Shayan shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail that manner and form in which they have complied with this order.

XX.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20)

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WILLIAM H. DAILEY  
Attorney for respondents

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NANCY S. WARDER  
Counsel for the Federal Trade Commission

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MICHELLE K. RUSK  
Counsel for the Federal Trade Commission

APPROVED:

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C. LEE PEELER  
Associate Director  
Division of Advertising Practices

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JOAN Z. BERNSTEIN  
Director  
Bureau of Consumer Protection

## ATTACHMENT A

### TO BE DELIVERED BY CERTIFIED MAIL OR IN PERSON

[To be printed on Global World Media Corporation letterhead]

[date]

Dear [name]:

This letter is to inform you that Global World Media Corporation ("GWMC") recently settled a civil dispute with the Federal Trade Commission ("FTC") regarding certain alleged claims about Ecstasy or Herbal Ecstasy tablets ("Ecstasy"). Although we do not admit the violations alleged in the FTC complaint, we have entered into this settlement with the FTC to avoid litigation. As part of the settlement, we are required to notify our employees and others who make or receive calls about Ecstasy, or other ephedrine-containing products sold by GWMC, to stop making certain statements prohibited by the order and to notify the caller of the potentially serious health risks associated with taking these products.

Effective immediately, you **must** comply with the following requirements when contacting potential purchasers or responding by telephone, in writing, or by any other means to any inquiry about Ecstasy or any other ephedrine-containing product sold by GWMC. These products include [list here by product name any ephedrine-containing products other than Ecstasy sold by GWMC as of the date of this notice]:

1. You **must** make the following disclosure in your communications about Ecstasy or any other ephedrine product:

- **"I am required to give you the following important information:**

**WARNING: This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious**

statement.

2. You must **not** make any statement or other suggestion about the number of tablets that users can take, other than to repeat the dose information on the product label.

Under the FTC order, we are required to get a signed statement from you that you have read this letter and intend to comply with its requirements. Accordingly, you must sign and return the following statement to us.

**Failure to sign and return the attached statement promptly or to comply with the provisions of this letter will result in your termination.**

Your cooperation in complying with this letter is appreciated. If you have any questions,

## ATTACHMENT B

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

[to be printed on Global World Media Corporation letterhead]

[date]

Dear [name]

This letter is to inform you that Global World Media Corporation (“GWMC”) recently settled a civil dispute with the Federal Trade Commission (“FTC”) regarding certain alleged claims about Ecstasy or Herbal Ecstasy tablets (“Ecstasy”). Although we do not admit to the violations alleged in the FTC complaint, we have entered into this settlement with the FTC to avoid litigation. As part of the settlement, we are required to notify anyone who purchases for resale Ecstasy or other ephedrine-containing products sold by GWMC, including [list any ephedrine-containing products sold by GWMC as of the date of this letter], to stop using advertising or promotional materials that make any of the representations prohibited by the settlement.

### Allegations of the FTC Complaint

The FTC complaint alleges that GWMC claimed that the use of Ecstasy in the recommended doses or other reasonably foreseeable amounts is absolutely safe and will cause no side effects. The complaint challenges these claims as false and unsubstantiated, noting that the use of products that contain ephedrine alkaloids, such as Ecstasy, can have dangerous effects on the central nervous system and heart. The complaint also charges that GWMC’s advertising for Ecstasy included false endorsements from fictitious persons, including Dr. Steven Jonson.

### FTC Order Provisions

The order we entered into as part of our settlement with the FTC requires us to comply with the following provisions:

1. We are prohibited from making claims in advertising, labeling and other promotions for Ecstasy, or any other food, drug or dietary supplement, that such product is absolutely safe or causes no side effects, or from making any other claim about the product’s safety or lack of side effects, unless the claim is true and we have competent and reliable scientific evidence to support it.
2. We are prohibited in advertising, labeling, and other promotions for Ecstasy or other products we sell that contain ephedrine, including those listed above, from recommending a dose

3. We are prohibited in advertising, labeling, and other promotions for any product from representing falsely that any testimonial or endorsement of the product reflects the actual experience and current opinions, findings, beliefs or experiences of the testimonialist or endorser.

4. We are required in all advertising, labeling, and other promotions for Ecstasy and other ephedrine-containing products to make the following disclosure clearly and prominently:

**WARNING:** This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose.

[In the event any FDA rule or regulation requires a different warning or disclosure in labeling, about safety or health effects of such products, substitute that warning or disclosure here.]

5. Finally, we are prohibited from marketing Ecstasy or any other ephedrine-containing product for its euphoric, psychotropic, or sexual effects, through any advertising, marketing, or other promotions directed at an audience with 50% or more of its members under the age of twenty-one.

As part of our settlement with the FTC, GWMC must take steps (such as sending you this letter) to ensure that people who purchase for resale Ecstasy or other ephedrine-containing products sold by GWMC stop using any advertising or promotional materials that do not fully comply with the requirements described above. If you continue to use materials that do not fully comply with such requirements, we are required by the settlement with the FTC to stop selling Ecstasy and other ephedrine-containing products to you.

Thank you for your assistance. If you have any questions, please contact William H. Dailey at (310) 458-0810 [in the event that he no longer represents GWMC, the name and telephone number of the acting attorney, or if none, an officer of GWMC, may be substituted].

Sincerely,

Sean Shayan  
President  
Global World Media Corporation



UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION

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In the Matter of	)	
	)	
GLOBAL WORLD MEDIA CORPORATION,	)	
a corporation, and	)	DOCKET NO.
	)	
SEAN SHAYAN,	)	
individually and as an officer	)	
of the corporation.	)	

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COMPLAINT

The Federal Trade Commission, having reason to believe that Global World Media Corporation, a corporation, and Sean Shayan, individually and as an officer of the corporation (“respondents”), have violated provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Global World Media Corporation is a California corporation with its principal office or place of business at 1501 Main Street, Venice, California 90291.
2. Respondent Sean Shayan is an officer of the corporate respondent. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the

means and instrumentalities to third party distributors to disseminate advertising on the World Wide Web, including but not necessarily limited to the attached Exhibits E and F. These advertisements and oral representations contained the following statements:

A. **ecstasy®**

**the world's first organic ecstasy (m.d.m.a.) alternative**

From Tokyo to South Africa to the United Kingdom to Argentina, with over 2 million units sold in over 15 countries, a product known as **herbal ecstasy®** is revolutionizing the way the world thinks of designer drugs. Using 9 exotic botanicals imported exclusively for this product, **herbal ecstasy®** has been carefully formulated to produce a considerable range of pleasurable effects.

“Reported effects last 4-8 Hours:

- euphoria
- tingly skin sensations
- highly increased energy levels
- increased sexual sensations
- mood elevation

(a mild serotonin inhibitor)”

Dr. Janis Burton  
New Psychology Magazine  
Paris, France

“Developed by many of the same doctors who created the chemical version, **herbal ecstasy®** is 100% natural & absolutely safe. **herbal ecstasy®** contains no chemicals or other impurities. This product is synergistically blended in order to maximize benefits and eliminate any possible side effects.”

Dr. Steven Jonson  
Tel Aviv, Israel  
(Exhibits A and B: Penthouse.)

- B. 2 dosages (10 tablets) \$19.99  
12 dosages (60 tablets) \$99.99  
18 dosages (90 tablets) \$149.99  
40 dosages (200 tablets) \$299.99

20 doses (100 tablets) \$99.99  
(Exhibit B: Penthouse.)

D. **toll free • 24 hour • 7 days**  
**1 - 800 - 365 - 0000**  
(Exhibits A and B: Penthouse.)

E. Consumers calling respondents' toll-free "800" number have been advised that if they fail to achieve the advertised euphoric, psychotropic, or sexual effects, they may ignore the dose suggested in advertising and labeling for the product (such as one (1) tablet every seventy-two (72) hours) and take more Ecstasy tablets, including doses of seven or eight tablets at one time.

F. Send Check or money order to:  
**Global World Media Corporation**

.....

Distribution and wholesale inquiries  
**FAX (310) 581-4456**  
(Exhibits A and B: Penthouse.)

G. SPOKESWOMAN: Introducing Herbal Ecstasy.

[Various shots of young people dancing, playing drums, embracing.]

SPOKESWOMAN: The world's first organic designer experience. A sacred blend of nine exotic herbs that produce a considerable range of pleasurable effects.

[SUPERSCRIPT: Satisfaction Guaranteed]

SPOKESWOMAN: Increased energy levels. Euphoric sensations with absolutely no side effects. . . .Herbal Ecstasy. The alternative. . . .  
(Exhibit C: Nickelodeon, 1995)

H. MALE ANNCR.: Are you ready for this? Introducing the world's first organic ecstasy alternative.

.....

MALE ANNCR.: Users reported keeping a clear head and a sense of heightened perception all night long with no side effects what so ever. So try the alternative, try Herbal Ecstasy.

.....

MALE ANNCR.: The world's first organic ecstasy alternative . . . .  
(Exhibit D: Radio Commercial Transcript, 1995)

I. **Herbal Ecstasy**

.....

"A fantastically light headed, tingly happy, happy buzz, with no side effects."  
Herb Garden Magazine, UK.

"The effects of herbal ecstasy™ beyond smart drug capacity include:

- euphoric stimulation
- highly increased energy levels
- tingly skin sensations
- enhanced sensory processing
- increased sexual sensations
- mood elevations

Dr. Janis Burton New Psychology Magazine  
(Exhibit E: World Wide Web Site, March 27, 1996)

J. **ecstasy**

***The Legal Alternative!***

.....

*" A fantastically light headed, tingly happy-happy buzz, with no side effects."*  
**Herb Garden Magazine, U.K.**

*"The effects of herbal ecstasy beyond smart drug capacity include:  
euphoric stimulation  
highly increased energy levels  
tingly skin sensations  
enhanced sensory processing  
increased sexual sensations  
mood elevations"*





The Federal Trade Commission has accepted an agreement to a proposed consent order from Global World Media Corporation ("GWMC"), the marketer of Herbal Ecstasy or Ecstasy ("Ecstasy"), and its owner, Sean Shayan [hereinafter sometimes referred to as respondents].

The proposed consent order has been placed on the public record for sixty (60) days for reception of public comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The Commission's complaint in this matter concerns safety claims respondents made in advertising for Ecstasy, a dietary supplement that respondents promoted as a natural "high" and expressly likened to the illegal street drug MDMA. More specifically, the complaint alleges that respondents represented that Ecstasy, when taken in the recommended doses or other reasonably foreseeable amounts, is absolutely safe and has no side effects. The complaint explains that Ecstasy contains a botanical source of ephedrine alkaloids, which can have dangerous effects on the nervous system and heart. Thus, according to the complaint, the claim that Ecstasy is safe and side effect free is both false and unsubstantiated.

In addition, the complaint charges that respondents represented in their advertising for Ecstasy, including in ads that ran on cable programming stations with substantial youth audiences,

Part III requires the following clear and prominent disclosure in all future advertising and labeling of, and all consumer communications concerning, any ephedrine-alkaloid-containing product sold by respondents:

**WARNING:** This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose.

Under Part III, if the product is subject to an FDA rule or regulation that requires a labeling warning, that warning is required in labeling in lieu of the warning set forth above.

Part IV prohibits respondents from assisting others, including by selling product to them, when respondents have reason to believe that they are deceptively promoting respondents' ephedrine-containing products.

Part V prohibits misrepresentations about endorsements and testimonials.

Part VI prohibits respondents from directing to individuals under the age of twenty-one advertising and promotional activities for Ecstasy or any other ephedrine product marketed as an alternative to an illegal drug or for its euphoric, psychotropic, or sexual effects. Part VI includes examples of prohibited activity, including advertisements and promotions to audiences half or more under twenty-one.

Part VII requires the respondents to conduct and submit annual analyses of the levels of ephedrine alkaloids in any ephedrine-containing product that they sell for the next five (5) years.

Part VIII provides that nothing in the order permits the respondents to market any product 1) in a state where its sale has been banned; 2) in a manner that is inconsistent with state restrictions on its sale; or 3) in a way that is inconsistent with any applicable FDA rule or regulation.

Parts IX and X provide safe harbors for claims approved pursuant to FDA's regulation of the labeling for drugs and foods, respectively.

Part XI requires respondents to send a letter (Attachment A to the order) to anyone who provides the public with information about any of respondents' ephedrine-containing products. The letter advises the recipient that the disclosure required by Part III of the order must be made in all communications with consumers concerning any of respondents' ephedrine-containing products and that the only permissible statement about the dose of any such product is the information on the label. Part XII sets forth the record keeping and surveillance requirements with respect to Part XI.

Part XIII requires respondents to send a letter (Attachment B to the order) to distributors



and resellers, including any person who purchases more than 100 units of any of respondents' ephedrine-containing products in any three (3) month period. The letter describes the Commission's action in this case and advises recipients to discontinue use of any promotional materials that do not comply with the order. Part XIV sets forth the record keeping and surveillance requirements with respect to Part XIII.

The remaining parts of the order contain standard provisions pertaining to record keeping, compliance, sunseting of the order, and similar matters.

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