

Complaint

IN THE MATTER OF

JORDAN-SIMNER, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3022. Complaint, June 19, 1980—Decision, June 19, 1980*

This consent order requires, among other things, a Ft. Lauderdale, Florida manufacturer of pharmaceutical products to cease making any misrepresentations of the efficacy or novel performance characteristics of its vaginal contraceptive suppository products. The order specifically prohibits any exaggerated efficacy claims for the products such as "highly" or "extremely" effective. Additionally, respondent is prohibited from making claims of efficacy without a reasonable basis consisting of a consistent body of valid and scientific evidence.

Appearances

For the Commission: *Susan Lerner.*

For the respondents: *Raymond D. McMurray, Hamel, Park, McCabe & Saunders, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Jordan-Simner, Inc., a corporation, and Robert Cohen, individually and as an officer of said corporation (hereinafter "respondents"), have violated Sections 5 and 12 of the Federal Trade Commission Act, and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

PARAGRAPH 1. Respondent Jordan-Simner, Inc. is a Florida corporation with its principal place of business at 6852 N.W. 12th Ave., Ft. Lauderdale, Florida.

Respondent Robert Cohen is an officer of said corporation. He formulates, directs and controls its acts and practices, including the acts and practices hereafter set forth. His business address is the same as said corporation.

Allegations stated in the present tense include the past tense.

PAR. 2. For purposes of this complaint the following definitions shall apply:

(1) A "vaginal contraceptive suppository" is a spermicidal contraceptive product which is inserted into the vagina prior to coitus. Body temperature or vaginal secretions dissolve the suppository and spread its sperm killing agent through the vaginal cavity.

(2) "Use effectiveness" means that level of effectiveness which is obtained when the contraceptive method is used by large numbers of subjects not all of whom follow the instructions accurately or use the contraceptive method each time they have sexual relations.

(3) "Commerce" means commerce as defined in the Federal Trade Commission Act, as amended.

PAR. 3. Respondents engage in the manufacturing, advertising, offering for sale and sale of pharmaceutical products, including a vaginal contraceptive suppository product named "S'Positive", a "drug" within the meaning of Section 15 of the Federal Trade Commission Act.

PAR. 4. Respondents cause their products when sold, to be shipped and distributed from their place of business to purchasers located in various other States of the United States and the District of Columbia. Respondents maintain a substantial course of trade in all their products, including their product S'Positive, in or affecting commerce.

PAR. 5. In the course and conduct of their business respondents disseminate or cause to be disseminated certain advertisements concerning S'Positive (1) by United States mails, or by various means in or having an effect upon commerce, including but not limited to insertion in newspapers or magazines of interstate dissemination for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of S'Positive, or (2) by various means, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of S'Positive in or having an effect upon commerce.

PAR. 6. Among the advertisements and other sales promotion materials, and typical of the statements and representations made in respondents' advertisements, but not all inclusive thereof, are the advertisements identified as Attachments 1 and 2.

PAR. 7. Through the use of such advertisements, and others not specifically set forth herein, respondents represent, directly or by implication, that:

1. S'Positive has an extremely high use effectiveness, approaching the level of oral contraceptives (hereinafter "the pill") or intrauterine devices (hereinafter "IUD").

2. S'Positive has novel contraceptive performance characteristics.

PAR. 8. In truth and in fact:

1. S'Positive's use effectiveness is approximately that of other vaginal contraceptive products. It is not considered to have a use effectiveness on the level of the pill or IUD.

2. S'Positive does not have novel contraceptive performance characteristics except as to the characteristics associated with its method of delivery. Its sperm killing ingredient, nonoxynol 9, has been in use for many years in various contraceptive products.

Therefore, the advertisements and representations referred to in Paragraphs Six and Seven are false, deceptive or misleading.

PAR. 9. Furthermore, through the use of the advertisements referred to in Paragraphs Five and Six, respondents represent, directly or by implication, that:

1. S'Positive has an extremely high use effectiveness.
2. S'Positive has novel contraceptive performance characteristics.
3. S'Positive has undergone years of successful medical or consumer testing.

PAR. 10. At the time respondents made the representations alleged in Paragraph Nine, respondents had no reasonable basis for making those representations. Therefore, the making and dissemination of such representations constitute deceptive acts or practices in or affecting commerce.

PAR. 11. Furthermore, respondents market or advertise S'Positive without disclosing to the purchasing public through their advertising that:

1. For best protection against pregnancy, it is essential that one follow instructions.
2. Women for whom pregnancy presents a special health risk should make a contraceptive choice in consultation with their physician.
3. Some S'Positive users experience irritation.
4. S'Positive requires a waiting period of fifteen minutes before intercourse to ensure effectiveness.
5. S'Positive is approximately as effective as vaginal foam contraceptives in actual use.

PAR. 12. The facts described in Paragraph Eleven are material with respect to the consequences which may result from use of S'Positive as a contraceptive under such conditions as are customary or usual. Respondents' failure to disclose these material facts renders the advertisements referred to in Paragraphs Five and Six false, deceptive or misleading.

PAR. 13. Furthermore, through the use of the advertisements referred to in Paragraphs Five and Six, respondents, directly or by implication, favorably compare some characteristics of S'Positive to

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the pill or the IUD and represent in the same advertisement that S'Positive has an extremely high use effectiveness. Favorable comparison of S'Positive to certain characteristics of the pill or IUD has the tendency and capacity to lead members of the public into the erroneous and mistaken belief that S'Positive's use effectiveness is equal to that of the pill or IUD. Respondents fail to disclose the fact that S'Positive has a use effectiveness below that of the pill or IUD and approximately the same as other vaginal foam contraceptive products.

PAR. 14. The fact described in Paragraph Thirteen is material in light of the comparative representations made in respondents' advertisements. Respondents' failure to disclose this material fact in advertisements containing such comparative representations renders the advertisements referred to in Paragraphs Five and Six false, misleading or unfair.

PAR. 15. In the course and conduct of its business, and at all times mentioned herein, respondents are in substantial competition in or affecting commerce with corporations, firms and individuals engaged in the sale of drugs or contraceptive products of the same general kind and nature as advertised or sold by respondents.

PAR. 16. The use by respondents of the aforesaid false, misleading, deceptive or unfair statements, representations, acts or practices, and the dissemination of the aforesaid false advertisements has the capacity and tendency to mislead members of the public into the erroneous and mistaken belief that said statements and representations are true and into the purchase of substantial quantities of respondents' products or services by reason of said erroneous and mistaken belief.

PAR. 17. The aforesaid acts and practices of respondents are all to the prejudice and injury of the public and of respondents' competitors and constitute unfair methods of competition or unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5 and 12 of the Federal Trade Commission Act. The acts and practices of respondents, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

S'POSITIVE.
 A new, medically tested,
 positive method of birth control.

S'Positive looks like a pill. But it isn't. Yet it does all the things you want the pill to do. And none of the things you don't want it to do: no harmful side effects and no effect upon your normal balance.

It's a new, one-step contraceptive. You see, S'Positive is a suppository, but unlike any other you've ever seen or heard about.

Here's how it works: As soon as it is inserted directly to the cervix, the chemistry of your body fluids the pill takes over, dissolving the S'Positive. This process allows the S'Positive to expand, blanketing the cervix and inner vaginal area with a medically safe and proven effective spermicide.

S'Positive is not detectable and its delicately scented formula acts as a gentle lubricant. There is no embarrassing messiness, no applicators, and nothing to remove, thereby eliminating troublesome before-and-after steps.

S'Positive comes in an attractive package that includes your own personal Retro-Matic (TM) Dispenser. Completely hygienic, the convenient 12-unit dispenser can easily be carried in pocket or purse. Ask your druggist for S'Positive. If it is not available in your area, write: Jordan-Simner, Inc., 15490 Northwest 7th Avenue, Miami, Florida 33159.

S'Positive. Thoroughly tested and proven effective. The modern method for today's modern women.



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IF YOU HAVE A PROBLEM CHOOSING A RELIABLE BIRTH CONTROL METHOD ...YOU NO LONGER HAVE A PROBLEM.

After years of successful medical and consumer testing, S POSITIVE is now available to you.

This proven method of birth control is different from anything else you may have tried. It's an easy-to-use, tiny vaginal suppository called S POSITIVE and it protects you against unwanted pregnancy two ways.

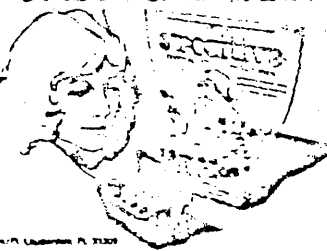
First, The formula contains a medically tested and proven effective spermicide. After insertion, the natural vaginal fluids dissolve the S POSITIVE suppository, dispersing the spermicide throughout the vaginal area.

Second, Simultaneously, a combination of ingredients forms a blanket of protection which seals the uterine opening and physically blocks sperm.

Unlike other vaginal contraceptives, there is no mess or inconvenience. Just insert S POSITIVE and forget it's there. Best of all, S POSITIVE was proven extremely effective in extensive clinical tests. When no contraceptive method is guaranteed, when used as directed, S POSITIVE can end your worry over birth control.

S POSITIVE suppositories are a welcome relief from messy, messy side effects of the pill, and potentially dangerous appliances. Now, the husbands of women in Europe and the United States rely with confidence on the effectiveness of S POSITIVE. Ask your doctor or pharmacist about S POSITIVE today. Available without prescription in handy 12 unit dispenser at leading pharmacies.

S POSITIVE
Double Birth Control Protection



©1978 Janssen-Behr, Inc. (Glanville Industrial Park, Ft. Lauderdale, FL 33305)

DECISION AND ORDER

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

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

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

1. Respondent Jordan-Simner, Inc. is a Florida corporation with its principal place of business at 6852 N.W. 12th Ave., Fort Lauderdale, Florida.

Respondent Robert Cohen is an officer of said corporation. He formulates, directs and controls its acts and practices, including the acts and practices hereafter set forth. His business address is the same as said corporation.

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

ORDER

This order applies to respondent Jordan-Simner, Inc., its successors, assigns, officers, agents and employees, and to respondent Robert Cohen, individually and as an officer of the corporation, whether

acting directly or through any corporation, subsidiary, division or other device. Except as otherwise provided, order provisions apply to any act taken in connection with respondents' advertising, offering for sale, sale or distribution of S'Positive or any OTC (over the counter) contraceptive product in or affecting commerce within the United States, including the Commonwealth of Puerto Rico and any territory or possession of the United States. The reasonable basis standards used in this order are not intended to set a standard for drug products other than OTC contraceptives.

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

1) "Use effectiveness" means that level of effectiveness which is obtained when the contraceptive method is used by large numbers of subjects not all of whom follow the instructions accurately or use the contraceptive method each time they have sexual relations.

2) "S'Positive" means the vaginal contraceptive suppository product marketed under the tradename S'Positive, or any vaginal contraceptive suppository product of substantially the same chemical formulation.

3) "Advertisement" means any written, verbal or audiovisual statement, illustration, depiction or presentation, which is designed to effect the sale of any OTC contraceptive product, or to create interest in the purchasing of such products (except a package or package insert), whether same appears in a brochure, newspaper, magazine, leaflet, circular, mailer, book insert) catalog, billboard, public transit card, point-of-sale display, film strip, video presentation, or in a radio or television broadcast or in any other media, regardless of whether such statement, illustration, depiction or presentation is characterized as promotional, educational or informative; *provided, however*, that the term advertisement does not include material which solely refers to the product without making any claims for the product.

4) "Product or use characteristic" includes but is not limited to efficacy, safety or convenience.

I.

It is ordered, That each respondent cease and desist from:

A. Making in consumer (lay) advertisements any contraceptive effectiveness claims regarding S'Positive which use the words "effective" or "reliable" in conjunction with any performance or quality heightening modifiers such as "highly", "extremely" and the like.

B. Misrepresenting, directly or by implication, the effectiveness of any OTC contraceptive product.

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- C. Representing, directly or by implication, that S'Positive has novel contraceptive performance characteristics except as to the characteristics associated with its method of delivery.
- D. Making any representation, directly or by implication, concerning the effectiveness or the testing of any OTC contraceptive product unless respondents have a reasonable basis for such representations consisting of a consistent body of valid and reliable scientific evidence; *provided, however*, that respondent may represent that S'Positive is effective or reliable or make other effectiveness claims as permitted by this order (for example, "S'Positive provides reliable protection against pregnancy:").

II.

It is further ordered, That each respondent make the following affirmative disclosures in any consumer (lay) print advertisement for S'Positive:

- For best protection against pregnancy, it is essential to follow package instructions.
- If your doctor has told you that you should not become pregnant, ask your doctor if you can use S'Positive.
- Some S'Positive users experience irritation in using the product.
- It is essential that you insert S'Positive at least fifteen minutes before intercourse.
- S'Positive is approximately as effective as vaginal foam contraceptives in actual use.

The above affirmative disclosures shall be made clearly and conspicuously. Disclosures C, D and E shall be made in the exact language indicated above; *provided, however*, that if respondent has a reasonable basis, consisting of valid scientific test(s) or study(ies), respondents may modify the words "fifteen minutes" in Disclosure D consistent with such reasonable basis. Disclosures D and E shall be made in typeface at least as large as the typeface of the major portion of the text of the ad copy. Disclosures D and E shall be separate and distinguishable from the main body of the advertisement for a period of 24 months following the date of service of this order or 27 months from the date of signing of this order, whichever expires earlier.

III.

It is further ordered, That respondents make the following affirma-

tive disclosure in any consumer (lay) advertisement for S'Positive in which any product or use characteristic of S'Positive is compared, directly or by implication, to any product or use characteristic of oral contraceptives or intra-uterine devices:

S'Positive is approximately as effective as vaginal foam contraceptives in actual use, but is not as effective as the pill or IUD.

OR

S'Positive is not as effective as the pill or IUD in actual use, but is approximately as effective as vaginal foam contraceptives.

Either above affirmative disclosure shall be made, where required, in lieu of the Disclosure II.E. The disclosure shall satisfy the requirements regarding exact language, size of type and relation to the main body of the ad specified for Disclosure II.E.

IV.

It is further ordered, That each respondent make the following disclosures in any consumer (lay) TV advertisements for S'Positive:

- A. Follow directions exactly, including the fifteen minute waiting period.
- B. Approximately as effective as contraceptives foams.

The above disclosures shall be made clearly and conspicuously as video supers and in the exact language indicated above; *provided, however,* that if respondents have a reasonable basis, consisting of valid scientific test(s) or study(ies), respondents may modify the words "fifteen minutes" in Disclosure A consistent with such reasonable basis.

V.

It is further ordered, That respondents make the following disclosure in any consumer (lay) radio advertisements for S'Positive:

S'Positive's effectiveness is approximately equal to contraceptive foams.

The above disclosure shall be made clearly and conspicuously and in the exact language indicated above.

VI.

It is further ordered, That respondents shall make the following disclosures in ethical (professional) advertisements for S'Positive:

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- A. Irritation accompanies use of the product in some instances.
- B. S'Positive must be inserted according to product instructions and at least fifteen minutes before intercourse.
- C. S'Positive is approximately as effective as vaginal foam contraceptives in actual use, but is not as effective as the pill or IUD.

OR

S'Positive is not as effective as the pill or IUD in actual use, but is approximately as effective as vaginal foam contraceptives.

Affirmative Disclosures A and B shall be made in language the same or substantially similar to the language set forth above; *provided however*, that if respondents have a reasonable basis, consisting of valid scientific test(s) or study(ies), respondents may modify the words "fifteen minutes" in Disclosure B consistent with such reasonable basis. Disclosure C shall be made in the exact language indicated above, in typeface at least as large as the typeface of the major portion of the text of the ad copy.

If respondents have a reasonable basis, consisting of a consistent body of valid and reliable scientific evidence, for any change in Disclosures contained in Paragraphs II.A, B, C or E, III, IV.B, V, and VI.A or C above, respondents may petition the Commission for appropriate modification of this order.

VII.

It is further ordered, That each respondent cease and desist from:

- A. Disseminating or causing the dissemination of any advertisement, by means of the United States mails or by any means in or affecting commerce within the United States, including the Commonwealth of Puerto Rico and any territory or possession of the United States, which contains any of the representations prohibited in Paragraph I. A-C of this order or fails to include any of the disclosures required by this order.
- B. Disseminating, or causing to be disseminated, by any means for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of S'Positive or any OTC contraceptive product in or affecting commerce within the United States, including the Commonwealth of Puerto Rico and any territory or possession of the United States, any advertisement which contains any of the representations prohibited in Paragraph I. A-C of this order or fails to include any of the disclosures required by this order.

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VIII.

It is further ordered, That respondents shall, within sixty (60) days after the date of service of this order, mail under separate cover a copy of either this order or the Federal Trade Commission's news release relating to this Order to:

- A. Every physician or health care professional to whom respondent previously sent any promotional materials regarding S'Positive.
- B. Every pharmacist who has sold S'Positive to the public within the two year period prior to the date of service of this order.

An affidavit of mailing shall be sworn to by an official of the corporate respondent verifying said mailing has been completed.

IX.

It is further ordered, That respondents maintain complete business records relative to the manner and form of their compliance with this order. Such records shall include but not be limited to, copies of and dissemination schedules for all advertisements or documents which substantiate or contradict any claim made in advertising, promoting or selling the product. Such records shall be retained for at least three (3) years beyond the last dissemination of any relevant advertising. Upon thirty (30) days' notice respondent shall make any and all such records available to Commission staff for inspection or photocopying.

X.

It is further ordered, That respondents forthwith deliver a copy of this order to each operating division and to all employees or agents now or hereafter engaged in the sale or offering for sale of S'Positive or in any aspect of the preparation, creation or placing of advertising for S'Positive on behalf of respondents. A statement acknowledging receipt of this order shall be obtained in each case.

XI.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in a corporate respondent in which the respondent is not a surviving entity, such as dissolution, assignment or sale resulting in the emergence of any successor corporation or corporations, or any other change in said corporations which may affect compliance obligations arising out of this order.

XII.

It is further ordered, That the individual respondent named herein promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment. In addition, for a period of five (5) years from the date of service of this order, the respondent shall promptly notify the Commission of each affiliation with a new business or employment whose activities include the sale or advertising of OTC contraceptive products or of his affiliation with a new business or employment in which his own duties and responsibilities involve the sale or advertising of OTC contraceptive products. Each such notice shall include the respondent's new business address and a statement of the nature of the business or employment in which the respondent is newly engaged, as well as a description of respondent's duties and responsibilities in connection with the business or employment. The expiration of the notice provision of this paragraph shall not affect any other obligation arising under this order.

XIII.

It is further ordered, That respondents shall, within sixty (60) days after service upon it of this order, file with the Commission a report setting forth in detail the manner and form in which it has complied with this order.

Commissioner Pitofsky did not participate.

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IN THE MATTER OF
AMERICAN HOME PRODUCTS CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3023. Complaint, June 19, 1980—Decision, June 19, 1980

This consent order requires, among other things, a New York City manufacturer of pharmaceutical products to cease making any misrepresentations of the efficacy or novel performance characteristics of its vaginal contraceptive suppository products. The order specifically prohibits any exaggerated efficacy claims for the products such as "highly" or "extremely" effective. Additionally, respondent is prohibited from making claims of efficacy without a reasonable basis consisting of a consistent body of valid and scientific evidence. Respondent is also required to distribute an information pamphlet discussing the advantages and disadvantages of various over-the-counter contraceptive methods as well as setting forth specifically required affirmative disclosures.

Appearances

For the Commission: *Barry E. Barnes, Susan Lerner and Rachel Wolkin Sesser.*

For the respondent: *William W. Vodra, Arnold & Porter, Charles F. Hagen and William P. Woods, New York City.*

COMPLAINT

The Federal Trade Commission, having reason to believe that American Home Products Corporation, a corporation, (hereinafter "respondent") has violated Sections 5 and 12 of the Federal Trade Commission Act, and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

PARAGRAPH 1. American Home Products Corporation is a Delaware corporation with its principal place of business at 685 Third Ave., New York, New York.

Allegations stated in the present tense include the past tense.

PAR. 2. For purposes of this complaint the following definitions shall apply:

1) A "vaginal contraceptive suppository" is a spermicidal contraceptive product which is inserted into the vagina prior to coitus. Body temperature or vaginal secretions dissolve the suppository and spread its sperm killing agent through the vaginal cavity.

2) "Use effectiveness" means that level of effectiveness which is