

IN THE MATTER OF

SORGA, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3058. Complaint, March 13, 1981—Decision, March 13, 1981.*

This consent order requires, among other things, a New York City advertising agency to cease, in connection with the advertising and sale of Semicid, or similar over-the-counter vaginal contraceptive suppository products, misrepresenting or failing to substantiate claims relating to the product's effectiveness, safety and performance characteristics. The firm is further prohibited from disseminating advertisements using performance or quality heightening modifiers such as "highly" or "extremely," in conjunction with words like "effective" or "reliable." Additionally, the order requires the company to disclose, in print, radio and TV consumer advertising, certain facts material to contraceptive suppository use; and to maintain business records for a period of three years.

Appearances

For the Commission: *Shirley F. Sarna and Paula K. Stein.*

For the respondent: *Evan A. Davis, Clearly, Gottlieb, Steen & Hamilton, New York City.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Sorga, Inc., 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. Sorga, Inc. is a New York corporation with its principal place of business at 300 East 42nd St., New York, New York. Sorga, Inc. previously did business under the name of Kelly, Nason-Univas, Inc. The name change to Sorga, Inc. was accomplished by amendment to the certificate of incorporation on June 29, 1979.

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 nor 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. Respondent was an advertising agency for American Home Products Corporation. In such capacity respondent has prepared and placed advertising for publication and has caused dissemination of advertising, including the advertising referred to herein, to promote the sale of a vaginal contraceptive suppository product named "Semicid", a "drug" within the meaning of Section 15 of the Federal Trade Commission Act.

PAR. 4. In the course and conduct of its business respondent has disseminated or caused the dissemination of certain advertisements concerning Semicid (1) by United States mail, or by various means in or having an effect upon commerce, including but not limited to insertion in newspapers or magazines of interstate dissemination and radio and television broadcasts of interstate transmission, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of Semicid, or (2) by various means, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of Semicid in or having an effect upon commerce.

PAR. 5. Among the advertisements and other sales promotion materials, and typical of the statements and representations made in respondent's advertisements, but not all inclusive thereof, are the advertisements identified as Attachments 1 through 4.

PAR. 6. Through the use of such advertisements, and others not specifically set forth herein, respondent represents, directly or by implication, that:

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

2. Semicid has novel contraceptive performance characteristics.

PAR. 7. In truth and in fact:

1. Semicid'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. Semicid 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 Five and Six are false, deceptive or misleading.

PAR. 8. Furthermore, through the use of the advertisements referred to in Paragraphs Four and Five, respondent represents, directly or by implication, that:

1. Semicid has an extremely high use effectiveness.
2. Semicid has novel contraceptive performance characteristics.
3. Semicid has been scientifically or medically proven to have an extremely high use effectiveness.

PAR. 9. At the time respondent made the representations alleged in Paragraph Eight, respondent had no reasonable basis for making those representations. Therefore, the making and dissemination of such representations constitute deceptive or unfair acts or practices in or affecting commerce.

PAR. 10. Furthermore, respondent advertises Semicid without disclosing to the purchasing public through its 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 Semicid users experience irritation.
4. Semicid requires a waiting period of fifteen minutes before intercourse to ensure effectiveness.
5. Semicid is approximately as effective as vaginal foam contraceptives in actual use.

PAR. 11. The facts described in Paragraph Ten are material with respect to the consequences which may result from use of Semicid as a contraceptive under such conditions as are customary or usual. Respondent's failure to disclose these material facts renders the advertisements referred to in Paragraphs Four and Five false, deceptive or misleading.

PAR. 12. Furthermore, through the use of the advertisements referred to in Paragraphs Four and Five, respondent, directly or by

implication, favorably compares some characteristics of Semicid to the pill or the IUD and represents in the same advertisements that Semicid has an extremely high use effectiveness. Favorable comparison of Semicid 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 Semicid's use effectiveness is equal to that of the pill or IUD. Respondent fails to disclose the fact that Semicid has a use effectiveness below that of the pill or IUD and approximately the same as other vaginal foam contraceptive products.

PAR. 13. The fact described in Paragraph Twelve is material in light of the comparative representations made in respondent's advertisements. Respondent's failure to disclose this material fact in advertisements containing such comparative representations renders the advertisements referred to in Paragraphs Four and Five false, misleading or unfair.

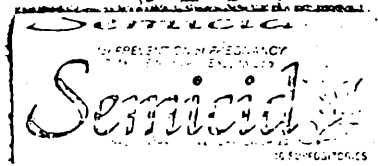
PAR. 14. In the course and conduct of its business, and at all times mentioned herein, respondent is in substantial competition in or affecting commerce with corporations, firms and individuals engaged in the sale of services of the same general kind and nature as are sold by respondent.

PAR. 15. The use by respondent 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 respondent's products or services by reason of said erroneous and mistaken belief.

PAR. 16. The aforesaid acts and practices of respondent as herein alleged, including the dissemination of false advertising, are all to the prejudice and injury of the public and of respondent's 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 respondent, as herein alleged, are continuing and will continue in the absence of the relief herein requested.

Commissioner Pitofsky did not participate.

Now you can say goodbye to the pill, the IUD, diaphragms, foams, creams and clumpy jellies



Semicid is here

A medically tested, vaginal contraceptive
suppository developed for the woman of today.

As a contemporary woman, you know about birth control. You know what works, what feels right, what is aesthetically pleasing.

Whatever method you choose, you want it to be effective, safe and easy to use.

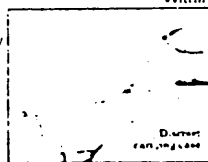
Now there's a non-hormonal contraceptive to satisfy your contemporary needs. Semicid.

Proven to be effective.

Semicid is an effective vaginal contraceptive for the prevention of pregnancy. It is a non-hormonal, vaginal mini-suppository that safely kills sperm in seconds. Semicid's active ingredient is nonoxonyl-9, a spermicide used effectively by millions of women for over 10 years.

Laboratory tested. Doctor tested.

A U.S. clinical study of hundreds of women of childbearing age over a four year period, proved Semicid's high degree of effectiveness. This study was conducted by a gynecologist and was carefully designed to compare the efficacy of Semicid with published reports of other contraceptive methods. Semicid is known to be effective in the prevention of pregnancy.



Semicid is safe.

Semicid contains no hormones. As a result, none can enter your bloodstream. What's more, Semicid is safer than the IUD, because it cannot pierce the uterine walls. Semicid is so safe that you can purchase it without a prescription, and it is non-irritating based on reports from doctors and from women using the product.

Easy and convenient to use.

Within minutes, Semicid dissolves and spreads a protective covering over the cervical opening and adjoining vaginal walls. And because Semicid is quick and easy to insert, it will not interfere with spontaneity.

The Semicid package is so small and discreet that it can be kept anywhere. Semicid has no application, so there is nothing to fill, clean or remove.

Semicid is lubricating and has no unpleasant taste or odor. It was formulated for the lady you are living today. Ask your gynecologist about it.

Semicid is from Whitehall Laboratories, one of the world's leading pharmaceutical companies. It's available at your local drugstore, or, as directed.

SEMICID. Today's contraceptive for today's woman.

Now. A safe, simple way to prevent pregnancy.

It's Semicid, a safe, easy-to-use vaginal contraceptive suppository with an active ingredient proven effective by millions of women.

If you're dissatisfied with your present birth control method, you should know about Semicid, a real alternative in contraception from Whitehall Laboratories, one of the world's leading pharmaceutical companies.

Semicid is safe and effective. It contains the maximum allowable level of nonoxonyl-9, an ingredient which safely kills sperm in seconds. It's the spermicide doctors recommend most and has been used effectively by millions of women for over 10 years. Now this tested, proven ingredient is available in Semicid.

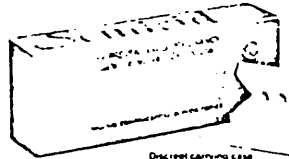
Semicid is safe, too. Unlike the pill, it has no hormonal side effects. And unlike the IUD, it can't damage uterine walls. Furthermore, Semicid does not effervesce the way the other vaginal suppository does. Semicid is non-irritating to most women. There's also no unpleasant odor. Neither you nor your partner will notice Semicid is there at all.

Semicid is neat and convenient. Slim, only an inch long, Semicid is so simple and easy to use. There's no applicator, so there's nothing to fill, clean, or remove. Semicid is not messy like foams, creams and jellies. And it's not awkward like the diaphragm. It lets love-making happen naturally, spontaneously.

Within minutes after you insert it, Semicid dissolves and spreads a protective covering over the cervical opening and adjoining vaginal walls.

Semicid comes in a small, discreet dispenser containing 10 suppositories. You can purchase it without a prescription.

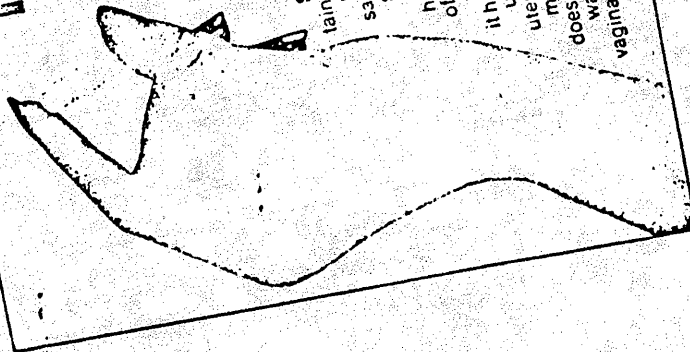
For more information about this remarkable contraceptive, ask your doctor. Use only as directed.



Discreet carrying case

Semicid.

Now. A safe, simple way to prevent pregnancy.



It's Semicid, a safe, easy-to-use vaginal contraceptive suppository with an active ingredient proven effective by millions of women.

Neat and convenient. Slim, only an inch long. Semicid is so simple and easy to use, it's not messy like foams. It's not awkward like the diaphragm. It lets love-making happen naturally.

Safe and effective. Semicid contains the maximum allowable level of nonoxonyl-9, an ingredient which safely kills sperm in seconds. It's the spermicidal ingredient in most and doctors recommend it by millions has been used effectively by millions of women for over 10 years.

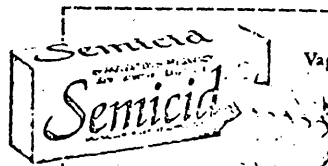
Semicid is safe, too. Unlike the pill, it has no hormonal side effects. And unlike the IUD, it can't damage uterine walls. Further, Semicid does not interfere the way the other vaginal suppository does.



Semicid

Do not use if you are pregnant.

Ask your doctor about Semicid.
You, too, may discover it's birth control
on your terms.



Name _____
Address _____
City _____ State _____ Zip _____

This offer is made available to persons over 18 years of age. Subject to state and local regulations. Offer valid in the State of Tennessee and where taxed, restricted or prohibited by law. Offer expires September 30, 1996. Canceled 10/1/96.

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 Sorga, Inc. is a New York corporation with its principal place of business at 300 East 42nd St., New York, New York.
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 Sorga, Inc., its successors, assigns, officers, agents and employees, 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 respondent's advertising, offering for sale, sale or distribution of Semicid 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*" or effectiveness "*in actual use*" 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) "*Method effectiveness*" means that level of effectiveness which is attained in a well-controlled clinical trial utilizing highly motivated volunteers who reportedly use the contraceptive method correctly with every act of sexual intercourse.

3) "*Semicid*" means the vaginal contraceptive suppository product marketed under the tradename Semicid, or any vaginal contraceptive suppository product of substantially the same chemical formulation.

4) "*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.

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

I

It is ordered, That respondent cease and desist from:

A. Making in consumer (lay) advertisements any contraceptive effectiveness claims regarding Semicid 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; unless respondent neither knew nor should have known that the representation was false, deceptive or misleading.

C. Representing, directly or by implication, that Semicid has novel contraceptive performance characteristics except as to the characteristics associated with its method of delivery.

D. Representing, directly or by implication, the results of any study of method effectiveness of any OTC contraceptive product as a measure of the use effectiveness of any such product.

E. Making any representation, directly or by implication, concerning the effectiveness of any OTC contraceptive product unless respondent has a reasonable basis for such representation consisting of a consistent body of valid and reliable scientific evidence; *provided, however*, that respondent may represent that Semicid is effective or reliable or make other effectiveness claims as permitted by this Order (for example, "Semicid provides reliable protection against pregnancy").

II

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

A. For best protection against pregnancy, it is essential to follow package instructions.

B. If your doctor has told you that you should not become pregnant, ask your doctor if you can use Semicid.

C. Some Semicid users experience irritation in using the product.

D. It is essential that you insert Semicid at least fifteen minutes before intercourse.

E. Semicid 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), respondent 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 advertising 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 respondent make the following affirmative disclosure in any consumer (lay) print advertisement for Semicid in which any product or use characteristic of Semicid is compared, directly or by implication, to any product or use characteristic of oral contraceptives (hereinafter "the pill") or intrauterine devices (hereinafter "IUD"):

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

OR

Semicid 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 Disclosure II.E above. The disclosure shall satisfy the requirements regarding exact language, size of type and relation to the main body of the advertisement specified for Disclosure II.E.

IV

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

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

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

V

It is further ordered, That respondent make the following disclosure in any consumer (lay) radio advertisements for Semicid:

Semicid'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 respondent shall make the following disclosures in ethical (professional) advertisements for Semicid:

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

OR

Semicid 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 respondent has a reasonable basis, consisting of valid scientific test(s) or study(ies), respondent 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 advertising copy.

VII

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

- A. Disseminating or causing the dissemination of any advertisement, by means of the United States mail 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-D 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 Semicid 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-D of this Order or fails to include any of the disclosures required by this Order.

VIII

It is further ordered, That in advertisements in languages other than English, exact language disclosures required by this Order shall be made in the non-English language equivalent and convey the same meaning as the English language disclosures.

IX

It is further ordered, That respondent maintain complete business records relative to the manner and form of its compliance with this order. Such records shall include but not be limited to, copies of and dissemination schedules for all advertisements and 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 advertisement. 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 respondent 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 Semicid or in any aspect of the preparation, creation or placing of advertising for Semicid on behalf of respondent. A statement acknowledging receipt of this Order shall be obtained in each case.

XI

It is further ordered, That respondent 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 corporation which may affect compliance obligations arising out of this Order.

XII

It is further ordered, That respondent shall, within sixty (60) days