

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

**COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary**

In the Matter of

**SNORE FORMULA, INC.,
a corporation,**

**DENNIS H. HARRIS, M.D.,
individually and as an officer
of Snore Formula, Inc.,**

DOCKET NO. C-4090

DECISION AND ORDER

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, or that the facts as alleged in such complaint, other than jurisdictional facts, are true 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 thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to § 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1.a. Respondent Snore Formula, Inc., is an Arizona corporation with its principal office or place of business at 4105 N. 40th

employees.

2. "Clearly and prominently" shall mean as follows:

A. In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and visual portions of the advertisement.

Provided, however, that in any advertisement presented solely through visual or audio means, the disclosure may be made through the same means in which the ad is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The visual 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. In addition to the foregoing, in interactive media, the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

B. In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.

C. On a product label, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.

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

3. In the case of advertisements disseminated by means of an interactive electronic medium such as the Internet or other online services, "in close proximity" shall mean on the same Web page and proximate to the triggering representation, and not on other portions of the Web site, accessed or displayed through hyperlinks or other means.

4. "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.

5. "Distributor" shall mean any purchaser or other transferee of any product or service covered by this order who acquires such product or service from one or more respondent, with or without valuable consideration, and who sells, or who has sold, such product or service to other sellers or to consumers, including but not limited to individuals, retail stores, or catalog sellers.

6. "Food," "drug," and "device," shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
7. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
8. "Endorsement" shall mean as defined in 16 C.F.R. 255.0(b).

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

- A. Such product or service prevents sleep apnea in adult or child users who would otherwise develop sleep apnea;
- B. Such product or service treats sleep apnea; or
- C. Such product or service eliminates, prevents, or reduces snoring in users of the product or service,

unless at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. *Provided that*, for any representation made by respondent Dennis H. Harris, M.D. as an expert endorser, respondent Dennis H. Harris, M.D. must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise in the form of an examination or testing of the product at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or service that has not been shown by competent and reliable scientific evidence to be effective in the treatment of sleep apnea, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the product or service is effective in eliminating, preventing, or reducing snoring, unless

they disclose, clearly and prominently, and in close proximity to the representation, that such product or service is not intended to treat sleep apnea; that the symptoms of sleep apnea include loud snoring, frequent episodes of totally obstructed breathing during sleep, and excessive daytime sleepiness; that sleep apnea is a potentially life-threatening condition; and that persons who have symptoms of sleep apnea should consult their physician or a specialist in sleep medicine. *Provided, however,* that for any television commercial or other video advertisement fifteen (15) minutes in length or longer or intended to fill a broadcasting or cablecasting time slot fifteen (15) minutes in length or longer, the disclosure shall be made within the first thirty (30) seconds of the advertisement and immediately before each presentation of ordering instructions for the product or service. *Provided further,* that, for the purposes of this provision, the presentation of a telephone number, e-mail address, or mailing address for listeners to contact for further information or to place an order for the product or service shall be deemed a presentation of ordering instructions so as to require the announcement of the disclosure provided herein.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dr. Harris' Original Snore Formula tablets or any other food, drug, device, service, or dietary supplement in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the effect of such food, drug, device, service, or dietary supplement on any disease, or about the effect of such food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of such product or service, unless, at the time the representations are made, respondents possess and rely upon competent and reliable scientific evidence, that substantiates the representation. *Provided that,* for any representation made by respondent Dennis H. Harris, M.D. as an expert endorser, respondent Dennis H. Harris, M.D. must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise in the form of an examination or testing of the product or service at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation.

IV.

IT IS FURTHER ORDERED that respondents Snore Formula, Inc., a corporation, its successors and assigns and its officers; Dennis H. Harris, M.D., individually and as an officer of the corporation; Ronald E. General, individually and as an officer of the corporation, and each of the above's agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, including franchisees, licensees, or distributors, shall not provide to any person or entity means and instrumentalities that contain any claim about the benefits, performance, efficacy, or safety of any food, drug, device, service, or dietary supplement, unless such claim is true, and

substantiated by competent and reliable scientific evidence. For purposes of this Part, "means and

- A. For a period of three (3) years following entry of this order, send a copy of the notice attached hereto (Attachment A) by first class mail, with postage prepaid, to any distributor of Dr. Harris' Original Snore Formula tablets, or any other product or service; *provided, however*, that the requirement of this subpart shall not apply to any distributor who received a copy of the notice attached hereto (Attachment A) pursuant to the requirements of subpart VI.B of this order. Such notice shall be sent within one (1) week from the first shipment of respondent's products or programs to said distributor. The mailing shall not include any other documents.
- B. Institute a reasonable program of surveillance adequate to reveal whether any of respondents' distributors are disseminating advertisements or promotional materials that contain any representation about Dr. Harris' Original Snore Formula tablets, or any other product or service manufactured by or purchased from respondent, that is prohibited by Parts I through V of this order.
- C. Terminate all sales of Dr. Harris' Original Snore Formula tablets, or any other food, drug, device, service, or dietary supplement to any distributor who is engaged in disseminating advertisements or promotional materials that contain any representation about Dr. Harris' Original Snore Formula tablets, or any other product or service manufactured by or purchased from one or more respondent, that is prohibited by Parts I through V of this order once respondent knows or should know that the distributor is or has been engaged in such conduct.

VIII.

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 medical device application approved by the Food and Drug Administration. Nor shall it 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.

IX.

IT IS FURTHER ORDERED that respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to 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, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

X.

IT IS FURTHER ORDERED that respondents 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.

XI.

IT IS FURTHER ORDERED that respondent Snore Formula, Inc., 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, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XII.

IT IS FURTHER ORDERED that respondents Dennis H. Harris, M.D.; Ronald E. General; and Gerald H. Harris, for a period of ten (10) years after the date of issuance of this order, notify the Commission on the date of issuance of this order. (theu-3080.X2d Oder; the propoEtion;) TjhTw wq11a0.3aining such30 T Ha

Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIII.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after 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 the manner and form in which they have complied with this order.

XIV.

This order will terminate on July 24, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark
Secretary

ISSUED: July 24, 2003
SEAL

ATTACHMENT A

LETTER SENT TO DISTRIBUTORS WITH WHOM RESPONDENT HAS DONE BUSINESS BETWEEN JANUARY 1, 2001, AND THE DATE OF SERVICE OF THIS ORDER

[To Be Printed on Snore Formula, Inc. letterhead]

[NAME AND ADDRESS OF RECIPIENT]

[DATE]

Dear [DISTRIBUTOR'S NAME]:

This letter is to inform you that Snore Formula, Inc., recently settled a civil dispute with the Federal Trade Commission regarding its advertising for *Dr. Harris' Original Snore Formula* tablets. Among other things, we have agreed to notify distributors of the settlement.

As a result of its agreement with the FTC, Snore Formula, Inc., has consented to desist from, among other practices, making any claims about the effect of any food, drug, device, service, or dietary supplement on any disease, or about the effect of such food, drug, device, service, or dietary supplement on the structure or function of the human body, or about any other health benefit, or the safety, of such product or service, that is not supported by competent and reliable scientific evidence. Competent and reliable scientific evidence is defined as 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. Anecdotal evidence and consumer testimonials are not considered competent and reliable scientific evidence.

According to the FTC complaint, we did not have a reasonable basis to claim that *Dr. Harris' Original Snore Formula* tablets can prevent sleep apnea in adult and child users of the product who would otherwise develop sleep apnea; can treat the early stages of sleep apnea; or can eliminate, prevent, or significantly reduce snoring; or that scientific testing demonstrates that *Dr. Harris' Original Snore Formula* tablets reduce or eliminate snoring or the sound of snoring for 86% of users.

As always, your responsibility as a distributor is to utilize only claims made directly from corporate communications or to have your advertising approved by the corporation before transmitting it. Failure to comply with these requirements can result in termination.

This letter has been provided for your files. If you have any questions or if you want a copy of the FTC order, please contact [insert name and telephone number of respondents' contact].

Snore Formula, Inc.