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UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS:

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

In the Matter of	)	
MED GEN, INC. a corporation, and	)	
PAUL B. KRAVITZ individually and as an officer of the corporation.	)	**DOCKET NO. C- 4053**

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection 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 attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all jurisdictional facts set forth in the aforesaid draft 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, 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 a 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 (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, and having determined to modify the Decision and Order in certain respects, 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 Med Gen, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its office and principal place of business at 7284 West Palmetto Road, Suite 106, Boca Raton, Florida 33433.

1.b Respondent Paul B. Kravitz is an officer of said corporation. He formulates and controls the policies, acts and practices of said corporation, and his principal office and place of business is located at the above stated address.

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

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 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 video portions of the advertisement. Provided, however, that in any advertisement presented solely through video 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 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. 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. Unless otherwise specified, "respondents" shall mean Med Gen, Inc. and its successors and assigns and its officers; Paul B. Kravitz, individually and as an officer of the corporation; and each of the above's agents, representatives, and employees.

4. "Drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

5. "Food" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

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 SNORenz or any other food, drug, or dietary supplement, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication that:

A. Such product reduces or eliminates snoring or the sound of snoring in users of the product;

B. A single application of such product reduces or eliminates snoring or the sound of snoring for any specified period of time; or

C. Such product can eliminate, reduce or mitigate the symptoms of sleep apnea including daytime tiredness and frequent interruptions of deep restorative sleep

unless at the time the representation 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 any product 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 is effective in reducing or eliminating snoring or the sounds of snoring, unless they disclose, clearly and prominently, and in close proximity to the representation, that such product 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. 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 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, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of SNORenz or any other product, service, or program in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy, or safety of any such product, service, or program, unless, at the time the representation is made, respondents possess and rely upon competent and reliable evidence, which, when appropriate, must be competent and reliable scientific evidence, that substantiates the representation.

IV.

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 any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

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 any product, service, or program in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the experience represented by any user testimonial or endorsement of the product, service, or program represents the typical or ordinary experience of members of the public who use the product, service or program unless:

A. At the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; or

B. Respondents disclose, clearly and prominently, and in close proximity to the endorsement or testimonial, either:

1. what the generally expected results would be for users of the product, or

2. the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to experience similar results.

For purposes of this Part, "endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

VI.

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 any product, service, or program in or affecting commerce, shall disclose, clearly and prominently, and in close proximity to the endorsement, a material connection, where one exists, between a person or entity providing an endorsement of any product, service, or program, as "endorsement" is defined 16 C.F.R. 255.0 (b) and any respondent, or any other individual or entity manufacturing, labeling, advertising, promoting, offering for sale, selling, or distributing such product, service or program. For purposes of this order, "material connection" shall mean any relationship that might materially affect the weight or credibility of the endorsement and would not be reasonably expected by endorsers.

VII.

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.

VIII.

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.

IX.

IT IS FURTHER ORDERED that, no later than the date this order becomes final, respondents shall pay to the Federal Trade Commission the sum of thirty thousand dollars ($30,000), under the following terms and conditions:

A. The payment shall be made by wire transfer to the Federal Trade Commission. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the amount due, together with interest as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.

B. The funds paid by respondents, together with any accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of SNORenz and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of the payment herein provided shall be deemed a payment of any fine, penalty or punitive assessment.

C. Respondents relinquish all dominion, control and title to the funds paid, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of respondents, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

X.

IT IS FURTHER ORDERED that respondent Med Gen, Inc., its successors and assigns, and respondent Paul B. Kravitz 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.

XI.

IT IS FURTHER ORDERED that respondent Med Gen, Inc., its successors and assigns, and respondent Paul B. Kravitz 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.

XII.

IT IS FURTHER ORDERED that respondent Med Gen, 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.

XIII.

IT IS FURTHER ORDERED that respondent Paul B. Kravitz, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. 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, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XIV.

IT IS FURTHER ORDERED that respondent Med Gen, Inc. and its successors and assigns, and respondent Paul B. Kravitz 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 the manner and form in which they have complied with this order.

XV.

This order will terminate on July 12, 2022, 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

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ISSUED: July 12, 2002