UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

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COMMISSIONERS:	Robert Pitofsky,	Chairman

Mary L. Azcuenaga Janet D. Steiger Roscoe B. Starek, III Christine A. Varney

In the Matter of) DOCKET NO. C-3716)

PHASEOUT OF AMERICA, INC. and) DECISION AND ORDER PRODUCTS & PATENTS, LTD., corporations.)

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 attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of the 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 sixty (60) days, 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. Respondent Phaseout of America, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 140 Broadway, in the City of Lynbrook, State of New York.

Respondent Products & Patents, Ltd. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 140 Broadway, in the City of Lynbrook, State of 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

DEFINITIONS

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

- 1. "Johns Hopkins study" shall mean the study that has been reported as Stitzer, Brigham and Felch, <u>Phase-Out Filter Perforation: Effects on Human Tobacco Smoke Exposure</u>, 41 Pharmacology, Biochemistry and Behavior 748 (1992).
- 2. "Smoking-cessation product" shall mean any product or program designed to aid or assist the user to stop or reduce the cigarette urge, break the cigarette habit, or stop or reduce smoking.
- 3. "Cigarette-modification product" shall mean any product or program designed to reduce the amount of tar, nicotine, carbon monoxide or other substance that smokers get from cigarettes, or reduce their risk of smoking-related health problems.
- 4. "Substantially similar product" shall mean any smoking-cessation product or cigarette-modification product that punches one or more holes in a cigarette or pack of cigarettes.
- 5. "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. Survey evidence may be appropriate depending on the representation made.

- 6. Unless otherwise specified, "respondents" shall mean Phaseout of America, Inc. and Products & Patents, Ltd., corporations, their successors, assigns, agents, representatives and employees.
- 7. "Purchaser for resale" shall mean any purchaser or other transferee of the PhaseOut device, or of the right or license to sell the PhaseOut device, other than respondents, who sells, or who has sold, the PhaseOut device to other purchasers or to consumers.
- 8. "In or affecting 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 the PhaseOut device or any substantially similar product in or affecting commerce, shall not represent, in any manner, expressly or by implication, that:

- A. The Johns Hopkins study proves that such product significantly reduces the amount of tar, nicotine, or carbon monoxide smokers get under normal smoking conditions:
- B. The Johns Hopkins study proves that such product is effective in enabling smokers to quit smoking; or
- C. The Johns Hopkins study proves that smokers who use such product and continue to smoke significantly reduce their risk of smoking-related health problems.

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 smoking-cessation product or cigarette-modification product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

1. The product reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get from smoking a cigarette;

- 2. The product is effective in enabling or helping smokers to quit smoking;
- 3. The product reduces the risk of smoking-related health problems, including, but not limited to, lung cancer or heart disease, for smokers who continue to smoke;
- 4. The product reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get without changing a cigarette's taste or draw;
- 5. Smokers using the product will not compensate for the product's effects by increasing the number of cigarettes they smoke per day;
- 6. The product is effective in enabling or helping smokers to quit smoking without withdrawal symptoms; or
- 7. The product provides immediate health benefits, including, but not limited to, reduced congestion, coughing or windedness, for smokers who continue to smoke:

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

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 any smoking-cessation product or cigarette-modification product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the performance, benefits or efficacy of such product, unless, at the time it is made, respondents possess and rely upon 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 smoking-cessation product or cigarette-modification product 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.

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 smoking-cessation product or cigarette-modification product 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 represents the typical or ordinary experience of members of the public who use the product, 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 Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall:

- A. Within forty-five (45) days after the date of entry of this order, compile a current mailing list containing the names and last known addresses of all purchasers of the PhaseOut device since January 1, 1992. Respondents shall compile this list by:
 - 1. Searching their own files for the names and addresses of such purchasers; and
 - 2. Using their best efforts to identify any other such purchasers, including but not limited to sending by first class certified mail, return receipt requested, within five (5) days after the date of entry of this order, to all purchasers for resale with which respondents have done business since January 1, 1992, an exact

copy of the notice attached hereto as Attachment A. The mailing shall not include any other documents. In the event that any such purchaser for resale fails to provide any names or addresses of purchasers in its possession, respondents shall provide the names and addresses of all such purchasers for resale to the Federal Trade Commission within forty-five (45) days after the date of entry of this order.

In addition, respondents shall retain a National Change of Address System ("NCOA") licensee to update this list by processing the list through the NCOA database.

- B. Within ninety (90) days after the date of entry of this order, send by first class postcard, postage prepaid, to the last known address of each purchaser of the PhaseOut device identified on the mailing list compiled pursuant to subparagraph A of this part, an exact copy of the notice attached hereto as Attachment B. The mailing shall not include any other documents.
- C. For one (1) year after the date of entry of this order, make the mailing described in subparagraph B of this part to any person or organization not on the mailing list prescribed in subparagraph A of this part about whom respondents later receive information indicating that the person or organization is likely to have been a purchaser of the PhaseOut device, and to any purchaser whose notification postcard is returned by the U.S. Postal Service and for whom respondents obtain a corrected address, from the U.S. Postal Service or elsewhere. The mailing required by this subparagraph shall be made within ten (10) days of respondents' receipt of a corrected address or information identifying each such purchaser.
- D. In the event that respondents receive any information that, subsequent to its receipt of Attachment A any purchaser for resale is using or disseminating any advertising or promotional material that contains any representation prohibited by this order, immediately notify the purchaser for resale that respondents will terminate the use of said purchaser for resale if it continues to use such advertising or promotional material; and
- E. Terminate the use of any purchaser for resale about whom respondents receive any information that such purchaser for resale has continued to use or disseminate advertising or promotional material that contains any representation prohibited by this order after receipt of the notice required by subparagraph D of this part.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall, for five (5) years after the last correspondence to which they pertain, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Copies of all notifications sent to purchasers pursuant to subparagraphs B and C of part VI of this order;
- B. Copies of all notification letters sent to purchasers for resale pursuant to subparagraph A of part VI of this order;
- C. Copies of all communications with purchasers for resale pursuant to subparagraphs D and E of part VI of this order.

VIII.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns 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.

IX.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall deliver a copy of this order to all current principals, officers, directors, and managers, and to all current employees, agents, and representatives having responsibilities with respect to the subject matter of this order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) 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 respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns 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.

XII.

This order will terminate on February 12, 2017, 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; <u>provided, however</u>, 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.

<u>Provided, further</u>, 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: February 12, 1997

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

[To be printed on Phaseout of America, Inc. letterhead]

[date]

Dear [purchaser for resale]:

This letter is to inform you that Phaseout of America, Inc. recently settled a lawsuit with the Federal Trade Commission ("FTC") concerning certain claims we made for our product, PhaseOut, which the FTC has challenged as deceptive. Although we do not admit the FTC's allegations, we have agreed to notify our distributors, wholesalers and others who sell PhaseOut to consumers to stop using or distributing advertisements or promotional materials containing those claims. We are also asking PhaseOut sellers to provide us with the names of their customers so that we may contact them directly.

The FTC Settlement

The FTC claimed that we made unsubstantiated claims about PhaseOut's effectiveness in reducing the adverse health effects of smoking and in helping smokers to stop smoking. The FTC also alleged that the company made misrepresentations about a study conducted at The Johns Hopkins University using PhaseOut.

• Claims about reduced tar, nicotine and carbon monoxide yields.

The FTC alleged that the company made unsubstantiated claims that PhaseOut reduces the amount of tar, nicotine and carbon monoxide smokers get from smoking a cigarette by specific, substantial percentages. The company has agreed that it will substantiate any future claims that PhaseOut reduces the amount of any component of cigarette smoke that smokers get from smoking a cigarette.

The FTC also alleged that the company misrepresented the Johns Hopkins test results by claiming that the study proved that PhaseOut significantly reduces the amount of tar, nicotine and carbon monoxide smokers get under normal smoking conditions. Smokers often compensate when smoking low tar or nicotine cigarettes by taking more puffs from a cigarette, inhaling more deeply or blocking ventilation holes, such as the perforation holes produced by the PhaseOut device. The company has agreed that it will accurately represent the results of the Johns Hopkins study and any other test or study.

Claims that PhaseOut is effective in enabling smokers to quit smoking.

The FTC alleged that the company made unsubstantiated claims that PhaseOut is effective in enabling smokers to quit smoking. The company has agreed that it will substantiate any future claims that PhaseOut is effective in enabling smokers to quit smoking.

The FTC also alleged that the company misrepresented the Johns Hopkins test results by claiming that the study proves PhaseOut is effective in enabling smokers to quit smoking. The company has agreed not to make this representation in the future.

• Claims that PhaseOut provides immediate health benefits and reduces the risk of smoking-related health problems for people who continue to smoke.

The FTC alleged that the company made unsubstantiated claims that smokers would derive substantial health benefits by using the PhaseOut product even if they continued to smoke. The company has agreed that it will properly substantiate any future claims of this type.

The FTC also alleged that the company misrepresented the Johns Hopkins test results by claiming that the study proved that smokers who use PhaseOut and continue to smoke significantly reduce their risk of smoking-related health problems. The company has agreed not to make this representation in the future.

• Claims that PhaseOut reduces tar, nicotine and carbon monoxide yields without changing a cigarette's taste or draw.

The FTC alleged that the company made claims that use of the PhaseOut device would not produce any change in a cigarette's taste or draw. The company has agreed to substantiate any future claims regarding taste or draw.

• Claims that PhaseOut is effective in enabling smokers to quit smoking without withdrawal symptoms.

The FTC alleged that the company made these claims without adequate substantiation. The company has agreed that it will have proper substantiation before making these claims in the future.

• Claims that users of PhaseOut will not compensate for the product's effects by increasing the number of cigarettes they smoke per day.

The FTC alleged that the company made these claims without adequate substantiation. The company has agreed to have proper substantiation before making these claims in the future.

 Claims that testimonials and consumer endorsements used in our ads reflect the typical or ordinary experiences of PhaseOut users.

The company has agreed that it will make these claims only if they reflect the typical experience of PhaseOut users or there is a proper qualifying disclosure to the effect that the results are not typical. No issue was raised regarding the authenticity of the actual testimonials and endorsements that have been used in PhaseOut advertising.

Our Obligations to Notify Distributors and Customers

In addition to our obligations discussed above, we have also agreed to provide notification of the FTC's allegations to consumers who have purchased PhaseOut. We need your assistance in complying with certain provisions of our settlement with the FTC.

First, we request that you discontinue using, relying on or distributing any PhaseOut advertising or promotional materials currently in your possession. We also ask that you notify any of your retail or wholesale customers who may have such materials to discontinue using them. These materials may contain claims that the FTC has alleged to be false or unsubstantiated. If you continue to use those materials, we are required by the FTC settlement to stop doing business with you. You should also avoid making any of the representations challenged by the FTC, as described in this letter.

Second, please send us immediately the names and last known addresses of all persons, including other resellers and consumers, to whom you have sold the PhaseOut device since January 1, 1992. We need this list in order to provide the notification required by our settlement with the FTC. If you do not provide this information, we are required to provide your name and address to the FTC.

If you have any questions, you may call us at (516) 599-1900 or you may call Devenette Cox at the FTC at (202) 326-3360. We apologize for any inconvenience this may cause you and thank you for your assistance.

Sincerely,

Irwin Pearl, President Phaseout of America, Inc.

ATTACHMENT B

Front of Postcard

Phaseout of America, Inc. 140 Broadway Lynbrook, New York 11563

[Name and address of PhaseOut purchaser]

IMPORTANT HEALTH NOTICE!

Back of Postc ard

Dear PhaseOut Purchaser:

Our records show that you bought the PhaseOut smoking cessation product. Phaseout of America, Inc. recently settled Federal Trade Commission charges that we made deceptive claims in our ads about the benefits of the PhaseOut product. Although we don't admit the FTC's allegations, we agreed to send this notice to people who bought the product.

According to the FTC, our ads deceptively claimed, among other things, that people who use PhaseOut could continue to smoke while substantially reducing the risk of smoking-related health problems, including lung cancer and heart disease. As part of our settlement, we agreed to stop making claims like this unless we have scientific proof to back them up. PhaseOut has <u>not</u> been proven to reduce the risk of smoking-related diseases or to make cigarettes "safer."

For more information about smoking-related health risks, call the National Cancer Institute's Cancer Information Service at 1-800-4CANCER.

Sincerely,

[Date]

Irwin Pearl, President of Phaseout of America, Inc.