

IN THE MATTER OF
CHESEBROUGH-POND'S INC.

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF
THE FEDERAL TRADE COMMISSION ACT

Docket C-602. Consent Order, Sept. 25, 1963—Modifying Order, Nov. 25, 1985

The Federal Trade Commission has modified a 1963 consent order issued against the New York City-based manufacturer and marketer of Vaseline petroleum jelly (63 F.T.C. 927). The modified order deletes provisions prohibiting the company from claiming that Vaseline provides a protective barrier to the skin and is effective for the relief of itching, and allows respondent to make limited claims about the product's beneficial effects, provided respondent has competent and reliable scientific evidence to support its claims. These modifications were granted based on reports from the Food and Drug Administration's over-the-counter drug review program. The modified order also allows respondent to compare Vaseline's effectiveness to that of other products, provided competent and reliable scientific evidence is available.

ORDER REOPENING THE PROCEEDING AND
MODIFYING CEASE AND DESIST ORDER

On April 11, 1985, Chesebrough-Pond's Inc. ("Petitioner") filed a request to reopen and to set aside or modify the consent order entered against it by the Commission on September 25, 1963, in Docket No. C-602 (63 F.T.C. 927). The order prohibits Petitioner from making certain usage and effectiveness claims with respect to the advertising of its over-the-counter drug product, "Vaseline" petroleum jelly.¹ The request to reopen and to set aside or modify the consent order was placed on the public record on April 23, 1985, and a press release regarding the request was issued on the same date. The public comment period ended May 23, 1985. Comments were filed by four individual consumers during that period.² The deadline to rule on Petitioner's request was subsequently extended to November 25, 1985.

The order requires Petitioner to cease making a variety of advertising claims with respect to the therapeutic and protective qualities of "Vaseline." The order contains twelve specific prohibitions relating

¹ "Vaseline" petroleum jelly is the product trade name. It is composed mostly of petrolatum, a purified mixture of semi-solid hydrocarbons derived from petroleum. "Vaseline" contains both white petrolatum and yellow petrolatum, which are essentially identical except for color. The terms "Vaseline", "petrolatum", and "product" are used interchangeably throughout this Decision and Order.

² All four commenters expressed that they have used the product for a number of years and have used it to treat minor burns, cuts, and scratches. Two of the commenters stated that they have used the product as a skin softener. One commenter stated that she has used the product on heat rash, as a preventative for diaper rash, and as a deodorant.

to the following types of claims: infections; skin injuries; a protective barrier; diaper rash; cradle cap; advertising slogans; and escape of tissue fluids.

Petitioner sets forth several arguments as justification for its request. First, it asserts that the Food and Drug Administration's (F.D.A.) over-the-counter drug review program has resulted in changed conditions of law and fact that require the order to be set aside or modified to allow those claims which the F.D.A. review program has substantiated. Second, Petitioner asserts that the order is no longer necessary or appropriate to protect consumers and thus should be set aside in its entirety. Finally, Petitioner asserts that the order should be modified to allow it to make any claim for which there is a reasonable basis.

Since the order's entry some twenty-two years ago, the F.D.A. has undertaken a comprehensive review evaluating the safety and effectiveness of the ingredients in over-the-counter drug products such as "Vaseline". Petitioner submits that several F.D.A. Advisory Review Panels have concluded that petrolatum, the principal ingredient in "Vaseline", is effective for claims prohibited by the order. It is Petitioner's position that the findings and conclusions of these panels now provide adequate substantiation for these prohibited claims which justifies setting aside these prohibitions.

As Petitioner points out, the Commission has allowed the conclusions and recommendations of F.D.A. Advisory Review Panels to demonstrate adequate substantiation for performance claims. In prior decisions, the Commission has held that F.D.A. final monographs³ may be relied upon to substantiate performance claims for over-the-counter drug products, *AHC Pharmacal, Inc.*, 101 F.T.C. 40 (1983); *Thompson Medical Co.*, Docket No. 9149, Slip. op. at 80 (November 23, 1984) [104 F.T.C. at 826]. In addition, the Commission has held that F.D.A. preliminary documents subject to revision, such as tentative final monographs, are also presumptively reliable for substantiation. *American Home Products Corp.*, 98 F.T.C. 136 (1981) at 368. We have reviewed the monographs relied on by Petitioner and compared the findings and conclusions of the various panels reviewing petrolatum with the claims prohibited by the order. Based on this review we conclude that the findings and conclusions do substantiate two of the claims now prohibited by the order.

Paragraph 1.(b) of the order prohibits Petitioner from making any claim that "Vaseline" provides a protective barrier to the skin unless such claim is limited to the water repellant effect of a continuous film

³ A monograph sets out the findings and conclusions of the F.D.A. Advisory Review Panels. A monograph can be published as a proposed monograph, a tentative final monograph, and a final monograph depending on the stage of the review process.

of the product. The Skin Protectant Panel conclusively states that petrolatum is a skin protectant. It defines a skin protectant as "any agent that isolates the exposed skin or mucous membrane surface from any harmful or annoying stimuli." 43 FR. 34630 (August 4, 1978). The panel further concludes that "protectants act as mechanical barriers that physically alter the superficial wound environment by excluding air, removing wetness, prevent drying and protecting from intertriginous contact." *Id.* In addition, the F.D.A. has published a tentative final monograph for skin protectants which determined that petrolatum "protects injured or exposed skin or mucous membrane surfaces from harmful or annoying stimuli." 48 FR. 6823 (February 15, 1983). We conclude that these findings and conclusions establish that petrolatum provides a protective barrier to skin without limitation to its water repellant effect, and accordingly decide that this paragraph of the order shall be set aside.

Paragraph 1.(c)(5) of the order specifically prohibits Petitioner from claiming that "Vaseline" will have any effect upon itching unless limited to itching from sunburned, dry, chapped, chafed or scraped skin or other minor skin injuries. The Skin Protectant Panel did find that petrolatum is effective for the treatment of itching associated with dry skin conditions. This panel found the product useful as a soothing topical lubricant. The Hemorrhoidal Panel went even further. It concluded that petrolatum is effective for (1) relief of itching or other anorectal discomfort; (2) for the temporary relief of anorectal itching; (3) for the temporary relief of itching associated with hemorrhoids and other anorectal disorders; and (4) in forming a protective coating over inflamed tissue that can relieve itching. 45 FR. 35628 (May 27, 1980). We conclude that these findings and conclusions substantiate that petrolatum relieves itching other than itching associated with sunburned, dry, chapped, chafed or scraped skin, and accordingly decide that the limitation on itching claims is inappropriate and shall set aside this paragraph of the order.

The findings and conclusions of the F.D.A. Advisory Review Panels fall short of providing adequate substantiation justifying the setting aside of the proscribed claims relating to burns (1.(c)(1)), scrapes (1.(c)(1)), scratches (1.(c)(1)), abrasions (1.(c)(1)), scabbed skin (1.(c)(2)), diaper rash (1.(c)(3)), cradle cap (1.(c)(4)), and escape of tissue fluids (1.(g)). These same findings and conclusions do not address other claims that are proscribed by the order, namely claims relating to the prevention of infection (1.(a)), treatment of cuts or open wounds, (1.(d)), or advertising slogans (1.(e)). Since the findings and conclusions of the F.D.A. panels are the only evidence Petitioner has submitted to support its request, there is nothing before us to support any action

with respect to provisions 1.(a), 1.(d) and 1.(e). Consequently, these provisions of the order will remain unchanged.

Petitioner next argues that the order is no longer necessary or appropriate to protect consumers. In essence, Petitioner argues that most of the proscribed claims have been addressed by the F.D.A. Advisory Review Panels and their findings and conclusions are in conflict with a number of the provisions of the order. In addition, Petitioner contends that combined with the ongoing F.D.A. review of over-the-counter drugs, the age of the order renders it obsolete.

The Federal Trade Commission Act, 15 U.S.C. 45(b) requires that an order be modified or set aside upon a satisfactory showing that changed conditions of law or fact requires such modification or setting aside. The Commission's rules implementing this statutory mandate amplify on this by stating that an order should be set aside or modified if "the public interest so requires." Rule 2.51(b) Commission's Rules of Practice, 16 C.F.R. 2.51. When an order no longer serves any useful purpose and impedes truthful advertising, it is clear under the statute and the rules that it should be set aside. However, where the provisions of an order are not inconsistent with the F.D.A. and its advisory review panels, such an order retains its usefulness irrespective of its age. Other than the provisions of the order we have decided should be set aside, several provisions, namely those relating to burns (1.(c)(1)), scrapes (1.(c)(1)), scratches (1.(c)(1)), abrasions (1.(c)(1)), scabbed skin (1.(c)(2)), diaper rash (1.(c)(3)), cradle cap (1.(c)(4)), and escape of tissue fluids (1.(g)), are not wholly consistent with the findings and conclusions of the advisory review panels. While these findings and conclusions do not justify setting aside the proscribed claims, they do justify some claims of a similar nature which the current order prohibits because of the absolute nature of these prohibitions. For example, the panels found that petrolatum is safe and effective in the temporary relief of minor skin irritations; soothes minor skin irritations; gives comfort to minor skin irritations; affords temporary protection of minor skin injuries; aids in the prevention of diaper rash; affords protection against wetness that causes diaper rash; softens skin; and prevents water loss from stratum corneum. Accordingly, we have concluded that these claims will be subjected to a reasonable basis standard, as requested by Petitioner as alternative relief, as being in the public interest.

This is appropriate relief under Commission policy. The Commission has long held that an advertiser is not required to demonstrate the absolute truth of a particular claim, only a reasonable basis for making it. Bureau of Consumer Protection, F.T.C. *Advertising Substantiation Program, Analysis of Public Comments and Recommended*

in *AHC Pharmacal, Inc.*, *supra*, where we modified an order to permit AHC to rely on F.D.A. panel recommendations as a reasonable basis for substantiating superiority claims. *See, also, Thompson Medical Co.*, *supra*, and *Ogilvy & Mather International Corp.*, 101 F.T.C. 1 (1983).

As noted above, the findings and conclusions of the F.D.A. Advisory Review Panels do justify the use of some claims of a similar nature to those prohibited under the order, namely qualified claims with respect to burns, scrapes, scratches, abrasions, scabbed skin, diaper rash, cradle cap and escape of tissue fluids. Petitioner does possess a reasonable basis for making these similar, albeit qualified claims but can not do so under the current order. Because of this dichotomy, we will modify the order to allow any such claims that can be supported by a reasonable basis consisting of competent and reliable scientific evidence. *See e.g., Sterling Drug, Inc.*, 101 F.T.C. 375 (1983). Although Petitioner has only presented the findings and conclusions of the various F.D.A. panels in support of its request, we do recognize that competent and reliable evidence consisting of tests, analyses, research, studies or other materials based on the expertise of professionals in the relevant area may also provide a reasonable basis to substantiate some of the claims in issue here. Consequently, either the findings and conclusions of the F.D.A. panels or competent and reliable scientific evidence may be used by Petitioner as a reasonable basis to substantiate such advertising claims, if such evidence does in fact support such claims. In addition, although it is not clear that the advisory review panels addressed this issue, we will also accord the comparative soothing and softening claims similar treatment in accord with our policy to encourage comparative claims where justified.

Because of the nature of the modifications granted hereby, it has been necessary to restructure the order. All reference to the two previously prohibited claims which we have decided to set aside will be deleted from the modified order. Part I of the modified order prohibits those claims for which no evidence justifying their vacation has been presented and will remain unchanged from the original order. Part II of the modified order prohibits the use of certain other claims unless substantiated by competent and reliable scientific evidence establishing a reasonable basis or which are supported by the findings and conclusions of the various F.D.A. Advisory Review Panels. The final sentence in Part II of the modified order is intended to clarify the fact that current versions of the F.D.A. Advisory Review Panels' findings and conclusions may be used as a reasonable basis for substantiating claims, unless and until such findings and conclusions are modified. Part III of the modified order prohibits the dissemination of

advertising of any representations or claims not allowed under the modified order.

It is therefore ordered, That the proceeding is hereby reopened and the Decision and Order issued September 25, 1963 in Docket No. C-602 is hereby modified to read as follows:

ORDER

I.

It is ordered, That respondent Chesebrough-Pond's Inc., a corporation, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of "Vaseline" petroleum jelly (White Petrolatum, U.S.P. or Yellow Petrolatum, N.F.), or any other preparation of similar composition or possessing substantially similar properties, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing in any manner, directly or indirectly:

- (a) That respondent's product is of value in preventing infection;
- (b) That respondent's product is of any benefit in the treatment of cuts or open wounds; or
- (c) That respondent's product is a substitute for a "First Aid Kit in a Jar" unless such slogan is used in direct connection with or in close proximity to illustrations or descriptions of the unprohibited first aid uses of the product.

II.

It is further ordered, That respondent, its successors and assigns, and its officers, representatives, agents and employees, directly or through any corporate or other device, in connection with the advertising, offering for sale, sale or distribution of "Vaseline" petroleum jelly (White Petrolatum, U.S.P. or Yellow Petrolatum, N.F.), or any other preparation of similar composition or possessing substantially similar properties, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing in any manner, directly or indirectly:

- (a) That respondent's product is of any benefit in curing, or in promoting or accelerating the healing of, burns, scrapes, scratches, abrasions, scabbed skin, diaper rash or cradle cap;

(b) That respondent's product will soothe and soften the skin better than competitors' products having substantially similar properties; or

(c) That respondent's product prevents the escape of tissue fluids from the skin;

Unless at the time that such representation is made respondent possesses and relies upon a reasonable basis consisting of reliable and competent evidence that substantiates the representation. Reliable and competent evidence establishing a reasonable basis for such representation shall consist of:

(a) Tests, analyses, research, studies or any other materials based on the expertise of professionals in the relevant area, provided such tests, analyses, research, studies or other materials are 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; or

(b) The findings and conclusions of the Food and Drug Administration (F.D.A.) or an F.D.A. Advisory Review Panel as published in the Federal Register to describe such findings and conclusions, unless and until any such findings or conclusions are modified.

Nothing herein shall be deemed to create or support an inference that evidence in existence at the time this Modified Order is issued does not constitute a reasonable basis for any representation subject to this paragraph.

Interlocutory Order

106 F.T.C.

IN THE MATTER OF
THE KROGER COMPANY

Docket 9102. Interlocutory Order, Nov. 26, 1985.

ORDER REVOKING *IN CAMERA* TREATMENT AND
PLACING DOCUMENTS ON THE PUBLIC RECORD

During the administrative hearing in this matter, certain documents and testimony received *in camera* treatment. On July 10, 1979, the Kroger Company filed a motion to revoke the *in camera* designation and to place on the public record the entire Initial Decision issued by the Administrative Law Judge and all the evidence and argument it offered during the proceeding. The Commission, in entering its final decision and order, 98 F.T.C. 639 (1981), *modified*, 100 F.T.C. 573 (1982), did not address respondent's pending motion that the *in camera* status of these materials be revoked. Respondent now asks the Commission to withdraw from *in camera* status and place on the public record certain internal documents admitted into evidence in the proceeding.

The exhibits accorded *in camera* treatment consist of documents provided by respondent and internal agency materials. Kroger consents to the public disclosure of its own materials.¹ The agency records were compiled in investigations that closed more than three years ago. We have determined that most of the agency materials made part of the *in camera* record no longer warrant confidential treatment and should be made part of the public record. Several exhibits, however, reflect the predecisional views of individual Commissioners and advice from the General Counsel. These sensitive deliberative materials are protected from public disclosure, *see NLRB v. Sears, Roebuck & Co.*, 421 U.S. 132 (1972), and the Commission believes there is good cause to preserve their *in camera* status. Accordingly, the Commission declines to revoke the *in camera* status of these documents.²

It is ordered, That the *in camera* treatment of exhibits received in evidence and of other documents in the record relating to those exhibits be eliminated in accordance with this order.

¹ Letter from N. Diamond, counsel for Kroger, dated May 14, 1985.

² In its letter dated May 14, 1985, Kroger's counsel advised that respondent was specifically interested in five exhibits, RX221, RX222, RX240, RX241 and RX1003. Portions of RX222 and RX1003 set forth the predecisional views of individual Commissioners and will remain nonpublic. The remaining portions of these exhibits as well as RX221, RX240 and RX241 will be publicly disclosed.