

IN THE MATTER OF
AMERICAN HOME PRODUCTS CORPORATION

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

Docket 8641. Order, June 9, 1970—Modifying Order, May 22, 1986

The Federal Trade Commission has modified a 1970 order with American Home Products Corp. (77 F.T.C. 726) by removing some restrictions on the company's advertising for Preparation H. The modified order allows respondent to use in its advertising any claims that the Food and Drug Administration has tentatively approved.

ORDER REOPENING THE PROCEEDING AND
MODIFYING CEASE AND DESIST ORDER

On January 21, 1986, American Home Products Corporation (Petitioner) filed a petition pursuant to Rule 2.51 of the Commission's Rules of Practice, 16 C.F.R. 2.51, and Paragraph III of the order in question to reopen the proceeding and modify the final cease and desist order entered against it by the Commission on June 9, 1970, in Docket No. 8641 (77 F.T.C. 726).

The final order in this matter was the product of extended litigation concerning therapeutic advertising claims for Preparation H Ointment or Suppositories. The order effectively proscribes all therapeutic advertising claims for Preparation H Ointment or Suppositories, or any other non-prescription drug product for the treatment or relief of hemorrhoids or any of its symptoms, except for three specifically enumerated claims. The three claims permitted under the order are (1) that the use of the product will help reduce swelling of hemorrhoidal tissue caused by edema, infection, or inflammation; (2) that the use of the product will help reduce swelling of hemorrhoidal tissue by lubricating the affected area; and (3) that use of the product will afford temporary relief of pain and itching of hemorrhoidal tissue in many cases. The order concludes with a proviso (Part III) that if the Food and Drug Administration (FDA) should approve for such products any other claims as permissible in labeling, respondent may petition for a modification of the order on that ground.

Subsequently, the Food and Drug Administration (FDA) undertook a comprehensive review of the safety and effectiveness of over-the-counter (OTC) drug products under the "Drug Amendments of 1962" to the "Federal Food, Drug and Cosmetic Act." As part of this review, the FDA appointed panels of independent experts in medicine and

pharmacology to review the available literature and data and evaluate the safety and effectiveness of ingredients used in OTC products. After completing their evaluations the panels reported their findings and conclusions concerning the classes of OTC products evaluated and recommended appropriate labeling claims for each of the classes of OTC products reviewed. The labeling recommendations are incorporated into proposed monographs which, after a three step procedure designed to determine appropriate revisions, if any, will be promulgated as final monographs or rules which will govern the labeling claims of OTC products. One such panel reviewed and evaluated OTC hemorrhoidal (anorectal) drug ingredients. Its findings and conclusions and recommendations and a proposed monograph for OTC anorectal drugs were published in the Federal Register on May 27, 1980. (45 FR 35575.)

It is this proposed monograph that forms the basis for Petitioner's requested modification. Under this proposed monograph OTC anorectal drug ingredients are classified into several groups on the basis of their pharmacologic action, such as local anesthetics, vasoconstrictors, protectants, and counterirritants. An OTC anorectal drug can be classified as a protectant if, for example, it contains cocoa butter 50 percent or greater per dosage unit or it contains white petrolatum USP 50 percent or greater per dosage unit. An OTC anorectal drug meeting these percentage requirements would be entitled under the proposed monograph to be labeled with certain specific protectant claims.

Petitioner claims that Preparation H Ointment contains 72.8% petrolatum and that Preparation H Suppositories contains 79.5% cocoa butter thereby qualifying those products as protectants under the proposed monograph. As a consequence, Petitioner argues that it should be entitled to make as labeling claims those claims permitted by the FDA under the proposed monograph. However, the Commission's final order prohibits the use of a number of these claims and Petitioner asserts this prohibition places it at a competitive disadvantage with OTC anorectal protectant drug products marketed by others. As a consequence, Petitioner has requested that the final order be modified to allow it to make all advertising claims it is allowed by the proposed monograph to use in its labeling for Preparation H Ointment or Suppositories.

We agree. In prior decisions, we have held that proposed FDA monographs may be relied on as a reasonable basis for performance claims. *AHC Pharmacal, Inc.*, 101 F.T.C. 40, 43 (1983); *Thompson Medical Co., Inc.*, 104 F.T.C. 648, 826 (1984); *Chesebrough-Pond's Inc.*, Docket No. C-602 (November 25, 1985) [106 F.T.C. 567]. Such relief is particularly appropriate where, as here, the advertising claims would

be dependent on their acceptability as labeling claims. Based on the foregoing, we conclude that Petitioner has made the requisite showing for a reopening of the proceeding and a modification of the order under Rule 2.51 and Paragraph III of the final order. Respondent has asked that Part III of the final order. Respondent has asked that Part III of the order be modified to make clear that it may make claims in advertising that the FDA has allowed in labeling.

It is therefore ordered, That the proceeding is hereby reopened and that Paragraph III of the final order issued June 9, 1970, in Docket No. 8641 be, and it hereby is modified to read as follows:

III. This order is not intended to nor does it prohibit respondent from making any representations for non-prescription drug preparations for the treatment or relief of hemorrhoids or any of their symptoms which the Food and Drug Administration has determined, in the course of its over-the-counter drug review, relate to conditions for which the drug preparation is generally recognized as safe and effective and not misbranded. In the event that respondent at any time in the future markets any non-prescription drug preparation for the treatment or relief of hemorrhoids or any of its symptoms for which it desires to make any of the representations now prohibited under Paragraph I of the order, it may petition the Commission for a modification of the order. Such petition shall be accompanied by a showing that the representation is not false or misleading within the meaning of the Federal Trade Commission Act.

Commissioners Oliver and Strenio did not participate.

Complaint

107 F.T.C.

IN THE MATTER OF

ALBERT SCHNEIDER

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF
THE FEDERAL TRADE COMMISSION ACT*Docket C-3184. Complaint, May 23, 1986—Decision, May 23, 1986*

This consent order requires, among other things, a corporate officer of Cellular Capital Corporation to cease making misrepresentations to induce consumers to purchase application preparation services for the cellular license lottery operated by the Federal Communications Commission. Additionally, respondent is required to make two affirmative disclosures to prospective applicants: (1) that the purchase of a cellular application is a high-risk investment, and (2) that an operating cellular system is unlikely to return any profits to its owners in the first three years of operation.

*Appearances*For the Commission: *David C. Fix.*For the respondents: *Pro se.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Albert Schneider, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent is an individual who has his business address at The Eighth Floor, One Erieview Plaza, Cleveland, Ohio.

PAR. 2. Respondent, individually and in cooperation with others, is now and for some time last past has been engaged in the offering for sale of application preparation and filing services in connection with the Non-Wireline Cellular Telephone Lottery (the "lottery") operated by the Federal Communications Commission ("FCC"). The lottery is a random drawing used by the FCC to select the non-wireline applicant in each geographical market who is to be awarded a license to construct and operate a new type of mobile telephone system called a cellular system. From 1981 until the institution of the lottery in 1984, such licenses were awarded on the basis of public hearings.