FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket 8918]

American Home Products Corp., et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Modifying order.

SUMMARY: The Federal Trade Commission has modified its Final Order In the Matter of American Home Products Corporation, et al., issued on Sept. 9, 1981 (46 FR 51900), in accordance with a decision rendered by the Court of Appeals for the Third Circuit on Dec. 3, 1982. The modification deletes the provision that had prohibited the maker of Anacin and Arthritis Pain Formula from making any non-comparative effectiveness or side effects claims for any over-the-counter drug product unless the company possessed a reasonable basis when making such claims.

DATES: Final Order issued September 9, 1981. Modifying Order issued April 6, 1983.

FOR FURTHER INFORMATION CONTACT: FTC/GE, Ernest J. Isenstadt Washington, D.C. 20580. (202) 523-3463.

SUPPLEMENTARY INFORMATION: In the Matter of American Home Products Corporation, a corporation, and Clyne Maxon, Inc., a corporation. Codification appearing at 46 FR 51[illegible] remains unchanged.

List of Subjects in 16 CFR Part 13

Advertising, Aspirin

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

The Modified Order to Cease and Desist is as follows:

Before Federal Trade Commission

Commissioners:
James C. Miller III, Chairman
David A. Clanton
Michael Pertschuk
Patricia P. Bailey
George W. Douglas

In the matter of American Home Products Corporation, a corporation, and Clyne Maxon, Inc., a corporation. Docket No. 8918.

Modified Order to Cease and Desist

Respondent American Home Products Corporation having filed in the United States Court of Appeals for the Third Circuit a petition for review of the Commission's order issued herein on September 9, 1981, and the Court having on December 3, 1982, rendered its decision modifying the Commission's order and, as so modified, affirming the order; and the time for filing a petition for certiorari having expired and no petition having been filed;

Now, Therefore, it is hereby ordered that, pursuant to 15 U.S.C. 45(l), the aforesaid order to cease and desist be, and it hereby is, modified in accordance with the decision and judgment of the Court of Appeals to read:

Order

I

It is ordered that respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that a claim concerning the superior effectiveness or superior freedom from side effects of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness or comparative freedom from side effects of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts: (1) That the drug will have the comparative effectiveness or freedom from side effects that it is represented to have, and (2) that such comparative effectiveness or freedom from side effects is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below:

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication; or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be [illegible] conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

1. The subjects must be selected by a method that:

a. Provides adequate assurance that they are suitable for the purposes of the investigation, and diagnostic criteria of the condition to be treated (if any);

b. Assigns the subjects to the test groups in such a way as to minimize bias; and

c. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than the test drugs.

2. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

3. The plan or protocol for the investigations and the report of the results shall include the following:

a. Clear statement of the objective of the investigation;

b. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of subject and observer;

c. A comparison of the results of treatments or diagnosis with a control in such a form as to permit quantitative evaluation of the precise nature of the [illegible] claimed and an explanation given of the methods use

to minimize bias on the part of the observers and the analysts of the data.

d. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

B. Making any representation, directly or by implication, of superior effectiveness or freedom from side effects of such product unless:

1. The superior effectiveness or superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, or

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the comparative efficacy or side effects claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

II

It is further ordered that respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any other non-prescription drug product, in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that such product contains any unusual or special ingredient when such ingredient is commonly used in other non-prescription drug products intended for the same use or uses as the product advertised by respondent.

B. Making any use representation that such product has more of an active ingredient than any class of competing products.

C. Misrepresenting in any manner any test, study or survey or any of the results thereof, concerning the comparative effectiveness or freedom from side effects of such product.

III

It is further ordered that respondent American Home Products Corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," "Arthritis Pain Formula," or any products in which "Anacin" or "Arthritis Pain Formula" is used in the name, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from failing to disclose clearly and conspicuously that the analgesic ingredient in such product is aspirin, if such is the case and when the advertisement makes any performance claim for the product.

IV

It is further ordered that respondent American Home Products Corporation, a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Anacin," in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, that Anacin relieves nervousness, tension, anxiety or depression or will enable persons to cope with the ordinary stresses of everyday life.

V

It is further ordered that respondent the C.T. Clyne Company, Inc., a corporation, its successors and assigns and respondent's officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising of "Arthritis Pain Formula" or any other non-prescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

A. Making any representation, directly or by implication, that such product contains any unusual or special ingredient when respondent knows or has reason to know that such ingredient is commonly used in other nonprescription internal analgesic products intended for the same use or uses as the product advertised by respondent.

B. Making any representation, directly or by implication, of superior freedom from side effects of such product, unless:

1. Respondent knows or has reason to believe that the superior freedom from side effects so represented has been established according to the terms set forth in paragraph I.A. of this Order, or

2. Each advertisement containing such representation contains a clear and conspicuous disclosure that there is a substantial question about the validity of the claim, or that the claim has not been proven. Such a disclosure may consist of a clear and conspicuous statement that the claim is "open to substantial question," or that the claim "has not been proven." If other language is used by respondent to convey the required message, respondent shall maintain, for a period of three (3) years after the dissemination of any advertisement containing such disclosure, records sufficient to demonstrate that the required message is effectively conveyed to the advertisement's intended audience.

VI

It is further ordered that respondents American Home Products Corporation and the C.T. Clyne Company, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change in their respective corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in their respective corporation which may affect compliance obligations under this Order.

It is further ordered that the respondents herein shall within sixty (60) days after service of this Order upon them, and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which they have complied or intend to comply with this Order.

By the Commission.

Issued: April 8, 1983.

Emily H. Rock,

Secretary.

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