

Modifying Order

103 F.T.C.

## IN THE MATTER OF

## AMERICAN HOME PRODUCTS CORPORATION

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF THE  
FEDERAL TRADE COMMISSION ACT*Docket 8918. Final Order, September 9, 1981—Modifying Order June 7, 1984*

This order reopens the proceeding and modifies the Commission's order issued on September 9, 1981, (98 F.T.C. 136), *modified* April 8, 1983 (101 F.T.C. 698), *modified further* Feb. 7, 1984 (103 F.T.C. 57) so that its basic provisions are in parity with the Commission order in *Bristol-Myers Company*, [102 F.T.C. 21 (1983)] and *Sterling Drug, Inc.*, [102 F.T.C. 395 (1983)]. Under the modified order, the company must have a reasonable basis consisting of reliable scientific evidence for all therapeutic performance or safety claims. The previous order covered such claims only if they compared one product to another.

ORDER REOPENING THE PROCEEDING AND MODIFYING  
CEASE AND DESIST ORDER

Respondent American Home Products Corporation in a "renewed request" filed on January 27, 1984, petitioned to reopen these proceedings and modify the Order. This request was placed on the public record for comment, with no comments filed.

On April 5, 1984, pursuant to discussion with Commission staff, respondent filed a proposed Order which was agreed to by staff. This proposed Order suggests changes in the Modified Order to Cease and Desist of April 8, 1983, as modified by Order of February 7, 1984. The proposed Order adds a new paragraph 1(A)(4) and substitutes new language for paragraphs 1(B), III, and IV. With these modifications the basic provisions of this Order will be in general parity with the Commission's Orders in *Bristol-Myers Company*, Docket No. 8917 [102 F.T.C. 21 (1983)] and *Sterling Drug, Inc.*, Docket No. 8919. [102 F.T.C. 395 (1983)]

The Commission being of the opinion that the public interest would be served by such reopening of the proceedings;

*Now, therefore, it is ordered*, That the proceedings in Docket No. 8918 be, and they hereby are, reopened; and

*It is further ordered*, That the Order in Docket No. 8918 be substituted as to respondent American Home Products Corporation by a modified Order as follows:

## 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 conducted on at least two conditions or diseases for which the drug is effective. The clinical investigation 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 include the following:

- a. 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 fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used 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.

4. A test or investigation which is not conducted in accordance with these procedures may be used to establish a claim only if respondent can show that, notwithstanding the failure to satisfy these procedures, the test or investigation would still be generally accepted by the relevant scientific community as sufficient to establish the truth of the claim.

B. Making any therapeutic performance or freedom from side effects claim for such product unless respondent possesses a reasonable basis for making that claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth in Order Paragraph IA shall be deemed to constitute a reasonable basis for a claim.

## 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," "Ar-

thritis 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 false 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 its 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," or "Arthritis Pain Formula," or any other nonprescription internal analgesic in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of another product if that product also contains aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin. This provision shall not become effective until Orders in Dockets 8917 and 8919 have become final. [102 F.T.C. 21, 395 (1983)]

### IV

If the Commission makes any changes in the Orders entered in Dockets 8917 and 8919, respondent American Home Products Corporation may petition the Commission to make similar changes in the corresponding provisions, if any, of this Order. This paragraph shall not be deemed to limit respondent's right to petition for modification pursuant to any applicable statute or regulation.

## V

*It is further ordered,* That respondent American Home Products Corporation, shall notify the Commission at least thirty (30) days prior to any proposed change in the respondent such as dissolution, assignment or sale resulting in the emergency of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations under this Order.

*It is further ordered,* That the respondent herein shall within sixty (60) days after service of this Order, 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 it has complied or intends to comply with this Order.

## IN THE MATTER OF

## E.I. DUPONT DE NEMOURS &amp; COMPANY

*Docket 9108. Interlocutory Order, June 12, 1984*

ORDER EXTENDING *IN CAMERA* TREATMENT

By Order of the Commission, dated January 21, 1981, certain exhibits in the record of Docket No. 9108 were accorded *in camera* status for a three year period. The Order has now expired and respondent, E.I. DuPont de Nemours and Company ("DuPont") has moved the Commission, pursuant to a January 20, 1984 motion, for return of all *in camera* exhibits in Docket No. 9108 which are part of the record in that proceeding. In the alternative, respondent has asked the Commission for an extension of *in camera* treatment for certain exhibits indefinitely, or at least for three additional years with a provision for further *in camera* treatment upon a showing of good cause therefor.

After consideration of DuPont's motion, the Commission denies respondent's request for return of all *in camera* exhibits in the record of the *DuPont* proceeding. The Federal Trade Commission Act ("FTC Act") and the Commission's Rules of Practice allow for return of documentary materials submitted to the Commission *except* those materials offered and received in evidence in a Commission proceeding.<sup>1</sup> The Commission's Rules reflect its desire to maintain a full and accurate record of Commission deliberative considerations, as well as to preserve records of Commission activities which have legitimate informational value to its law enforcement functions.<sup>2</sup>

The Commission also denies respondent's request for indefinite *in camera* treatment for certain specified exhibits. That request, seeking *in camera* protection in perpetuity, fails to meet the Commission standard for *in camera* treatment, *i.e.*, disclosure of documents must result in "clearly defined serious injury to the person or corporation

<sup>1</sup> Specifically, under Section 21(b)(5) of the FTC Act, when materials are produced in the course of an investigation and any proceeding arising out of the investigation is complete,

then the custodian shall, upon written request of the person who produced the material, return to the person any such material *which has not been received into the record* of any such proceeding.

(emphasis added). See also Commission rule 4.12(a) which states:

Any person who has submitted documentary material to the Commission . . . may obtain, on request, the return of material submitted to the Commission *which has not been received into evidence*. . . .

Because the FTC Act and the Commission's Rules do not provide for the return of the "originals" of the documents in question it is unnecessary to determine whether Dupont has met the "extraordinary circumstances" showing required by Rule 4.12(b) for the return of copies of documents made by the Commission.

<sup>2</sup> The Commission is required by Federal law to preserve records received by the agency in connection with the transaction of public business "as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the Government or because of the informational value of data in them." Federal Records Act, 44 U.S.C. 3301; see also Commission's Rules of Practice, Rule 4.12(c).