FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket 8919]

Sterling Drug Inc., et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: This order requires a New York City manufacturer of nonprescription drug products, among other things, to cease advertising that "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol" or any other nonprescription internal analgesic has been proven to be superior to other pain relieving products, unless such claim has been substantiated by two well-controlled clinical tests. The company must have reasonable basis to support any claim that its pain relievers are therapeutically superior to others, as well as competent and reliable scientific evidence for representations that the comparative pharmaceutical qualities of its analgesics have been proven or established. The order further prohibits the manufacturer from advertising that its products contain any unusual or special ingredient, when in fact such ingredient is commonly used in similar products; or from making any claim which misrepresents the product's analgesic ingredient.

DATES: Complaint issued Feb. 23, 1973. Final Order issued July 5, 1983.[1]

FOR FURTHER INFORMATION CONTACT: FTC/PC, Joel Brewer, Washington, D.C. 20580. (202) 633–6947.

[1] Copies of the Complaint, Initial Decision and the Opinion of the Commission filed with the original documents.

SUPPLEMENTARY INFORMATION: In the Matter of Sterling Drug Inc., a corporation, Dancer-Fitzgerald-Sample, Inc., a corporation, and Lois Holland Callaway, Inc., a corporation. The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Advertising Falsely or Misleadingly: § 13.10 Advertising Falsely or misleadingly; § 13.20 Comparative data or merits; § 13.170 Qualities or properties of product or service; § 13.175 Quality of product or service; § 13.205 Scientific or other relevant facts; § 13.280 Unique nature or advantages. Subpart—Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements. Subpart—Misrepresenting Oneself and Goods—Goods: § 13.1575 Comparative data or merits; § 13.1715 Quality; § 13.1740 Scientific or other relevant facts; § 13.1770 Unique nature or advantages. Subpart—Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1855 Identity; § 13.1895 Scientific or other relevant facts.

List of Subjects in 16 CFR Part 13

Advertising, Analgesics, Trade practices.

(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, 52)

The Final Order, including further order requiring report of compliance therewith, is as follows:

In the Matter of Sterling Drug Inc., a corporation, Dancer-Fitzgerald-Sample, Inc., a corporation, and Lois Holland Callaway, Inc., a corporation; Docket No. 8919.

Final Order

The matter has been heard by the Commission upon the appeal of counsel for respondent Sterling Drug, Inc., and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for reasons stated in the accompanying Opinion, has granted a portion of respondent's appeal and denied that of complaint counsel. Therefore

It is ordered that the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered that the following Order to Cease and Desist be entered.

Order

I

It is ordered that Sterling Drug, Inc., 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 "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or other nonprescription internal analgesic product, 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 a claim concerning the superior effectiveness 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 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 that it is represented to have, and (2) that such comparative effectiveness 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 investigations shall be conducted as follows:

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

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

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

3. 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 test drugs.

B. 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.

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

1. A clear statement of the objective of the investigation;

2. 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 the subject and observer;

3. 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;

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

D. 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.

II

It is further ordered that respondent Sterling Drug, Inc., a 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 "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic product, 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 the superior freshness, purity, stability, or speed of disintegration of such product has been established, demonstrated, or proven unless at the time such representation is made, respondent possesses and relies upon competent and reliable scientific

evidence which would permit qualified experts to conclude that the product has the comparative pharmaceutical qualities it is represented to have.

III

It is further ordered that respondent Sterling Drug, Inc., 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 "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol" 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 making any therapeutic performance 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 I shall be deemed to constitute a reasonable basis for a claim.

IV

It is further ordered that respondent Sterling Drug, Inc., 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 "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription drug product in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication that such product contains any unusual, special or unique ingredients or ingredient when such ingredient or ingredients are commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

V

It is further ordered that respondent Sterling Drug, Inc., 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 "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," 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 resondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

VI

It is further ordered that respondent Sterling Drug, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in its corporation which may affect compliance obligations under this Order.

VII

It is further ordered that the respondent herein shall within sixty (60) days after service of this Order upon it 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.

Complaint paragraphs Eight A.2, Eight B, Eight C, Ten B, Twelve, Thirteen, Fourteen, Fifteen A, Seventeen, Twenty-Three, Twenty-Four, and that portion of Twenty-Nine which refers to Seventeen are hereby dismissed.

Issued July 5, 1983.

By the Commission.

Emily H. Rock,

Secretary.

Separate Statement of Commissioner Pertschuk Concurring in Part and Dissenting in Part [1]

For the reasons stated in my separate opinion in *Bristol-Myers* (D. 8917), announced today, I dissent from that portion of the Commission's opinion which reverses the "substantial question" doctrine developed in *American Home Products*, 98 F.T.C. 136 (1981), *aff'd*, 695 F. 2d 681 (3d Cir. 1982). Therefore, I dissent from the Commission's decision to dismiss paragraphs 12 through 14 of the complaint.

I also dissent from the portion of the Commission's opinion which dismisses complaint paragraphs 17 and 29, which allege that Sterling violated Section 5 by making contemporaneous inconsistent claims for its OTC internal analgesic drug products. The Commission dismisses these charges, not because Sterling did not make such claims, but because it sees the basis of the charge as a "new theory of advertising substantiation which would shortcut and be contrary to principles of law set forth in *Pfizer* and its progeny." Slip op. at 50.

I disagree. The inconsistent contemporaneous claims allegation stems directly from the reasonable basis doctrine set out in *Pfizer*. In my view, application of the reasonable basis doctrine to an examination of the claims made by Sterling in this case leads inexorably to the conclusion that Sterling has made unsubstantiated claims in violation of Section 5.

The Commission agrees that Sterling represented that Vanquish was better than aspirin in relieving pain and in avoiding stomach upset (slip op. at 16, 18), and that Cope was superior to any OTC analgesic for the relief of nervous tension headache (slip op. at 20). At the same time it was making those claims, however, Sterling was *also* claiming that Bayer aspirin was just as good as *any* internal analgesic in relieving pain and nervous tension headaches, and avoiding stomach upset. (F. 398–402)

There is simply no way those statements can be reconciled. Sterling's claims that Vanquish and Cope were more effective than aspirin plainly conflict with Sterling's contemporaneous claim that Bayer aspirin was just as effective as any OTC internal analgesic—presumably, including Vanquish and Cope. Both statements can not be true at the same time.

Nevertheless, the Commission declines to find a violation on the ground that a reasonable basis analysis does not determine whether a claim is true, and that therefore it is "theoretically possible that two inconsistent claims can both be substantiated with a reasonable basis." Slip op. at 51.

While it might be theoretically possible for two inconsistent claims to be adequately substantiated, the problem with the Commission's rationale is that it fails to consider whether it is even theoretically possible for each claim made by Sterling in *this*

[1] Statements by Chairman James C. Miller III and Commissioners Patricia P. Bailey and George W. Douglas concerning this order are published in this issue with the Final Order in Bristol-Myers Co., et al. (Dkt. 8917)

case to be adequately substantiated. It appears obvious to me that they cannot. If Sterling has a reasonable basis for a claim that Vanquish provides superior pain relief to aspirin, it cannot have a reasonable basis for a claim that Bayer aspirin relieves pain just as well as all OTC internal analgesics. Conversely, if Sterling has reasonable basis for a claim that aspirin relieves pain just as effectively as all OTC internal analgesics, it cannot have a reasonable basis for a claim that Vanquish relieves pain better than aspirin. Where as advertiser makes an objective and verifiable claim that its product performs better than any other product, adequate substantiation for that claim necessarily precludes the advertiser from having a reasonable basis for a claim that another product works better than, or as well as, the one advertised.

The Commission seems troubled, however, by the application of an "inconsistent contemporaneous claims" theory. It notes the apparent discrepancy between the case where a single advertiser is held liable for making inconsistent claims, and the case where the same claims are made separately by two different advertisers and the Commission finds each adequately substantiated. In fact, such a result would not be anomalous. Indeed, it would be perfectly consistent with the reasonable basis doctrine, which takes into account not only the sufficiency of the evidence on which an advertiser relies but also "the reasonableness of the advertiser's action and his good faith." *National Dynamics Corp.*, 82 F.T.C. 488, 553 (1973). In considering an advertiser's reasonableness, the Commission routinely considers information in the advertiser's possession which might give the advertiser reason to question the evidence relied upon to substantiate a claim. Clearly, an advertiser possessing data which directly contradicts a claim cannot have a reasonable belief in the truth of that claim. On the other hand, if the contradictory evidence exists but the advertiser is unaware of it and would have no reason to know about it, the advertiser would not be precluded from making the claim. In other words, whether or not there is liability depends, at least in part, on the advertiser's knowledge. The application of the inconsistent contemporaneous claims theory simply is one example of the effect of this standard, and accordingly reflects no deviation from the established reasonable basis doctrine.

It is true, as the majority notes, that we could have proceeded to determine which of Sterling's claims was the one that lacked a reasonable basis. But where the conclusion is inescapable, as it is here, that one claim or the other lacked a reasonable basis, it seems like a waste of resources to require both sides to go through the full panoply of evidentiary exchanges just to find out which claim was the one to violate Section 5. Accordingly, I would have sustained the allegations of the complaint with respect to the making of contemporaneous inconsistent claims.

Issued July 5, 1983.

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