

Exhibit D

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Citation: **118 F.T.C. 1030**

*118 F.T.C. 1030; 1994 FTC LEXIS 222, **

In the Matter of SCHERING CORPORATION, a corporation

Docket No. 9232

Federal Trade Commission

118 F.T.C. 1030; 1994 FTC LEXIS 222

October 31, 1994

ORDER:

[*1]

DECISION AND ORDER

The Commission having heretofore issued its complaint charging the respondent named in the caption hereof with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended, and the respondent having been served with a copy of that complaint, together with a notice of contemplated relief; and

The respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(b) of its Rules; and

The Commission having considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record **[*2]** for a period of sixty (60) days, now in further conformity with the procedure prescribed in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

1. Respondent Schering Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at 2000 Galloping Hill Road, in the City of Kenilworth, State of New Jersey.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that respondent Schering Corporation, 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, labeling, packaging, offering for sale, sale or distribution of Fibre Trim or any other food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any misrepresentation, **[*3]** directly or by implication,

- a. about the amount of fiber or any other nutrient or dietary constituent contained in the product, whether described in quantitative or qualitative terms; or

b. that the product is a high, rich, excellent or superior source of fiber or any other nutrient or dietary constituent using those words or words of similar meaning.

PROVIDED that nothing in this Part shall prohibit any representation as to the amount of fiber or any other nutrient or dietary constituent in any product if such representation is specifically permitted in labeling, for the serving size advertised or promoted for such product, by regulations promulgated by the United States Food and Drug Administration (FDA) pursuant to the Nutrition Labeling and Education Act of 1990.

II.

IT IS FURTHER ORDERED that respondent, 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, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission [*4] Act, do forthwith cease and desist from making any representation, directly or by implication,

a. regarding the actual or comparative amount of fiber or the type(s) of fiber, or the actual or comparative amount of any other nutrient or dietary constituent in the product;

b. that the product provides any appetite suppressant, weight loss, weight control, or weight maintenance benefit; or

c. that the product provides any health benefit associated with the intake of fiber, or any other nutrient or dietary constituent

unless, at the time that it makes such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "competent and reliable scientific evidence" shall mean those tests, analyses, research, studies, or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession or science to yield accurate and reliable results.

PROVIDED that, for purposes of any representation covered by subpart (b) of this Part that a fiber supplement or any other food supplement or drug is an effective [*5] appetite suppressant or that it effectuates weight loss, weight control, or weight maintenance through reduction in appetite or any other physiological mechanism, "competent and reliable scientific evidence" shall mean at least two adequate and well-controlled, double-blinded clinical studies that conform to acceptable designs and protocols and are conducted by different persons, independently of each other. Such persons shall be qualified by training and experience to conduct such studies.

PROVIDED further that nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

PROVIDED further that nothing in subparts (a) or (c) of this Part shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

III.

IT IS FURTHER ORDERED that respondent, its successors and assigns, [*6] and its officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, labeling, packaging, offering for sale, sale or distribution of any food, food supplement or drug in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall, whenever a product's fiber content is described in advertising or labeling, directly or by implication, in quantitative or qualitative terms, disclose clearly and prominently in immediate proximity to such description the number of grams of dietary fiber contained per serving of the product.

PROVIDED that if such fiber content descriptor is a term defined by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990, compliance with said regulations will be deemed compliance with Part III of this Order.

IV.

IT IS FURTHER ORDERED that, for three (3) years from the date that the representation is last disseminated, respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

1. All materials that were relied upon to substantiate any [*7] representation covered by this Order; and
2. All test reports, studies, surveys, demonstrations or other evidence in respondent's possession or control, or of which it has knowledge, that contradict, qualify, or call into question such representation or the basis upon which respondent relied for such representation.

V.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in the 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 the corporation which may affect compliance obligations arising out of this Order.

VI.

IT IS FURTHER ORDERED that respondent shall, within thirty (30) days after service of this Order, distribute a copy of this Order to each of its operating divisions responsible for the preparation or placement of advertisements, promotional materials, product labels, or other such sales materials covered by this Order.

VII.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after service of this Order and at such other times as the Commission may require, [*8] file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied or intends to comply with this Order.

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