

IN THE MATTER OF

SCHERING CORPORATION

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9232. Complaint, Sept. 22, 1989--Decision, Oct. 31, 1994

This consent order prohibits, among other things, a New Jersey manufacturer of the diet product, Fibre Trim, from claiming that any food, food supplement, or drug product provides any appetite suppressant, weight loss, weight control, or weight maintenance benefit without possessing and relying upon competent and reliable scientific evidence to substantiate the claim.

Appearances

For the Commission: *Theodore H. Hoppock and Susan Cohn.*

For the respondent: *Joni Lupovitz, Amy E. Hancock, Albert W. Shay, James H. Sneed and Paul J. Pantano, McDermott, Will & Emery, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Schering Corporation ("respondent"), a corporation, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Schering Corporation is a New Jersey corporation, with its office and principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey.

PAR. 2. Respondent has advertised, offered for sale, sold and distributed Fibre Trim to the public as a high fiber supplement, and a weight loss and weight control aid.

PAR. 3. For the purposes of Section 12 of the Federal Trade Commission Act, 15 U.S.C. 52, Fibre Trim is a drug or food as defined in Section 15 of the Act, 15 U.S.C. 55.

PAR. 4. The acts or practices of respondent alleged in this complaint have been in or affecting commerce.

PAR. 5. Typical of respondent's advertisements and promotional materials, but not necessarily all-inclusive thereof, are the attached Exhibits A through H. The aforesaid advertisements and promotional materials contain the following statements:

1. "One of the best sources of dietary fiber is Fibre Trim - the safe, all natural aid to weight control developed in Scandinavia." [Exhibit A]
2. "High Fiber Supplement" [Exhibit B]
3. "[Serving size] 5 Fibre Trim Diet Tabs with 8 oz. water, Calories: 5, Dietary fiber (grams): 2.35. [Exhibit G]
4. "Because Fibre Trim extracts its fiber from two food sources, citrus and grain, it too, is an excellent source of both soluble and insoluble fibers." [Exhibit G]
5. "And Fibre Trim even offers you all of fiber's wonderful health benefits as well." [Exhibit E]
6. "Healthy Reasons to take FIBRE TRIM." [Exhibit H]
7. "If your diet has been low in fiber, you may take a few days to adjust to the healthier level of dietary fiber. As a result, a temporary and slight abdominal discomfort may develop, though this soon disappears. This is a positive sign that your digestive system is becoming healthier." [Exhibit F] [emphasis in original]
8. "Take Fibre Trim to ensure a well-balanced, fiber-rich diet, and feel good knowing you're doing something good for yourself." [Exhibit F]
9. "Slims you the natural way - while providing fiber's healthful benefits." [Exhibit B]
10. "Fibre Trim was developed by scientists in Scandinavia and has been tested and enthusiastically received by consumers." [Exhibit A]
11. "It's proven: Fibre Trim has successfully helped European women lose weight and keep it off." [Exhibit D]
12. "A PROVEN, NATURAL WAY TO LOSE WEIGHT" [Exhibit C]
13. "It's sensible: it makes you feel satisfied with less food." [Exhibit D]
14. "Because fiber creates a pleasant feeling of fullness, you'll be satisfied with smaller portions, which means you'll be reducing your calorie intake." [Exhibit A]
15. "Fibre Trim also helps stave off hunger pangs between meals, and keeps those midnight binges at bay." [Exhibit E]
16. "You can even use it for maintenance, to keep those extra pounds from creeping back on again. [Exhibit E]

PAR. 6. Through the use of the statements referred to in paragraph five and others in advertisements and promotional materials not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Fibre Trim is a high fiber supplement.
2. The recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber.

3. The recommended dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day.

PAR. 7. In truth and in fact:

1. Fibre Trim is not a high fiber supplement.
2. The recommended daily dosage of Fibre Trim does not provide most of a person's daily requirements of dietary fiber.
3. The recommended dosage of Fibre Trim does not provide about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day.

Therefore, the representations set forth in paragraph six were, and are, false and misleading.

PAR. 8. Through the use of the statements and representations referred to in paragraphs five and six, and others not specifically set forth herein, respondent has represented, directly or by implication, that at the time it made said representations, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 9. In truth and in fact, at the time respondent made said representations, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eight was, and is, false and misleading.

PAR. 10. Through the use of the statements referred to in paragraph five, and others in advertisements or promotional materials not specifically set forth herein, respondent has represented, directly or by implication, that:

1. Fibre Trim is an effective appetite suppressant, weight loss, weight control or weight maintenance product; and
2. Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food.

PAR. 11. Through the use of the statements and representations referred to in paragraphs five and ten, and others not specifically set forth herein, respondent has represented, directly or by implication, that at the time it made said representations, respondent possessed and relied upon a reasonable basis for such representations.

PAR. 12. In truth and in fact, at the time respondent made said representations, respondent did not possess and rely upon a reasonable basis for such representations. Therefore, the representation set forth in paragraph eleven was, and is, false and misleading.

PAR. 13. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

Chairman Steiger recused.

EXHIBIT A

Safe, sensible weight loss with Fibre Trim

Some diet aids contain drugs that can have harmful side effects. Fibre Trim is all natural. There are no artificial colors, flavors or additives. Fibre Trim contains no salt, caffeine, added sugars or starches. And no drugs.

Fibre Trim was developed by scientists in Canada and is the only natural weight loss aid available in the US from Schering Corporation, one of the world's most respected pharmaceutical companies.

Leading diet product in Europe and Canada where millions of people use Fibre Trim daily to help lose weight and keep it off. Now Fibre Trim is available in the US from Schering Corporation, one of the world's most respected pharmaceutical companies.

makers of such products as: Amic, Chl, Fibre Trim, Concedin, Divalin, and Thucin.

Safe, sensible weight loss with Fibre Trim

...about fiber and your diet

What is fiber?

Fiber is the part of plant foods that cannot be digested by the body. The term "dietary fiber" describes several different kinds of fibers found in plant foods. When you eat fiber, it forms bulk in the digestive system by absorbing water.

How can fiber help you lose weight and keep it off?

Because of its bulk-forming properties, foods that are high in fiber are generally more filling than low-fiber foods. Eating a fiber-rich diet keeps you feeling satisfied so you are less likely to overeat. And fiber-rich diets will make you feel satisfied longer, helping you reduce between-meal snacking.

Good sources of fiber

All plant foods contain dietary fiber, although the amount of fiber is diminished when the food is processed. Whole grains, such as whole wheat, rye, bran, oatmeal, and oat bran, are good fiber sources. There are other fiber-rich foods:

Cereals	Fruits	Vegetables
cornmeal	apples	asparagus
oatmeal	bananas	beans (black)
popcorn (oil-free)	berries	broccoli
wheat wheat	blackberries	brussels sprouts
	blueberries	cauliflower
	cranberries	celery
	grapes	corn
	peaches	cornmeal
	pears	eggplant
	plums (and other nuts)	garlic
	raisins	green beans
	strawberries	green peas
	tomatoes	green beans
	whole wheat	potatoes
		spinach

One of the best sources of dietary fiber, "Fibre Trim" is the safe, all-natural and low-calorie weight loss aid. It's made from a natural source of fiber. Fibre Trim contains concentrated plant and

Exhibit A Page 1

SCHERING CORPORATION

Complaint

EXHIBIT A

Fiber every day— good health

One of the most important things you can do for your health is to eat a diet high in fiber. Fiber is a natural part of many fruits, vegetables, and grains. It helps you feel full, keeps your digestive system moving smoothly, and can help lower your cholesterol and blood sugar levels. Fiber is also important for maintaining a healthy weight.

Other benefits of fiber

Fiber helps you feel full, so you can eat less. It also helps you feel better. Fiber is a natural part of many fruits, vegetables, and grains. It helps you feel full, keeps your digestive system moving smoothly, and can help lower your cholesterol and blood sugar levels. Fiber is also important for maintaining a healthy weight.



Diet and exercise

In order to lose weight, you must eat fewer calories than you burn. This means you need to eat a diet that is low in calories and high in fiber. Exercise is also important for losing weight. It helps you burn more calories and keeps your metabolism going.

Calories burned for 30 minutes of activity

Activity	120 lbs	130 lbs	140 lbs	150 lbs	160 lbs	170 lbs	180 lbs
Walking	120	130	140	150	160	170	180
Swimming (moderate)	200	210	220	230	240	250	260
Swimming (vigorous)	250	260	270	280	290	300	310
Swimming (strenuous)	300	310	320	330	340	350	360
Swimming (very strenuous)	350	360	370	380	390	400	410
Swimming (strenuous)	400	410	420	430	440	450	460
Swimming (very strenuous)	450	460	470	480	490	500	510
Swimming (strenuous)	500	510	520	530	540	550	560
Swimming (very strenuous)	550	560	570	580	590	600	610
Swimming (strenuous)	600	610	620	630	640	650	660
Swimming (very strenuous)	650	660	670	680	690	700	710
Swimming (strenuous)	700	710	720	730	740	750	760
Swimming (very strenuous)	750	760	770	780	790	800	810
Swimming (strenuous)	800	810	820	830	840	850	860
Swimming (very strenuous)	850	860	870	880	890	900	910
Swimming (strenuous)	900	910	920	930	940	950	960
Swimming (very strenuous)	950	960	970	980	990	1000	1010

Weight progress chart

Fill in your weight goal and record your progress on this chart.

Month	Weight
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	

Weight progress chart. Fill in your weight goal and record your progress on this chart.

Making fiber a part of your weight loss plan

Many people have trouble losing weight because they don't eat enough fiber. Fiber helps you feel full, so you can eat less. It also helps you feel better. Fiber is a natural part of many fruits, vegetables, and grains. It helps you feel full, keeps your digestive system moving smoothly, and can help lower your cholesterol and blood sugar levels. Fiber is also important for maintaining a healthy weight.

Weight progress chart. Fill in your weight goal and record your progress on this chart.

EXHIBIT C



HOW FIBRE TRIM® GAVE NEW STRENGTH TO THE FRENCH RESISTANCE.

It's never easy to say "no" to food. Especially in a country totally obsessed with it.

Small wonder the French flocked to Fibre Trim: It's a thoroughly natural way to help you fight hunger, and lose weight. A way that works.

When you're not feeling hungry all the time, you can find the strength to say "no" to crêpes, and croissants, and even chocolate-laden éclairs.

In France, they embraced it. In fact, Fibre Trim is so successful, it's Europe's number one diet aid.

Now, it is here.

A PROVEN, NATURAL WAY TO LOSE WEIGHT

Fibre Trim is natural food fiber. But all fiber is not alike.

Fibre Trim is created from different types of grain and citrus fiber, in a unique blend designed to help you lose weight.



Taken before meals, Fibre Trim helps you eat less without constantly feeling hungry. It can even help you cope with snacking.

WIN THE DAILY BATTLES, AND THE WAR

Fibre Trim isn't magic. But it's help in a sane, gradual approach to weight loss. Follow the Fibre Trim plan, move around more, and be patient. You may not lose 10 pounds by Thursday, but you'll likely see lasting results.

Since Fibre Trim is simply natural fiber, it can become a sensible way of life—even after you reach your goal. It's the healthy way to stay trim for good.

Take a cue from the food-loving French, and boost your willpower with a little help from Fibre Trim. Vive la resistance!

THE EUROPEAN WAY TO SLIM. FOR GOOD.

LADIES FIRST SOURCE 7/86

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EXHIBIT D

NEW! ALL-NATURAL FIBRE TRIM!

TO THE DEALER: This coupon will entitle you to a \$100 rebate. For rebate (specified price of \$100), provided coupon is received from customer (or purchaser or local merchandiser). Proof of purchase of sufficient stock of merchandise to cover your rebate submitted must be shown on request. If sales to comply with all conditions submitted for consideration. Rebate amount not honored through brokers or other outside agencies. Coupons are non-transferable, and void if not in proper order. Void, restricted, or where prohibited. Customer must pay all sales tax. Cash redemption value: 1/2004. For redemption must be in home country. Fax: P.O. Box 4074, Chicago, Illinois 60674. Offer good only in U.S.A. Good only on FIBRE TRIM. Any other use constitutes fraud. Limit: One coupon per purchase. Expiration: Expires September 15, 1986.

Save \$100 now with this coupon.
Save an additional \$100. See package for details.

\$100 Off

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Try new Fibre Trim™ and save!

Europe's #1 diet product is finally here.

It's proven: Fibre Trim has successfully helped European women keep their weight and keep it off.

It's sensible: it makes you feel satisfied with less food.

It's all-natural: made from concentrated grain and citrus fiber. No drug side-effects.

It's unique: made from an exclusive European formula.

It's Fibre Trim: The safe, sensible all-natural aid to weight loss.



EXHIBIT E

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HOW FIBRE TRIM™ CHANGED THE SHAPE OF EUROPE.



It didn't happen overnight.

But gradually
Europe has taken on
sleeker new proportions.

Throughout Europe, thousands have been losing weight—and keeping it off—with the help of an intriguing product called Fibre Trim.

It's a thoroughly natural weight loss product. A product so successful for over 5 years, it's the number one diet aid in Europe.

Now, Fibre Trim is here in America.

A UNIQUE BLEND OF FIBERS PROVEN IN EUROPE

Fibre Trim contains no drugs of any kind. It's simply a unique combination of natural source fibers specifically balanced to help you eat less, and lose weight.

All fiber is not alike. Fibre Trim contains a blend of four different fibers from grain and

citrus. A blend proven successful all over Europe. A blend that works.

And Fibre Trim even offers you all of fiber's wonderful health benefits as well.

TRIUMPH OVER HUNGER PANGS

Taken with water before meals, Fibre Trim gives you a pleasant feeling of fullness. So you can still eat normally, but eat less without feeling starved. Fibre Trim also helps stave off hunger pangs between meals, and keeps those midnight binges at bay.

With Fibre Trim, you're fighting hunger without interfering with your body. Because there are no drugs, there are no drug side effects either.

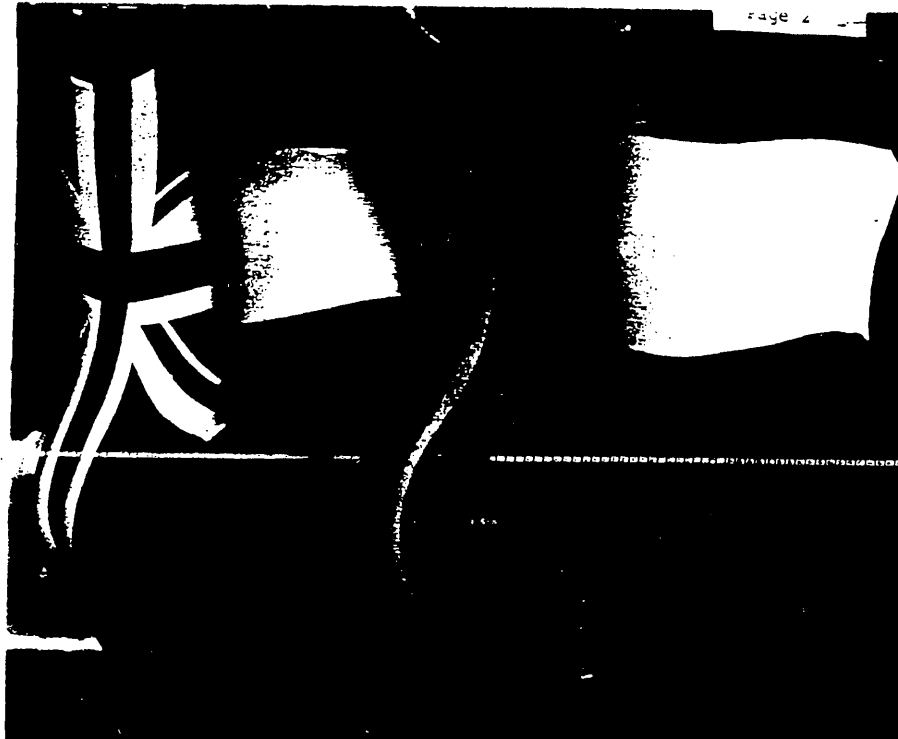
GRADUALLY IS THE WAY TO LOSE WEIGHT PERMANENTLY

Fibre Trim is for those who are serious

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EXHIBIT E



about their bodies. People who are smart enough to realize that the results of fad diets almost inevitably evaporate. People with sense enough to know there's just no magical way to lose weight.

You're far more sure of losing weight and keeping it off when you go about it sensibly, and take your time.

That's the Fibre Trim way. A very rational plan designed specifically for gradual weight loss.

SENSIBLE, SO SENSIBLE

Since Fibre Trim offers a safe, natural way to lose weight, it's a program you can live with until you banish

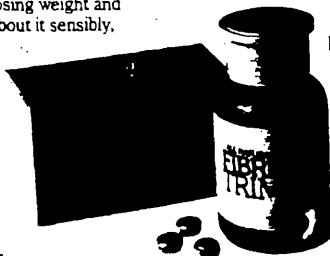
every extra pound. You can even use it for maintenance, to keep those extra pounds from creeping back on again.

But face it. You can't eat cheesecake for breakfast, lunch and dinner and lose weight.

Every dieter knows the basics. Eat right, eat less, and move around more. It's not easy, but Fibre Trim will surely help make it easier.

Because for once, there's a perfectly natural way to lose weight. And keep it off.

Get ready, America. With Fibre Trim, your shape will be changing, too.



THE EUROPEAN WAY TO SLIM. FOR GOOD.

EXHIBIT F

FIBRE TRIM.

EXHIBIT F
Page 1

YOUR ALL-NATURAL AND SAFE AID TO WEIGHT LOSS

Choosing Fibre Trim to help you lose weight is a sensible decision. After all, it's the #1 diet product in Europe and Canada. Losing excess weight can help you look better, feel better and may contribute to your overall health as well. Fibre Trim is designed to help you lose weight and keep it off—safely, sensibly and without drugs.

What is Fibre Trim?

- Fibre Trim is an all-natural product, specially developed for weight loss. Through a unique process, concentrated dietary fiber from grain and citrus fruits is compressed into easy-to-take FibreTabs.
- Fibre Trim contains no added sugars or starches, no artificial color or flavor, and no chemical preservatives. It's sodium-free and caffeine-free. And there's only one calorie per FibreTab.
- Fibre Trim contains no drugs of any kind, so you don't have to worry about drug-related side effects commonly associated with many other weight loss products.



How Fibre Trim Helps You Lose Weight and Keep It Off

- Fibre Trim helps you improve your eating patterns. Its concentrated fiber lets you enjoy the good foods you like, while feeling satisfied with smaller portions. And because Fibre Trim makes you feel satisfied longer, it takes the edge off hunger, helping you reduce between-meal snacking.
- Fibre Trim is your partner—a helper—that makes it easier to stay with your weight loss program because it keeps you satisfied.
- Fibre Trim works naturally, so it works gradually. People who lose weight gradually tend to keep it off. And for assistance in maintaining your ideal weight, Fibre Trim can help. Because it's safe and natural, you can take it as long as you like.

Fibre Trim—A Healthy Addition to Your Daily Routine

More and more Americans are recognizing the importance of eating right, exercising and keeping fit. We know that when we feel better we look better, and we enjoy life more.

- Results of medical studies indicate that the average person can benefit from increasing the amount of fiber in his or her diet. Fiber-rich diets

have been linked to promoting healthier digestive systems.

- Typical American diets consist largely of processed foods—foods low in fiber. Even though we need more fiber in our diets, it's difficult to consume enough fiber without a lot of extra calories. Fibre Trim is a superior source of dietary fiber. No other food contains as much fiber with so few calories.
- So use Fibre Trim as a daily dietary fiber supplement. Make it as regular a part of your daily routine as brushing your teeth.

Being fit is a new way of life. Avoiding overweight, getting more exercise and including more fiber in your diet are just a few of the steps you can take to better health. Fibre Trim is a natural answer.

How To Use Fibre Trim

Take five FibreTabs with a large (8 oz.) glass of water three times daily, 15 to 30 minutes before each meal. You'll feel satisfied while eating less.

Once you've reached your weight goal, take two or three FibreTabs before mealtime to help maintain your desired weight and to benefit from the healthier fiber level that Fibre Trim provides.

Should you feel hungry between meals, take two to three additional FibreTabs with a large (8 oz.) glass of water. Since Fibre Trim is a safe, natural food fiber product, you can continue to take it as long as you like.

Note: It is important to use Fibre Trim as recommended with plenty of water over a period of several weeks to achieve the desired long-term effects. Remember, gradual weight loss tends to be long-lasting weight loss.

If your diet has been low in fiber, you may take a few days to adjust to the healthier level of dietary fiber. As a result, a temporary and slight abdominal discomfort may develop, though this soon disappears. This is a positive sign that your digestive system is becoming healthier. Should you experience discomfort, take 3 FibreTabs before each meal for the first few days while your system adjusts to the new fiber level of your diet. Then increase to the usual 5.

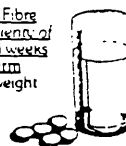


EXHIBIT F

FIBRE TRIM'S FOUR STEPS TO SLIMNESS

 EXHIBIT F
Page 2

Follow these four steps to a slimmer figure and healthy weight control.

1. Think Thin— Eat Smart!

Think before you eat. The U.S. Dietary Guidelines recommend that Americans eat less sugar, fat, cholesterol, and sodium, and **MORE FIBER** to avoid overweight.

So, eat smaller portions, consume fewer high calorie drinks, and increase your fiber intake.



2. Be More Active— Get More Exercise!

This doesn't mean you have to train for a marathon. Any activity—whether walking, running, swimming or cycling—is good for you, makes you feel good and promotes weight control. Be more active and watch the results!



3. Be Good to Yourself— Use Fibre Trim Every Day!

Make Fibre Trim a part of your healthier lifestyle. Take Fibre Trim to ensure a well-balanced, fiber-rich diet, and feel good knowing you're doing something good for yourself.



4. Keep Your Chin Up and Watch Your Weight Go Down!

Don't give up, don't stop! Keep at it and remember gradual weight loss is healthy weight loss.

Your Fibre Trim Weight-Loss Progress Chart

Fill in your weight goal and record your progress on this handy chart. And remember, it's important to use Fibre Trim as recommended on a daily basis to achieve the desired long-term effects.

	Date	Pounds
My Weight Now		
My Weight Goal		
My Progress	Date	Weight
2 weeks		
3 weeks		
4 weeks		
5 weeks		
6 weeks		
7 weeks		
8 weeks		

Don't Forget: Fibre Trim as suggested three times a day—every day!

Ingredients: Natural fiber from grain and citrus fruit, whey protein concentrate (non-nutritive dietary fiber: 44%). Manufactured in Denmark for Schering Corporation.

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Nutritional Information: Serving size: 5 tablets. Calories per serving: 5 (1 per FibreTab). Protein: less than 1 gram. Carbohydrate: less than 1 gram. Fat: less than 1 gram. Sodium-free. Contains less than 2% of the U.S. RDA of protein, vitamin A, vitamin C, thiamin, riboflavin, niacin, calcium and iron.

As with any diet plan, consult a health professional before starting your diet.

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EXHIBIT G

GETTING STARTED ON THE FIBRE TRIM DIET PLAN

STEP 1: DETERMINE YOUR DESIRABLE WEIGHT

There are several scientific ways to find your ideal weight... weight charts, and more. But you need to go to extremes to find out if you need to shed a few pounds...

STEP 2: SET A REALISTIC WEIGHT LOSS GOAL

To lose weight you need a positive state of mind and a commitment to your goal... Reaching your ideal weight means balancing what you eat against what your body uses for energy...

STEP 3: START A REGULAR ACTIVITY PROGRAM

Adding exercise to your daily routine not only helps you burn calories faster, but makes you look better and feel better about yourself... You don't have to go to extremes when exercising...

STEP 4: START THE FIBRE TRIM DIET

The Fibre Trim Diet provides 1,200 calories and about 30 to 40 grams of dietary fiber daily... The calorie level is the level at which most women are able to lose weight healthfully...

Choose the level that is most comfortable for you... 1,200 calories means you consume a particular diet which is severely restricted in calories...

Table for DAY 1 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1180 31.2

Table for DAY 2 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1296 37.2

Table for DAY 3 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1296 37.2

FIBRE TRIM DIET 7-DAY MENU PLAN

The Fibre Trim Diet, based on the nutritional needs of the average healthy adult, provides 1,200 calories. These are 1,500 calories consumed without any additional serving of milk, fruit and raw nuts or bread.

TIPS FOR SUCCESS

- 1. Increase your fluid intake by drinking a glass of water... 2. Weigh down the recommendations under what a you measure of fat grams... 3. Record your weight before you start and keep your progress up to date with a weight scale and record.

Table for DAY 4 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1270 33.6

Table for DAY 5 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1296 37.2

Table for DAY 6 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1296 37.2

Table for DAY 7 showing meal breakdown: BREAKFAST (Eggs, Bacon, Toast), LUNCH (Salad, Chicken, Potatoes), DINNER (Steak, Potatoes, Salad). Total: 1296 37.2

EXHIBIT H

Healthy Reasons to Take FIBRE TRIM[®]

Taken with water before meals, Fibre Trim helps you feel pleasantly full. So you can enjoy the foods you like yet be satisfied with eating less. Fibre Trim can also help to curb that between-meal urge to snack.

How is Fibre Trim Different?

All fiber products are not alike. Developed in Scandinavia, Fibre Trim is a unique blend of four different fibers. A blend that works.

Fibre Trim Offers a Choice.

Watching your weight may mean cutting back on foods rich in bone-building calcium.

So we also offer Fibre Trim with Calcium. It's just like regular Fibre Trim, but provides 600 mg of calcium in one day's supply.

Fibre Trim Makes Sense for Everyone.

Medical studies have shown that fiber is important to everyone's health, whether or not you're dieting. And few foods contain as much fiber with so few calories as Fibre Trim.

Watching your weight, getting more exercise and including more fiber in your diet are important to good health. Make Fibre Trim or Fibre Trim with Calcium a part of your healthy lifestyle.



Schering Corporation, Kenilworth, NJ 07033. All rights reserved. 7-080/14-307.

INITIAL DECISION

BY LEWIS F. PARKER, ADMINISTRATIVE LAW JUDGE
SEPTEMBER 16, 1991

I. INTRODUCTION

The Commission issued its complaint in this proceeding on September 22, 1989, charging that respondent Schering Corporation ("Schering") violated Sections 5(a) and 12 of the Federal Trade Commission Act by representing, directly or by implication, that, at the time it made certain claims for its product Fibre Trim, it possessed and relied upon a reasonable basis for such claims, when, in fact, it did not.

The complaint charges in paragraph six, subparagraphs 1, 2, and 3, that Schering, through advertisements and promotional materials, represented, directly or by implication, that:

1. Fibre Trim is a high fiber supplement;
2. The recommended daily dosage of Fibre Trim provides most of a person's daily requirements of dietary fiber;
3. The recommended daily dosage of Fibre Trim provides about 2.35 grams of dietary fiber per serving or about seven grams of dietary fiber per day (Cplt, paragraph 6);¹

The complaint charges, in paragraph ten, subparagraphs 1 and 2, that Schering represented that:

1. Fibre Trim is an effective appetite suppressant, weight loss, weight control or weight maintenance product; and
2. Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Cplt, paragraph 10).

¹ The following abbreviations are used in this opinion:

Cplt:	Complaint
Ans.:	Answer
CX:	Commission Exhibit
RX:	Respondent's Exhibit
Tr.:	Transcript
F.:	Finding of Fact
CPF:	Complaint Counsel's Proposed Findings
RPF:	Respondent's Proposed Findings

The complaint charges that since Schering did not possess and rely upon a reasonable basis for the alleged claims, Schering's claims were false and misleading.

Schering's answer admitted the allegations contained in subparagraphs 1 and 3 of paragraph six of the complaint. It also admitted the allegations contained in subparagraph 1 of paragraph ten of the complaint, but denied that it represented Fibre Trim to be an effective appetite suppressant (Ans., paragraphs 6 and 10).

Schering denied the other allegations of paragraphs six and ten.

After extensive discovery, trial was held from January 22, 1991, to March 28, 1991. The parties called several expert witnesses. Those testifying for the Commission were:

Dr. Terence Shimp, a professor of marketing, University of South Carolina (Tr. 52), is an expert in consumer information processing and in judging the likelihood that advertising will leave consumers with particular impressions (Tr. 71).

Dr. Alan Levy, head of the consumer research staff of the Center for Food Safety and Applied Nutrition, Food and Drug Administration (Tr. 188), is a social psychologist and an expert in environmental research methods and health behavior, including consumer awareness of diet and disease relationships (Tr. 189, 199).

Dr. Jon Story, a professor of nutritional physiology, Department of Food and Nutrition, Purdue University, is an expert in nutrition and physiology, particularly in the areas of diets, effects on cholesterol, bile and metabolism, and the effects of dietary fiber (Tr. 472).

Dr. Harry Kissileff, Associate Professor of Clinical Psychology, Department of Psychiatry and Medicine, Columbia University College of Physicians and Surgeons (Tr. 658), is an expert in human eating behavior and its physiological and psychological controls (Tr. 670).

Dr. Alan Levine, Deputy Associate Chief of Staff for Research, Minneapolis Veterans Administration Medical Center (Tr. 748), is an expert in body weight regulation, including the regulation of food intake and energy expenditure (Tr. 759).

Dr. David Levitsky, professor of nutrition and psychology, Cornell University (Tr. 881), is an expert in the control of food intake and body weight, human obesity, statistics and the design of clinical trials (Tr. 911).

Dr. Elaine Lanza, a nutritionist with the National Cancer Institute, National Institute of Health (Tr. 1180), is an expert in nutrition, cancer, the physiological effects of dietary fiber, and the conduct and review of clinical trials involving nutrition intervention, including dietary fiber (Tr. 1209-10).

The following experts testified for Schering:

Elizabeth Fazio, of VOPAN Marketing Research Corporation (Tr. 1794), is an expert in marketing and advertising research (Tr. 1809).

David M. Kweskin, Senior Vice President, Client Services, Ross-Cooper Associates (Tr. 1860-62), is an expert in the design, execution and analysis of consumer research studies, including what messages an advertisement communicates to consumers, the evaluation of products and marketing concepts, and consumers' needs (Tr. 1866-68).

David A. Leury, Vice President and Senior Methodologist, Total Research Corp. (Tr. 1906-07), is an expert in market research (Tr. 1924).

Dr. David Stewart, a professor of marketing, University of Southern California (Tr. 2031), is an expert in advertising, marketing and consumer responses to advertising (Tr. 2039).

Dr. Evelyn Albu, a former Director of Medical Marketing for Schering (Tr. 2176), is an expert in the analysis of medical and scientific literature and the analysis of clinical studies (Tr. 2187).

Dr. Domenic Iezzoni, Director of Medical Services for Schering (Tr. 2393), is an expert in the analysis of the medical validity of reports of clinical trials (Tr. 2405).

Dr. Frank Hurley, a biostatistician and President of Biometric Research Institute (Tr. 2566-67), is an expert in biostatistics, the design, analysis, coordination and management of clinical trials, and Food and Drug Administration requirements for such trials (Tr. 2586).

Dr. Nelson Schimmel, a self-employed consultant and a former Vice President of Regulatory Affairs for Schering (Tr. 2779, 2784), is an expert in the evaluation of scientific and medical literature and clinical trials (Tr. 2787).

Dr. Stig Larsen, a statistician and the President of MEDSTAT, a company which does statistical analyses in epidemiology studies and clinical trials (Tr. 2900-03), is an expert in mathematics, medical statistics, and the statistical evaluation of clinical trials (Tr. 2918).

Dr. David Ahern, a clinical psychologist employed by the Institute for Behavioral Medicine, Providence, R.I. (Tr. 3207), is an expert in the design, conduct and statistical evaluation of clinical trials (Tr. 3220).

Dr. Martin Eastwood, a gastroenterologist, a member of the Faculty of Medicine, University of Edinburgh, and a National Health Service consultant physician (Tr. 3380), is an expert in gastroenterology, human nutrition, the physiological effects of dietary fiber, and the design, conduct and analysis of clinical trials (Tr. 3390).

Dr. Alvan Feinstein, a professor of medicine and epidemiology at the Yale University School of Medicine (Tr. 3534), is an expert in biostatistics, epidemiology and the design, conduct and statistical evaluation of clinical trials (Tr. 3542).

Dr. James Anderson, a physician on the staff of the University of Kentucky Hospital, and a professor of medicine and clinical nutrition with the Hospital (Tr. 3733), is an expert in human nutrition and the physiological effects of dietary fiber (Tr. 3739).

Dr. Joanne Slavin, associate professor of nutrition, Department of Food Science and Nutrition, University of Minnesota (Tr. 3837), is an expert in human nutrition, the physiological effects of dietary fiber on humans, and the design, conduct and analysis of clinical trials (Tr. 3845).

The parties filed their proposed findings of fact and conclusions of law on June 10, 1991. Answers were filed on July 15, 1991. The Commission granted me an extension of time to October 15, 1991, to file this initial decision.

This decision is based on the transcript of testimony, the exhibits which I received in evidence and the proposed findings of fact and conclusions of law and answers thereto filed by the parties. I have adopted several of the proposed findings verbatim. Others have been adopted in substance. All other findings are rejected either because they are not supported by the record or because they are irrelevant.

II. FINDINGS OF FACT

A. *The Business Of Schering*

1. Schering, a subsidiary of Schering-Plough, is a corporation organized, existing, and doing business under and by virtue of the

laws of New Jersey, with its offices and principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey (Ans., paragraph 1). Its principal business is the development and marketing of prescription and over-the-counter ("OTC") drugs (Tr. 2411, 2809), such as Afrin, Coricidin, Drixoral and Tinactin (CX 144).

B. Schering's Decision To Market Fibre Trim

2. Farma Food A/S ("Farma Food"), a Danish company headquartered in Copenhagen which was started in the early 1970s principally to develop dietary fiber products, is the manufacturer of Fibre Trim (Tr. 305-06; RX 313, p. 1).

3. Before it was marketed in the United States, Fibre Trim, which is composed of natural fiber from citrus fruit and grain compressed into tablets, was the best selling diet aid in Europe, Canada and other parts of the world (Tr. 305, 1458-59, 1564, 2199; RX 263, RX 313, p. 2, RX 358, p. 1).

4. During negotiations with a pharmaceutical company, A.H. Robbins, regarding another product, Schering was informed that Robbins had considered and rejected marketing Fibre Trim in the United States. After a series of meetings with representatives of Farma Food, Schering decided, in late 1984, to enter into an agreement with Farma Food to market Fibre Trim in the United States (Tr. 305-06, 1456-57, 1471).

5. Charles Bonfield, the Vice President, and later President, of Farma Food's U.S. subsidiary, was the liaison between Farma Food and the Schering marketing department regarding Fibre Trim (Tr. 307-08), and sent Schering a series of letters detailing the characteristics and effects of dietary fiber and the demand for diet products in the United States (Tr. 1464-65). He also gave Schering copies of clinical studies of Fibre Trim's efficacy as a weight loss product (Tr. 308).

6. Since Fibre Trim would be the first non-drug product marketed by Schering, it conducted extensive market research into the proper positioning of Fibre Trim in the diet aids market (Tr. 1468-69, 1499, 1564-65).

7. Consumer research confirmed that because of the increase in obesity in the United States (CX 142, p. 1) a market existed for an all-natural aid to weight loss different from other products, particularly those using Phenylpropanolamine ("PPA") as the active ingredient

since PPA can cause side effects such as nervousness, dizziness and sleeplessness (Tr. 672, 1471-72f 156465, 1602; RX 313, p. 4).

8. The amount of market and consumer research conducted for Fibre Trim was significantly greater than that for other Schering products (Tr. 1499). Schering contracted with several independent market research firms to conduct consumer research prior to test marketing Fibre Trim, while Schering's Marketing Research Department also continued to conduct consumer studies on its own (Tr. 1564-65).

9. Early concept testing showed that greatest consumer interest was generated by positioning Fibre Trim as a sensible way to lose weight. The "sensible" concept became the central message of the Fibre Trim creative strategy and was incorporated into virtually every Fibre Trim advertisement (Tr. 1488, 1579-82, 1589-91, 1824, 1825, 1829, 2053, 2060, 2062-63; RX 240, p. 7).

10. The target audience for Fibre Trim was seen to be females who were relatively sophisticated, intelligent, somewhat upscale economically, and knowledgeable about diet advertising (Tr. 78, 108, 1477; RX 229).

11. After test marketing Fibre Trim from May to August 1985 (Tr. 1494, 1509-70), Schering's top management authorized the marketing department to introduce Fibre Trim nationwide (Tr. 1502, 1514-15, 1642-43). According to Schering, Fibre Trim became the top-selling diet product in its category within a few months of its national introduction (CX 347).

12. During the first year following its introduction in the United States, Schering spent \$16.6 million advertising Fibre Trim and realized \$48.5 million in sales, garnering approximately 17 percent of the diet product market, second only to Thompson Medical's Dexatrim (CX 182, pp. 1, 4). Schering continued to expend significant resources advertising Fibre Trim in 1987, spending \$9.6 million in the first half of the year alone (CX 181, p. 2).

13. Fibre Trim is sold in bottles of 100 or 250 tablets (*e.g.*, CX 351). One-hundred-tablet bottles have accounted for approximately two-thirds of total sales, and 250-tablet bottles have accounted for approximately one-third of sales. The suggested retail price for the 100 and 250-tablet bottles was \$5.99 and \$12.69 (CX 310, p. 3; Tr. 1518).

C. Jurisdiction

14. Schering has advertised, offered for sale, sold and distributed Fibre Trim to the public as a high fiber supplement, and as a weight loss and weight maintenance product (Ans., paragraph 2).

15. At all times relevant to the complaint, the acts and practices of respondent alleged in the complaint have been in or have affected commerce (Ans., paragraph 4).

D. Schering's Advertising Of Fibre Trim

1. Introduction

16. The advertisements and promotional materials at issue were disseminated in a long-running advertising campaign, beginning with the test marketing in 1985, and continuing nationwide from January 1986 until the present (Tr. 1594, 1681, 1694, 1726; *see* CX 280). Schering's 1986 advertising expenditures for Fibre Trim of about \$16.6 million were the highest of any diet product (CX 182, pp. 1, 10).

17. Schering's six-year advertising and promotion effort has used television and radio advertisements and promotions, as well as print media, newspaper supplements, free-standing inserts, in-package coupons and direct mail (*see, e.g.*, CX 339, CX 278, CX 291; Tr. 1600-04).

18. Schering also disseminated promotional materials to physicians, pharmacists, retailers and others who sell or recommend the purchase of weight loss products or fiber supplements to consumers (*e.g.*, CX 354, CX 358; Tr. 1734).

19. The test marketing of Fibre Trim, from May - August 1985, used television and print advertisements, free-standing inserts and promotional materials for members of the trade, and reached millions of consumers (Tr. 1502, 1528-29, 1656; CX 321, CX 396).

2. Television Advertisements

20. Among the first advertisements to be disseminated in the national campaign were the 15-second and 30-second versions of the "French Girls" television commercial (CX 339, CX 343, CX 344) which were broadcast on the three major networks or cable networks

during the test marketing in 1985 and at various times through 1989 (CX 368, Interrog. No's. 2, 3, CX 305, CX 316, CX 321, CX 339).

21. The "Take It Off" television commercial (CX 340, CX 343) was broadcast on selected test market television stations in 1985 (CX 368, Interrog. No. 2).

22. The "Italian Men" television commercial (CX 341, CX 343) was broadcast on three networks throughout 1987 (CX 368, Interrog. No. 2).

23. The "English Maids" television commercial (CX 342, CX 343) was broadcast on three networks throughout 1987 (CX 368, Interrog. No. 2, CX 305, p. 2).

24. The 15-second and 30-second versions of the "Enfants" television advertisement (CX 343, CX 344) were broadcast on three networks in 1987 and 1988 (CX 368, Interrog. No. 3, CX 305, CX 316, pp. 1, 2).

3. Radio Advertisements

25. The radio advertisement entitled "Interview/Consumer Hotline with Audrey Cross" (CX 291) was distributed to 1,009 radio stations and aired by 313, with a total reach of almost five million listeners (CX 317, p. 1, CX 322, p. 1, CX 368, Interrog. No. 1).

4. Print Advertisements

26. Two brochures entitled "Fibre Trim Diet Plan" (CX 284, CX 288) were offered by Audrey Cross on television shows and radio programs during 1986 and 1987. They were also disseminated at retailer displays, physicians' offices, pharmacy counters and by mail request directly from Schering Corporation (CX 368, Interrog. No. 1).

27. The newspaper advertisement entitled "Health Hints, Fiber and Weight Loss" (CX 289) was printed in 4,000 different newspapers during the week of February 19, 1986 (CX 368, Interrog. No. 1).

28. The newspaper advertisement entitled "Quick Quiz" (CX 290) was disseminated to 3,800 different newspapers on April 4, 1986 (CX 318, CX 368, Interrog. No. 1).

29. Five different print advertisements were included as free-standing inserts in Sunday newspaper supplements as follows:

CX 271 -- January 18, 1987
CX 272 -- February 15, 1987
CX 278 -- August 10, 1986
CX 287 -- January 10, 1988
CX 293 -- April 27, 1986

Schering intended to distribute 47 million copies of CX 293 nationally (RX 254, p. 22).

30. The newspaper advertisement entitled "Fibre Trim Changed The Shape Of Europe" (CX 279) was printed in the Good Health Magazine of The New York Times, in January 1986 (CX 368, Interrog. No. 1).

31. The newspaper advertisement, with a coupon, entitled "Try New Fibre Trim And Save" (CX 387) appeared as a free-standing insert in the test market and in the national launch of the product (Tr. 1627).

32. The advertisement entitled "Shape Up For Summer" (CX 274) appeared in major national magazines such as Health, Weight Watchers and American Health, in May 1987 (CX 368, Interrog. No. 1).

33. The advertisements entitled "Lately, There's A Lot Less To Pinch In Italy" (CX 285) and "How Fibre Trim Stopped The British Pound From Fluctuating" (CX 286) appeared in major national magazines such as Family Circle, Ladies Home Journal, Redbook, Woman's Day, Cosmopolitan, Glamour, Harpers Bazaar, Health, People, Self, and Working Mother, in 1986 (Tr. 1663; CX 310, CX 325, CX 368, Interrog. No. 1).

34. The advertisement entitled "How Fibre Trim Gave New Strength To The French Resistance" (CX 287) was printed in the major national magazine Health, in February 1987 (CX 368, Interrog. No. 1).

35. The advertisement entitled "Fibre Trim Changed The Shape Of Europe" (CX 292) appeared nationally in magazines during the test market (Tr. 1620; CX 368, Interrog. No. 1).

36. The print advertisement entitled "Lose Weight With The Help Of Phenylpropanolamine Hydrochloride" (CX 294) (also called "Pills") appeared in major national magazines such as New Woman, American Health, Ladies Home Journal, Self, Hippocrates, Health, People, US, Working Woman, Redbook, Vogue, Family Circle,

Better Homes and Gardens, Working Mother and Cooking Light, in 1988 (Tr. 1697; CX 368, Interrog. No. 1).

37. Several similar print advertisements entitled "How Fibre Trim Changed The Shape Of Europe" were disseminated. CX 295 was disseminated in magazines in 1986 (CX 368, Interrog. No. 1). CX 296 was disseminated in magazines during the test market in 1985 (CX 368, Interrog. No. 1; *see* Tr. 1520-22, 1525). CX 297 was disseminated in major national magazines, such as Time on June 24, 1985, Newsweek on July 22, 1985, Family Circle on August 13, 1985, Health in August 1985, Ladies Home Journal in August 1985, Redbook in August 1985, Sunset in August 1985, Woman's Day on August 13, 1985, and on September 2, 1985, and in Parade Magazine on August 10, 1985 (CX 368, Interrog. No. 1; *see* Tr. 1520-22). CX 299 [RX 397] was disseminated in early 1986 (CX 368, Interrog. No. 1; Tr. 1620). CX 300 was disseminated in major national magazines, such as Better Homes and Gardens in August 1985, Health in July 1985, Time on June 17, 1985, Newsweek on June 24, 1985, Sunset in July 1985, Good Housekeeping in August 1985 and 1,001 Home Ideas in August 1985 (Tr. 1620; CX 368, Interrog. No. 1).

38. The print advertisement entitled "Healthy Reasons To Take Fibre Trim" (CX 273) was disseminated to the public by direct mail in 1987 (CX 368, Interrog. No. 1).

39. The brochure entitled "Fiber Facts" (CX 275 [RX 356]) was disseminated to consumers through displays set up at retailers, pharmacies and dieticians' and doctors' offices, as well as through other public relations efforts, during the test marketing and the first half of 1986 (CX 368, Interrog. No. 1; Tr. 1628).

40. The advertisement entitled "Fibre Trim Diet Plan" (CX 276) was disseminated to consumers through distribution to retailers for placement on the shelf beside the product in early 1986 (CX 368, Interrog. No. 1).

5. Advertisements to the Trade

41. The print advertisement entitled "There's A New High Fiber Supplement To Help Your Patients Lose Weight. . . ." (CX 349) was distributed to physicians (CX 369, Respondent's Supplemental Responses to Complaint Counsel's Second Set of Interrogatories [hereinafter "S. Interrog."], No. 1).

42. The brochure entitled "For Your Patients Who Have Trouble With Dieting Programs" (CX 354) was distributed through Schering retail representatives, who called on physicians in 1987 (CX 369, S. Interrog. No. 1).

43. The print advertisement entitled "Losing Weight Safely, Sensibly, Gradually. . . ." (CX 346) was published in magazines such as Drug Topics and Drug Store News, which are aimed at pharmacists and pharmaceutical wholesalers (CX 369, S. Interrog. No. 1).

44. The brochures entitled "Get Ready With Fibre Trim" (CX 352) and "Stock Display And Recommend New Fibre Trim" (CX 357) were distributed to pharmacists in 1985 (CX 369, S. Interrog. No. 1).

45. Letters to pharmacists, beginning with "Your Customers Often Ask Your Advice When Choosing A Diet Product" (CX 356) and "Schering Corporation Is Pleased To Introduce A New Unique Diet Product. . . ." (CX 358) were distributed to pharmacists in 1985 (CX 369, S. Interrog. No. 1).

46. The product information sheet entitled "Fibre Trim With Calcium" (CX 347) was distributed to Schering sales personnel in 1987 (CX 369, S. Interrog. No. 1).

47. The brochure entitled "All Natural Fibre Trim, High Fiber Food Supplement" (CX 350) was distributed to Schering sales personnel in the fall of 1986 (CX 369, S. Interrog. No. 1).

48. Two product information sheets entitled "Fibre Trim" (CX 355, 351) were distributed to Schering sales personnel in 1985 and 1986 (CX 369, S. Interrog. No. 1).

49. The product information document entitled "Introducing All Natural Fibre Trim" (CX 353) was distributed to Schering sales personnel in November 1985 (CX 369, S. Interrog. No. 1).

50. Two sales brochures entitled "Fibre Trim" (CX 348) and "New All-Natural Fibre Trim" (CX 359) were distributed to retailers and wholesalers in 1985 (CX 369, S. Interrog. No. 1).

6. Inserts

51. The package insert entitled "Fibre Trim" (CX 280) was placed in the Fibre Trim package from 1985 to the present (CX 368, Interrog. No. 1).

E. The Claims Made In Schering's Advertisements

1. The Health Benefits Claim

a. The Advertisements

52. References to health in some of the Fibre Trim advertisements were intended to convey the message that it is a healthy, natural way to lose weight and to differentiate it from drug-based diet products (Tr. 1625-26): "And since Fibre Trim is nothing but natural fiber, it can become a healthy way of life. A way to stay slim long after the party's over" (RX 396). "Increasing the amount of fiber in your diet is a healthy way to help you take the pounds off and keep them off naturally" (RX 353; CX 275). "Since Fibre Trim is simply natural fiber, it can become a sensible way of life -- even after you reach your goal. It's the healthy way to stay trim for good" (RX 355; CX 287). "Being fit is a new way of life. Avoiding overweight, getting more exercise and including more fiber in your diet are just a few of the steps you can take to better health" (RX 358; CX 280).

53. However, other Fibre Trim advertisements go beyond the claim that Fibre Trim is a healthy way to lose weight and emphasize the health benefits associated with dietary fiber without regard to Fibre Trim's primary use as a weight loss aid. For example, the headline of CX 273 "Healthy Reasons to Take Fibre Trim" suggests that there are reasons, not a single reason, to use Fibre Trim, and other language states that these reasons involve health, not simply diet: "Medical studies have shown that fiber is important to everyone's health, whether or not you're dieting" (emphasis added).

54. Other advertisements stress the health benefits of fiber without limiting them to those associated with a reduced calorie diet:

CX 275 states that "fiber is essential for good nutrition and good health," that Fibre Trim may be used to "maintain your overall good health," and that it is one of the best sources of dietary fiber.

The Fibre Trim package insert, CX 280, states: "Fibre Trim -- A Healthy Addition to Your Daily Routine," claims that medical studies have shown that "[f]iber-rich diets have been linked to promoting healthier digestive systems," and concludes that "Fibre Trim is a superior source of dietary fiber. No other food contains as much fiber with so few calories" (emphasis in original).

Various versions of the “Shape of Europe” advertisement state that Fibre Trim provides “all of fiber’s wonderful health benefits to boot” (CX 295, CX 296, CX 297, CX 300) or “fiber’s health benefits” (CX 278, CX 293).

Other advertisements state that “Fibre Trim provides needed fiber that many doctors, nutritionists, and scientists have been saying we lack in our diets” (CX 279, p. 2, CX 292, p. 1).

Fibre Trim advertisements disseminated to retailers, pharmacists, or other members of the trade refer to fiber’s health benefits.

Healthy--adds beneficial dietary fiber... superior source of low-calorie fiber... Fiber-rich diets linked to healthier digestive systems (CX 266).

Fibre Trim contributes to the daily intake of dietary fiber, an essential component of good health (CX 349).

[Fibre Trim provides] the healthy benefits of fiber supplementation (CX 352).

You’ve been hearing about the benefits of fiber for years. Now you have convenient Fibre Trim. . . . (CX 356, CX 358).

55. After reviewing Schering’s advertisements, Dr. Shimp concluded that they made product claims related to health by associating one object, Fibre Trim, with another object, fiber, and by explicitly and implicitly asserting that Fibre Trim will provide the same health benefits that fiber or fiber-rich foods provide (CX 266, CX 273, CX 275, CX 278, CX 279, CX 280, CX 292, CX 293, CX 296, CX 295, CX 297; Tr. 123-25, 128-30, 133-34, 136-37, 138-42, 146-50).

56. After reviewing Dr. Shimp’s analysis and the advertisements in question, I find that they make the claim that Fibre Trim provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food. Although the advertisements do not specify the particular benefits that Fibre Trim will provide, they do represent that whatever health benefits the individual consumer associates with fiber will be provided by taking Fibre Trim (*see, e.g.*, Tr. 124-25 re CX 273; Tr. 137 re CX 296). The FDA’s health and diet surveys reveal the health benefits that consumers associate with fiber.

b. The FDA’s Health and Diet Surveys

57. The Health and Diet Survey is a biennial telephone survey conducted by the Food and Drug Administration (“FDA”) which

focuses on consumers' knowledge of diet and health issues (Tr. 190-91, 205). The survey's sample size is composed of approximately 4,000 respondents who are randomly subdivided into four equal sub-samples called "replicates." The questions are different for each replicate, each addressing the same topics from different perspectives. In essence, the Health and Diet Survey is four related, but different, surveys (Tr. 196, 205-07).

58. The 1986 Survey included a number of questions relating to consumer understanding of the health effects of fiber, and Dr. Levy of the FDA testified to conclusions which can be drawn from responses to those questions (CX 103; Tr. 211).

59. Question 41 in the fourth replicate asked respondents if they had "heard about any health problems that might be related to how much or how little fiber people consume?" (Tr. 211; CX 2103, p. 13). Only if they responded "yes" to this screener question were they asked question 42, an open-ended question: "What health problems might be related to not consuming enough fiber?" (CX 103, p. 14; Tr. 212). Question 42 was followed by a probe: "Are there any other problems that might be related to not consuming enough fiber?" (CX 103, p. 14; Tr. 212).

60. In response to question 41, 57% of the replicate said they had heard of health effects associated with fiber; they were then asked question 42 (Tr. 213; CX 103, p. 42). Thirty-nine percent of the replicate sample of 1,000 respondents mentioned cancer as a health problem related to not consuming enough fiber (Tr. 214; CX 382, p. 1). Of those respondents who were more articulate and specified a particular form of cancer, 28% mentioned cancer of the colon, intestines or bowels as a health problem related to insufficient fiber (Tr. 215; CX 282, p. 2).

61. Forty-nine percent of those respondents with more than a high school education believed cancer to be related to insufficient fiber consumption. Women were significantly more likely than men to mention cancer as a health problem related to not consuming enough fiber (Tr. 218-19).

62. Its laxative effect was the next most frequently mentioned effect of fiber (14%) (Tr. 216; CX 382, p. 2).

63. Respondents in the third replicate were asked question 33: "Have you heard about any things people could eat or drink that might help prevent cancer?" (CX 103, p. 11; Tr. 210, 220). Those who responded affirmatively were then asked question 34: "What

things could people eat or drink that might help prevent cancer?" This open-ended question was followed with the probe "are there any other things that people eat or drink that might help prevent cancer?," providing an opportunity for respondents to supply up to four answers (CX 103, p. 11). Thirty-two percent of the 1,000 subjects in this replicate responded that fiber was a cancer preventative (Tr. 221-22; CX 103, p. 54).

64. Respondents in the second replicate were asked "What about cancer of the colon, rectum, or intestines: As you understand it, what things might make people more likely to get these cancers?" (CX 103, p. 8 (question 25); Tr. 224-25). In response to this open-ended question, which, unlike the two previously discussed questions, was not limited to dietary factors, approximately 29% mentioned "too little fiber" as a risk factor for developing these cancers (Tr. 226; CX 103, p. 38).

65. Dr. Levy concluded that in 1986, the most frequently mentioned cancer preventative was fiber consumption and that upscale consumers, Fibre Trim's target market, were even more likely to make this association (Tr. 223-26).

66. The 1988 Survey produced similar results: 25% of the respondents in replicate C mentioned cancer, the most frequently given response, as a health problem associated with not consuming enough fiber (Tr. 232; CX 105, p. 29). The laxative effect of fiber was also a frequently mentioned health benefit (Tr. 233). Twenty-eight percent of respondents in replicate B answered that fiber was a cancer preventative (Tr. 235-36; CX 105, p. 6), and Dr. Levy stated that the 1988 Survey revealed that the public considered fiber to be the primary dietary factor related to cancer prevention (Tr. 238).

67. Twenty-one percent of the respondents in the B replicate named fiber as something one could eat that might prevent heart attacks or lower blood cholesterol (Tr. 239-40; CX 105, pp. 5, 129, 139). Forty-three percent of respondents in the A replicate stated that eating more high-fiber foods might have a large effect in preventing heart disease or heart attack, and 38% responded that it might have a moderate effect (Tr. 243-44; CX 105, p. 38).

68. The results of the 1986 and 1988 surveys represent the knowledge and attitude of the U.S. population as a whole with respect to the relationship between fiber and disease and can be used to determine their interpretation of advertising claims for fiber (Tr. 248-50).

69. The responses to the 1986 and 1988 surveys demonstrate that cancer prevention was the primary benefit that consumers associated with a high fiber diet and that a considerable portion of the population also associates such a diet with reduction in the risk of heart disease. The laxative effect of fiber was also mentioned by a significant number of survey respondents.

c. The Views of Schering Employees

70. Mr. Walsh, the senior director of OTC marketing for Schering, was responsible for approving draft advertising copy for Fibre Trim; he testified that the language in CX 296 “Fibre Trim even offers all of fiber’s wonderful health benefits to boot” suggests that “whatever those healthy things that you can gain from fiber as it relates to the diet you would get from this product” (Tr. 1525-26).

71. Dr. Albu, the head of Schering’s professional services department, testified that the claim in CX 297 that “Fibre Trim even offers you all of fiber’s wonderful health benefits to boot” was supported because “fiber is fiber,” and therefore whatever health benefits are provided by fiber-containing foods are also provided by Fibre Trim, and that the health benefits associated in the literature with increased fiber intake included reduced risk of colon cancer and reduction in serum cholesterol (Tr. 2365-66). Dr. Iezzoni, who was responsible for the medical department’s review of Fibre Trim advertisements, gave similar testimony (Tr. 2536, 2547-49).

72. Sharon McGee, a senior brand manager who was responsible for the Fibre Trim brand from October 1984 through February 1987, testified that Schering undertook a public relations campaign to “[c]reate a positive environment among consumers for the benefits of fiber for . . . general health prior to the start of advertising” (Tr. 1558, 1604-05; CX 308, p. 10).

73. Materials which Schering provided to its sales force contain many references to the health benefits of fiber, including cancer prevention, cholesterol reduction and treatment of diabetes and diverticulosis (CX 142, pp. 42-46, CX 143, pp. 10, 11, 13, 16, 19, 20, 27-28), and Schering knew that consumer “awareness of the benefits of a diet rich in fiber is rising” (CX 143, p. 17):

There is not a week without an article on fiber in a health or women’s magazine. The introduction of FIBRE TRIM is, as you can see, very timely. FIBRE TRIM will benefit from this favorable environment. *Id.*

74. In materials it disseminated at the press conference announcing the national launch of Fibre Trim (CX 310, p. 13; *see* Tr. 1517), Schering claimed that dietary fiber had value in preventing some digestive conditions and that high fiber diets may reduce the risk for certain kinds of colon cancer. Those same materials stated that “[o]ne of the best sources of dietary fiber is FIBRE TRIM. . . .” (CX 310, p. 16).

d. Schering’s Consumer Research

75. Dr. Stewart, Schering’s advertising expert, testified that no advertisements for Fibre Trim made express claims that it provides the health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Tr. 2091) and Dr. Shimp agreed that Fibre Trim advertisements which he was questioned about do not specify any particular health benefits provided by Fibre Trim (Tr. 124, 137).

76. Dr. Stewart also testified that the following research conducted by or for Schering reveals that consumers did not take away from Fibre Trim advertisements the message that it will provide the health benefits associated with a diet rich in fiber or a high intake of dietary fiber (Tr. 2057-76).

- (1) Initial Focus Group Consumer Testing: “In Search of A
Concept Statement For Fiber [sic] Trim,”
(Marketing Perceptions, Inc.) (November 1984)

77. In October 1984, at Schering’s request, the market research firm, Marketing Perceptions, Inc. (“Marketing Perceptions”), conducted initial diet market consumer focus groups relating to Fibre Trim (Tr. 1469, 1564; RX 235). Focus groups yield qualitative results about consumer beliefs that are not achieved with consumer surveys (Tr. 2065-66). The purpose of this study was to explore consumers’ feelings and perceptions about dieting in general (Tr. 1564-65). Dr. Stewart testified that the focus group consumers did not take away from Fibre Trim commercials the health benefits claim (Tr. 2066, 2068), and Ms. McGee concluded that the target audience realized that Fibre Trim was not magical but was a sensible diet aid (Tr. 1567-68).

(2) Diet Concept Study (VOPAN Marketing Research)
(January 1985)

78. From December 1984 to early 1985, Schering contracted with another independent market research firm, VOPAN, to conduct a qualitative study of Fibre Trim concepts for consumer advertising (RX 239; Tr. 1573-74, 1809, 2059). VOPAN stands for Voice Pitch Analysis, a sophisticated technique which measures two types of consumer response: (1) voice pitch changes; and (2) consumer recall of advertising messages (Tr. 1573-74, 1798-1800, 2059). The basic premise of this methodology is the belief that consumers' true feelings can be discerned from variations in the intonations in their voices (Tr. 1487, 1573, 1798-99).

79. The specific objective of the VOPAN study was to determine which one of four concepts for Fibre Trim was most persuasive and seemed to communicate the best information about the product (RX 192, p. 3; Tr. 1814).

80. VOPAN's methodology involved a mall intercept test of forcing exposure of one of the four concepts to 150 women who had dieted in the past year, who planned to diet in the future and who were 25-49 years of age (RX 192, p. 4; Tr. 1812).

81. The consumers reviewed one of four "concepts," rather than specific advertisements (Tr. 1814-15), which were developed by the advertising agency (Ogilvy & Mather), Schering and VOPAN (Tr. 1576).

82. According to Dr. Stewart and Ms. Fazio, the results of the VOPAN test do not indicate that consumers took away the message that Fibre Trim would provide specific health benefits associated with a fiber-rich diet or a high intake of dietary fiber from food (Tr. 1831, 2060, 2062). Ms. Fazio concluded that no data in this study indicated that the Fibre Trim positioning communicated to consumers that it is an effective appetite suppressant which works like Dexatrim (Tr. 1832; RX 192) or that Fibre Trim would produce weight loss without needing to cut back on calories (Tr. 1835).

83. Elements of all the concepts which tested favorably were incorporated into commercials and other Fibre Trim advertising (Tr. 1487, 2063-65).

