

Complaint

116 F.T.C.

IN THE MATTER OF

ABBOTT LABORATORIES

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

Docket C-3442. Complaint, June 24, 1993--Decision, June 24, 1993

This consent order prohibits, among other things, an Illinois-based marketer of very-low-calorie diet programs (rapid weight loss, modified fasting diets of 800 or fewer calories per day) from making false or unsubstantiated claims about health risks, weight loss, or weight loss maintenance; and requires certain disclosures in conjunction with safety and weight loss maintenance claims.

Appearances

For the Commission: *Brinley H. Williams* and *David V. Plottner*.

For the respondent: *Katherine M. Grundin*, in-house counsel,
Abbott Park, IL.

COMPLAINT

The Federal Trade Commission, having reason to believe that Abbott Laboratories, a corporation (hereinafter "respondent"), 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 Abbott Laboratories is an Illinois corporation, with its offices and principal place of business at One Abbott Park Road, Abbott Park, Illinois.

PAR. 2. Respondent is engaged, and has been engaged, in the sale and offering for sale of the physician-supervised New Direction Weight Control System (hereinafter "New Direction") very-low-calorie diet ("VLCD") programs and related nutritional products to the public through cooperating physicians, hospitals and clinics.

VLCDs are rapid weight-loss, modified fasting diets of 800 calories or less per day requiring medical supervision. The New Direction VLCD diet programs provide 800 or fewer calories per day. The New Direction diet programs include "foods" within the meaning of Section 12 of the Federal Trade Commission Act, 15 U.S.C. 52.

PAR. 3. Respondent has created advertisements and provided camera-ready advertising copy to participating physicians, hospitals and clinics for placement in various periodicals that are in general circulation to the public to promote its New Direction diet programs to prospective patients. Respondent further advertises its New Direction diet programs to the public by means of brochures and pamphlets that it provides to participating physicians, hospitals and clinics to give to patients and prospective patients. Typical of respondent's advertising and promotional materials, but not necessarily all-inclusive thereof, are the advertisements attached hereto as Exhibits A through H.

PAR. 4. The acts and practices of respondent alleged in this complaint are, and have been, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 5. Respondent's advertising and promotional materials contain the following statements.

(A) The Safety Claims

- (1) The NEW DIRECTION System is safe: Metabolic and clinical tests have proven NEW DIRECTION Nutritional Beverage to be safe and effective for rapid weight loss. [Exhibit A.]
- (2) Using a very-low-calorie beverage, lose weight quickly and safely in a hospital-based program operated by our medical staff. [Exhibit B.]
- (3) It's a hospital-based, medically supervised program of rapid, safe weight loss and complete education to help you keep the weight off. [Exhibit C, p. 2.]
- (4) Rapid, safe weight loss, using New Direction Nutritional Beverage, which provides 100% of the US RDA for vitamins, minerals and protein. [Exhibit C, p. 2.]
- (5) With NEW DIRECTION, losing weight is medically supervised, safe and long-lasting. Break the cycle. And head in a NEW DIRECTION. [Exhibit F.]

(B) The Maintenance Claims

- (1) Learn to stay slimmer for life: We'll help you learn to eat, think and exercise differently to keep extra weight off. [Exhibit B.]
- (2) It's a hospital-based, medically supervised program of rapid, safe weight loss and complete education to help you keep the weight off. [Exhibit C, p. 2.]
- (3) It's the one weight control system with everything you need to lose weight for life. It begins with medically supervised, safe, rapid weight loss and nutrition education. [Exhibit D.]
- (4) Lose weight quickly, safely, and permanently. [Exhibit E.]
- (5) . . . proven technique for lifelong weight loss. [Exhibit G.]
- (6) You name the diet-I've tried it. They all start out the same. First come the promises-the enthusiasm-the hunger-finally: the panic! And I gain back everything I've lost. How can I take control?
Head in a NEW DIRECTION. After do-it-yourself diets you gain back all the weight you lost. But the NEW DIRECTION Weight Loss Program is different. [Exhibit F.]
- (7) Our NEW DIRECTION program has physicians, psychologists and dietitians working with you right here at our hospital, to take weight off and keep it off. [Exhibit F.]
- (8) Diets, diets, diets. Everyone's got a diet. There's the grapefruit diet-the Malibu diet-the lose-while-you-snooze-diet. But whatever I lose, I always gain right back. Isn't there a way to keep the weight off?
Head in a NEW DIRECTION. Fad diets might take weight off, but they can't keep it off. The NEW DIRECTION Weight Loss Program is different. [Exhibit H.]
- (9) NEW DIRECTION is a total, step-by-step medical program that works with your mind as well as your body. Psychologists, physicians and dietitians counsel with you right here at our hospital to help you develop new habits for lasting weight control . . . [Exhibit H.]

PAR. 6. By and through the use of the statements referred to in paragraph five(A), above, and others of similar import and meaning not specifically set forth herein, respondent represents and has represented, directly or by implication, that the New Direction diet programs are safe. Respondent has failed to disclose that physician supervision is required to minimize the potential risk to patients of the development of health complications on very-low-calorie diets. In view of the representation that the New Direction program is safe, the disclosure as to the requirement for medical supervision is necessary. Therefore, in light of respondent's failure to disclose, said representation was and is misleading.

PAR. 7. By and through the use of the statements referred to in paragraph five(B), above, and others of similar import and meaning not specifically set forth herein, respondent represents and has represented, directly or by implication, that:

(A) The New Direction diet programs are successful long-term or permanent treatments for obesity; and

(B) The typical New Direction patient is successful in maintaining achieved weight loss.

PAR. 8. By and through the statements and representations referred to in paragraphs five(B) and seven, above, respondent represents and has represented, directly or by implication, that at the time respondent made those representations, respondent possessed and relied upon a reasonable basis for those representations.

PAR. 9. In truth and in fact, at the time respondent made the statements and representations referred to in paragraphs five(B) and seven, above, respondent did not possess and rely upon a reasonable basis for those representations. Therefore, the representation set forth in paragraph eight was and is false and misleading.

PAR. 10. The dissemination of the aforesaid false and misleading representations constituted, and now constitutes, unfair or deceptive acts or practices in or affecting commerce, and false advertisements, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. 45(a) and 52.

EXHIBIT A

Don't choose a weight loss program until you weigh all the evidence

The NEW DIRECTION® System for Lasting Weight Control is a comprehensive, scientific, profitable approach that offers hospitals more than other hospital-based weight loss programs. Just weigh the evidence.

The NEW DIRECTION System is comprehensive. The protocol is a medically supervised, multidisciplinary approach that includes nutrition education, behavior modification and exercise for lifelong weight control, yet is flexible and simple to run.

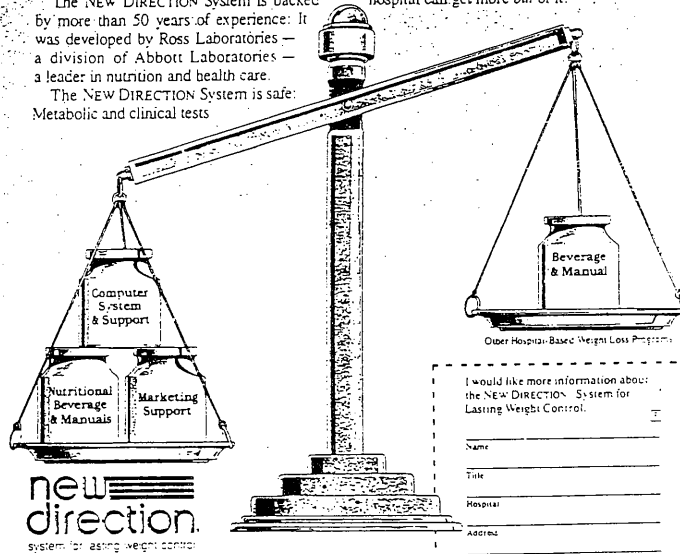
The NEW DIRECTION System is backed by more than 50 years of experience. It was developed by Ross Laboratories — a division of Abbott Laboratories — a leader in nutrition and health care.

The NEW DIRECTION System is safe. Metabolic and clinical tests

have proven NEW DIRECTION® Nutritional Beverage to be safe and effective for rapid weight loss.

The NEW DIRECTION System is efficient to operate. It includes a dedicated, computer hardware-software package that maximizes operating efficiencies and profitability, with minimal personnel — and no surprise costs.

Don't choose a weight loss program without weighing the evidence. We've put more into the NEW DIRECTION System so your hospital can get more out of it.



I would like more information about the NEW DIRECTION® System for Lasting Weight Control.

Name _____

Title _____

Hospital _____

Address _____

City _____ State _____ Zip _____

Phone _____

Mail to: NEW DIRECTION Center, Dept.
Ross Laboratories
625 Cleveland Avenue
Columbus, Ohio 43216
or call (614) 229-7273

new direction

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B1125430
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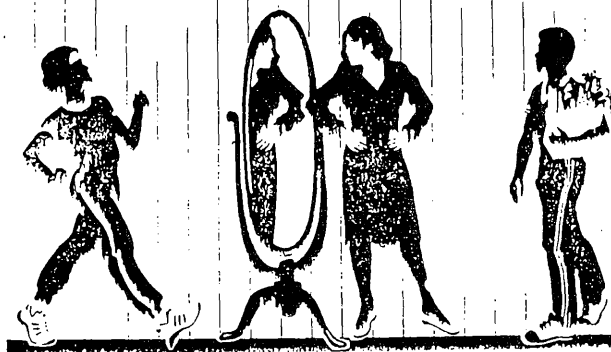
EXHIBIT A

EXHIBIT B

new direction[™]

system for lasting weight control

- For adults with at least 30 pounds to lose.
- Using a very-low-calorie beverage, lose weight quickly and safely in a hospital-based program operated by our medical staff.
- Learn to *stay slimmer* for life: We'll help you learn to eat, think and exercise differently to keep extra weight off.
- Head in a new direction: Call today for a free orientation session.!



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"Are You Ready For Weight Control?"



"If you have more than 40 pounds to lose (50 pounds for men) and you're ready to make some lifestyle changes in how you eat and exercise — and in how you think about yourself — it's time for the New Direction. So start on a Lasting Weight Plan."

EXHIBIT C - PAGE 2 OF 5



"This is a true answer to the questions most people ask about the New Direction System. For more information, call your local New Direction office to see the New Direction System."

What is the New Direction System?

It's a hospital-based, medically supervised program of rapid, safe weight loss and complete education to help you keep the weight off. It emphasizes lifelong weight control rather than just dieting alone. After a thorough screening, the program has three phases. Medical professionals — physicians, registered dietitians and nurses, behaviorists and exercise specialists — work with you in each phase.

Screening

- Thorough medical examination
- Careful psychological, behavioral and nutritional evaluations
- Possibly an exercise stress test

1. Reducing

- Rapid, safe weight loss using New Direction® Nutritional Beverage, which provides 100% of the US RDA for vitamins, minerals and protein
- Careful monitoring by hospital medical staff

EXHIBIT C - PAGE 3 OF 5

- Weekly educational and support sessions
- Nutrition education, behavior modification and changes in everyday activity habits to help you avoid regaining weight
- Structured exercise program encouraged

2. Adapting

- Gradual return to eating regular foods
- Practicing new food, eating and exercise habits
- Weekly education-support sessions
- Medical monitoring by hospital professionals

3. Sustaining

- Eating a balanced diet of regular foods
- Weekly education-support sessions
- Fine-tuning new eating and exercise habits
- Individual professional help, if necessary

*How
much
weight
can I
lose?*

Many people lose 6 to 10 pounds the first week and 3 to 6 pounds the second week, much of it water. During the Reducing Phase, most participants lose 2 to 4 pounds per week, most of which is fat.

Weight loss often is not the only result. People with hypertension will have lower blood pressure and people with high blood sugar will experience improvement. Other medical benefits include lower serum cholesterol and triglyceride levels and less pain in weight-bearing joints.

*How long
is the
program?*

Depending on how much weight you need to lose, the Reducing Phase may last 3 to 6 months or longer. Adapting takes 5 weeks. We ask participants to attend Sustaining sessions for at least 6 months—preferably a year—to settle into habits that help keep weight off.

*How
much
does it
cost?*

The cost of Screening depends on what your hospital charges for a complete physical exam with EKG, blood tests and urinalysis. Screening also includes interviews with the behaviorist and dietitian. After you enroll, fees are based on the phase you are in and are billed weekly or monthly. Total cost depends on how much weight you need to lose and how quickly you meet the goals you set for yourself.

Compare the cost of the program with what you spend now for food, medical care for weight-related conditions and higher-risk health insurance. When you deduct food costs (during Reducing) and any reimbursement you may receive from your health insurance, the net cost of the program may be small.

If you have a weight-related health condition, insurance may pay for part or all of Screening and medical monitoring and some other costs, too. Much of each insurance claim form is filled out

*What if
I have
problems
making
changes
I'll
need for
lasting
weight
control?*

by the New Direction computer, often resulting in quicker reimbursement.

Since we are part of a hospital system, help is just moments away. Many problems can be solved in weekly education-support sessions. For those that can't be, the professional staff is available for individual counseling. And remember, we ask for at least a 6-month commitment to the Sustaining Phase to help participants grow strong in new habits and overcome difficult problems for lasting weight control.

EXHIBIT C - PAGE 5 OF 5

"If you're ready..."



"The New Direction System offers an intensive, yet cautious approach to weight loss and weight control. It is not a quick fix or an easy answer.

"It works, with your help.

"If you're ready to put time, money and effort into a lighter, healthier you, call your New Direction hospital for more information."

NEW DIRECTION
HOSPITALS
INC.

ROSS LABORATORIES

© 1975

MADE IN USA

EXHIBIT D

new
direction

C3442
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NOTE: Use this prepared newspaper ad stick to fit a 14" x 5 column ad space

**"I diet all the time.
Why am I still
OVER-
weight?"**

Dieting alone won't help you take weight off and keep it off.

NEW DIRECTION® can.

It's the one weight control system with everything you need to lose weight for life. It begins with medically supervised, safe, rapid weight loss and nutrition education. These are combined with behavior modification and physical activity to help keep weight off.

So if you have at least 30 pounds to lose and want a medically supervised program, come to NEW DIRECTION.

Free orientation session
(800) 000-0000

Hospital logo and
address go here.

new
direction
PHYSICIAN (BY MAILING #1252) (800) 000-0000

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EXHIBIT E

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**Lose weight quickly,
safely, and permanently**

Feel good about you! If you have 40 lbs. or more to lose and are serious about losing weight, has the weight loss program for you. New Direction combines rapid weight loss with counseling and classes on nutrition and exercise for permanent weight loss. Participants are under the care of a physician, a psychologist, nurses, registered dietitian, and exercise physiologists.

for a free information session,
**Call and
Head in a New
Direction**

EXHIBIT E

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Complaint

EXHIBIT F

Booth-read radio
commercial scripts

The following are two 60-second radio commercial
scripts, entitled Diet Vet and Diet Man.

#1-DietVet

WOMAN: You name the diet-I've tried it. They all start out the same. First come the promises-the enthusiasm-the hunger-finally: the panic! And I gain back everything I've lost. How can I take control?

ANN*: Head in a NEW DIRECTION. After do-it-yourself diets you gain back all the weight you lost. But the NEW DIRECTION Weight Loss Program is different.

WOMAN: That's what they all say.

ANN: Our NEW DIRECTION program has physicians, psychologists and dietitians working with you right here at our hospital, to take weight off and keep it off.

WOMAN: I won't gain it back?

ANN: With NEW DIRECTION, losing weight is medically supervised, safe and long-lasting. Break the cycle. And head in a NEW DIRECTION.

WOMAN: NEW DIRECTION is different. I'm losing weight. I'm keeping it off. I'm holding my own.

ANN: The NEW DIRECTION Weight Loss Program. Only at (NAME OF HOSPITAL). Call 000-0000. That's 000-0000.

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*ANN=Announcer

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EXHIBIT G

What Have You
Got To Lose?

If you're more than 30 pounds over your recommended weight, you've got a lot to lose. The New Direction Weight Management Program is medically supervised and safe. Come and learn more about this proven technique for lifelong weight loss.	Tuesday, January 13 7:00 p.m. Hospital Speaker-Nutritionist Free of Charge. Call for registration or information
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EXHIBIT H

#2 DietMan

MAN: Diets, diets, diets. Everyone's got a diet. There's the grapefruit diet-the Malibu diet-the lose-while-you-snooze diet. But whatever I lose, I always gain right back. Isn't there a way to keep the weight off?

ANN*: Head in a NEW DIRECTION. Fad diets might take weight off, but they can't keep it off. The NEW DIRECTION Weight Loss Program is different.

MAN: Oh, sure it is.

ANN: NEW DIRECTION is a total step-by-step medical program that works with your mind as well as your body. Psychologists, physicians and dietitians counsel with you right here at our hospital to help you develop new habits for lasting weight control.

MAN: I won't gain the weight back?

ANN: With NEW DIRECTION, losing weight can be for life. Break the cycle. And head in a NEW DIRECTION.

MAN: NEW DIRECTION is different. I'm losing weight. I'm keeping it off. I'm in control.

ANN: The NEW DIRECTION Weight Loss Program. Only at (NAME OF HOSPITAL). Call 000-0000. That's 000-0000.

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*ANN=Announcer

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Cleveland Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; 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 aforesaid draft of 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, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that Complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such Agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Abbott Laboratories is an Illinois corporation, with its offices and principal place of business at One Abbott Park Road, Abbott Park, Illinois.
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

DEFINITIONS

(1) For purposes of this order, "*competent and reliable scientific evidence*" means those tests, analyses, research, studies, surveys or other evidence conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the relevant profession or science to yield accurate and reliable results.

(2) "*Very-low-calorie diet*" or "*VLCD*" means any dietary regimen that provides 800 calories per day (K cal/day) or less.

I.

It is ordered, That respondent Abbott Laboratories, a corporation, its successors and assigns, officers, representatives, agents and employees, directly or through any corporation, subsidiary, division or other device in connection with the advertising, promotion, offering for sale or sale of any weight loss or weight control product, program or service, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

(A) Making any representation, directly or by implication, regarding the safety of any very-low-calorie diet ("VLCD") program, unless respondent clearly and prominently discloses, in close proximity to any such representation, that physician monitoring is required to minimize the potential for health risks, or otherwise misrepresenting any health risk of the program.

(B) Misrepresenting the likelihood that patients of respondent's diet program(s) will regain all or any portion of lost weight.

(C) Making any representation, directly or by implication, about the success of patients on any diet program in achieving or maintaining weight loss or weight control unless, at the time of making such representation, respondent possesses and relies upon a

reasonable basis consisting of competent and reliable scientific evidence substantiating the representation; *provided, however*, that for any representation that:

(1) Any weight loss achieved or maintained through any diet program is typical or representative of all or any subset of patients using the program, said evidence shall, at a minimum, be based on a representative sample of:

(a) All patients who have entered the program, where the representation relates to such persons; or

(b) All patients who have completed a particular phase of the program or the entire program, where the representation only relates to such persons; and

(2) Any weight loss is maintained long-term, said evidence shall, at a minimum, be based upon the experience of patients who were followed for a period of at least two years after completion of respondent's program (including any periods of participation in active maintenance); and

(3) Any weight loss is maintained permanently, said evidence shall, at a minimum, be based upon the experience of patients who were followed for a period of time after completing the program that is either:

(a) Generally recognized by experts in the field of treating obesity as being of sufficient length to constitute a reasonable basis for predicting that weight loss will be permanent; or

(b) Demonstrated by competent and reliable survey evidence as being of sufficient duration to permit such a prediction.

(D) Representing, directly or by implication, that any patients of any diet program have successfully maintained weight loss, unless respondent discloses, clearly and prominently and in close proximity to such representation:

(1) The following information:

(a) The average percentage of weight loss maintained by those patients;

(b) The duration over which the weight loss was maintained, measured from the date that patients ended the active weight loss phase of the program; *provided, however*, that if any portion of the time period covered includes participation in respondent's maintenance program(s) that follows active weight loss, such fact must also be disclosed; and

(c) If the patient population referred to is not representative of the general patient population for that program, the proportion of the total patient population in respondent's programs that those patients represent, expressed in terms of a percentage or actual numbers of patients, or the statement, "New Direction makes no claim that this [these] result[s] is [are] representative of all patients in the New Direction program;" and

(2) The statement:

"For many dieters, weight loss is temporary;"

provided, however, that respondent shall not represent, directly or by implication, that the above-quoted statement does not apply to dieters in respondent's diet program.

II.

It is further ordered, That respondent shall notify the Commission at least thirty (30) days prior to the effective date of any proposed change in the corporate respondent, such as dissolution, assignment or sale resulting in the emergence of a successor corporation(s), the creation or dissolution of subsidiaries, the filing of a bankruptcy petition or any other change in the corporation(s) that may affect compliance obligations arising out of this order.

III.

It is further ordered, That respondent shall maintain for a period of three (3) years after the date on which the representation was last made, and make available to the Federal Trade Commission staff upon request for inspection and copying, all materials possessed and relied upon to substantiate any claim or representation covered by this order, and all test reports, studies, surveys or information in its possession or control and which, to its knowledge, contradict, qualify or call into question any such claim or representation.

IV.

It is further ordered, That respondent and its successors or assigns shall forthwith distribute a copy of this order to each of its officers, agents, representatives, independent contractors and employees, including participating hospitals or clinics, that are engaged in the preparation and placement of advertisements or promotional materials, who communicate with patients or prospective patients, or who have any responsibilities with respect to the subject matter of this order; and, for a period of ten (10) years from the date of entry of this order, distribute same to all of respondent's future officers, agents, representatives, independent contractors and employees having said responsibilities. *Provided, however,* that nothing in this order shall obligate respondent with respect to advertising or promotional materials of participating physicians, hospitals and clinics that are neither owned, operated nor controlled by respondent when said advertising is not prepared, approved or placed by respondent.

V.

It is further ordered, That respondent and its successors and assigns shall, within sixty (60) days after service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

Commissioner Owen dissenting with respect to the numerical disclosure requirements for short radio and television advertisements.

Complaint

116 F.T.C.

IN THE MATTER OF

SHARPER IMAGE CORPORATION, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3443. Complaint, June 28, 1993--Decision, June 28, 1993*

This consent order prohibits, among other things, a San Francisco-based retail chain and mail order company and its president from making false or unsubstantiated advertising claims for a telephone tap detector (Tap Detector V), an exercise device (Chest Maximizer), and an anti-fatigue nutritional supplement (Essential Factors) or similar products.

Appearances

For the Commission: *C. Steven Baker* and *Alan E. Krause*.

For the respondents: *Vincent A. Ruiz, Gutierrez & Associates*,
San Francisco, CA.

COMPLAINT

The Federal Trade Commission, having reason to believe that Sharper Image Corporation, a corporation, and Richard Thalheimer, individually and as an officer of said corporation ("respondents"), have 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 Sharper Image Corporation is a Delaware corporation, with its office and principal place of business located at 650 Davis Street, San Francisco, California.

Respondent Richard Thalheimer is an officer and director of the corporate respondent. Individually or in concert with others, he formulates, directs and controls the acts and practices of the corporate respondent, including the acts and practices alleged in this