

UNITED STATES OF AMERICA  
FEDERAL TRADE COMMISSION

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In the Matter of	)	)
KCD HOLDINGS, INC.,	)	
KCD, INCORPORATED,	)	
and DEERFIELD CORPORATION,	)	FILE NO. 942 3237
corporations, and	)	
	)	
CLARK M. HOLCOMB,	)	AGREEMENT CONTAINING
individually and as a former officer of	)	CONSENT ORDER AS TO
KCD Holdings, Inc., and KCD, Incorporated,	)	KCD HOLDINGS, INC.,
	)	KCD, INCORPORATED,
BONNIE L. RICHARDS,	)	DEERFIELD CORPORATION,
individually and as an officer of	)	CLARK M. HOLCOMB,
KCD Holdings, Inc., and KCD, Incorporated,	)	BONNIE L. RICHARDS AND
and	)	GERALD E. HATTO
	)	
GERALD E. HATTO,	)	
individually and as an officer of	)	
Deerfield Corporation.	)	

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The Federal Trade Commission (“Commission”) has conducted an investigation of certain acts and practices of KCD Holdings, Inc. (“KCD Holdings”), KCD, Incorporated (“KCD”), corporations, and their former officer, Clark M. Holcomb, and current officer, Bonnie L. Richards, and Deerfield Corporation (“Deerfield”), a corporation, and its principal, Gerald E. Hatto ("proposed respondents"). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

**IT IS HEREBY AGREED** by and between KCD Holdings, KCD and Deerfield, by their duly authorized officers, and Clark M. Holcomb, individually and as a former officer of KCD Holdings and KCD, Bonnie L. Richards, individually and as an officer of KCD Holdings and KCD, and Gerald E. Hatto, individually and as a principal of Deerfield, and counsel for the Commission that:

1.a. Proposed respondent KCD Holdings is a Nevada corporation with its principal office or place of business at 2835 Townsgate Road, Suite 110, Westlake Village, California 91361.

1.b. Proposed respondent KCD is a California corporation with its principal office or place of business at 2835 Townsgate Road, Suite 110, Westlake Village, California 91361. KCD is a wholly owned subsidiary of KCD Holdings.

1.c. Proposed respondent Deerfield is a California corporation with its principal office or place of business at 1455 Valley High Avenue, Thousand Oaks, California 91359. Respondent Deerfield is an advertising agency of KCD and KCD Holdings.

1.d. Proposed respondent Clark M. Holcomb was the president, director and a majority shareholder of KCD Holdings and KCD from November 1993 through April 1996. Individually or in concert with others, he has formulated, directed, controlled or participated in the acts and practices of KCD Holdings and KCD. His principal office or place of business is the same as that of KCD Holdings and KCD.

1.e. Proposed respondent Bonnie L. Richards is vice president, secretary and director of KCD Holdings and KCD. Individually or in concert with others, she formulates, directs, controls or participates in the acts and practices of KCD Holdings and KCD. Her principal office or place of business is the same as that of KCD Holdings and KCD.

1.f. Proposed respondent Gerald E. Hatto is an officer and the owner of Deerfield. Individually or in concert with others, he formulates, directs, controls or participates in the acts and practices of Deerfield. His principal office or place of business is the same as that of Deerfield.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.

3. Proposed respondents waive:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider

appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

## ORDER

### DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "KCD respondents" shall mean KCD Holdings, Inc. ("KCD Holdings"), KCD Incorporated ("KCD"), corporations, their successors and assigns and their officers; Clark M. Holcomb ("Holcomb"), individually and as a former officer of the corporations; Bonnie L. Richards ("Richards"), individually and as an officer of the corporations; and each of their agents, representatives and employees.

3. "Deerfield respondents" shall mean Deerfield Corporation ("Deerfield"), a corporation, its successors and assigns and its officers; Gerald E. Hatto ("Hatto"), individually and as an officer of the corporation; and each of their agents, representatives and employees.

4. Unless otherwise specified, "respondents" shall mean KCD Holdings, KCD and Deerfield, corporations, their successors and assigns and their officers; Holcomb, Richards and Hatto, individually and as officers or former officers of the corporations; and each of the above's agents, representatives and employees.

5. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. Section 44.

#### I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of SeQuester or any product or program, marketed or sold under any name, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such product or program prevents or reduces the body's absorption of fat or sugar from consumed food, unless the representation is true and, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

#### II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of SeQuester or any product or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that any such product or program:

- A. Provides any weight loss benefit;
- B. Causes greater loss of body fat than diet and exercise alone;
- C. Allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease or other health problems associated with a high-fat diet; or
- D. Reduces, or reduces the risk of, high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet,

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

### III.

IT IS FURTHER ORDERED that the KCD respondents, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of SeQuester or any product or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that any such product or program can be used, beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless, at the time the representation is made, the KCD respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

### IV.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of SeQuester or any product or program, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study or research.

### V.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division or other device, in connection with the labeling, advertising, promotion, offering for sale, sale or distribution of SeQuester or any product or program, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the benefits, performance, efficacy or safety of any such product or program unless, at the time the representation is made, respondents possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence, that substantiates the representation.

### VI.

IT IS FURTHER ORDERED that with respect to the Deerfield respondents, it shall be a defense to Sections I, II and V of this order that they neither knew nor had reason to know of an inadequacy of substantiation for any such representation; provided further that it shall be a defense to Section IV of this order that they neither knew nor had reason to know that the test, study or research did not prove, demonstrate or confirm that representation.

## VII.

IT IS FURTHER ORDERED that KCD Holdings, Inc., KCD Incorporated and Bonnie L. Richards, their successors and assigns, shall deposit into an escrow account, to be established by the Commission for the purpose of receiving payment due under this order (“escrow account”), the sum of one hundred and fifty thousand dollars (\$150,000). This payment shall be made in the following manner:

A. By certified or cashier’s check made payable to the Federal Trade Commission, in thirteen installments, the first installment of twenty-five thousand dollars (\$25,000) to be made no later than the date that this order becomes final; the next eleven payments of ten thousand, four hundred and sixteen dollars (\$10,416) to be made no later than the first day of each of the following eleven months; and the final installment of ten thousand, four hundred and twenty-four dollars (\$10,424) to be made no later than one year from the date that this order becomes final. The checks shall be deliverable to Regional Director, Federal Trade Commission, 915 Second Avenue, Suite 2896, Seattle, Washington 98174.

B. In the event of any default in payment, which default continues for ten (10) days beyond the due date of payment, the entire amount due, together with interest, as computed pursuant to 28 U.S.C. § 1961 from the date of default to the date of payment, shall immediately become due and payable.

C. In order to secure payment of respondents’ indebtedness to the Commission, within seven (7) days of the date that this order becomes final, respondents shall cause to be transferred to the Commission a security interest in the property described in Appendix A, which property has been determined by an independent appraisal to have a value of one hundred and twenty-five thousand dollars (\$125,000) or more in excess of all other perfected security interests, as security for the payments required to be made by respondents in Part VII(A) of this order. The respondents shall, within seven (7) days of the date that this order becomes final, file all documents necessary to perfect and record the Commission’s security interest in the property described in Appendix A, in conformity with appropriate state law. The respondents shall, within ten (10) days of the date that this order becomes final, furnish to counsel for the Commission complete documentation evidencing that the Commission’s security interest in the property described in Appendix A has been correctly perfected and recorded. The Commission will release this security interest upon receipt of all payments required by Part VII(A) of this order.

D. The funds paid by respondents, together with accrued interest, shall, in the discretion of the Commission, be used by the Commission to provide direct redress to purchasers of SeQuester in connection with the acts or practices alleged in the complaint, and to pay any attendant costs of administration. If the Commission determines, in its sole discretion, that redress to purchasers of this product is wholly or partially impracticable or is otherwise unwarranted, any funds not so used shall be paid to the United States Treasury. Respondents shall be notified as to how the funds are distributed, but shall have no right to contest the manner of distribution chosen by the Commission. No portion of

the payment as herein provided shall be deemed a payment of any fine, penalty or punitive assessment.

E. At any time after this order becomes final, the Commission may direct the escrow agent to transfer funds from the escrow account, including accrued interest, to the Commission to be distributed as herein provided. The Commission, or its representative, shall, in its sole discretion, select the escrow agent.

F. Respondents relinquish all dominion, control and title to the funds paid into the escrow account, and all legal and equitable title to the funds vests in the Treasurer of the United States and in the designated consumers. Respondents shall make no claim to or demand for return of the funds, directly or indirectly, through counsel or otherwise; and in the event of bankruptcy of respondents, respondents acknowledge that the funds are not part of the debtor's estate, nor does the estate have any claim or interest therein.

### VIII.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any drug under any tentative final or final standard promulgated by the Food and Drug Administration ("FDA"), or under any new drug application approved by the FDA.

### IX.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

### X.

IT IS FURTHER ORDERED that respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable written request make available to the Commission for inspection and copying:

- A. All advertisements or promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## XI.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors and managers, and to all current and future employees, agents and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order, such statements to be retained by respondents for a period of five (5) years. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

## XII.

IT IS FURTHER ORDERED that respondents KCD Holdings, KCD and Deerfield, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

## XIII.

IT IS FURTHER ORDERED that respondents Holcomb, Richards, and Hatto shall, for a period of five (5) years after the date of issuance of this order, notify the Commission within thirty (30) days of the discontinuance of their current business or employment, and of their affiliation with any new business or employment. The notice shall include the respondents' new business addresses and telephone numbers, current home addresses, and a description of the nature of the business or employment and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

## XIV.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after the date of

service of this order, and at other such times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XV.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 199\_\_

KCD HOLDINGS, INC. AND KCD,  
INCORPORATED

\_\_\_\_\_  
By:  
President and Chief Executive Officer

DEERFIELD CORPORATION

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By: GERALD E. HATTO  
Officer and Principal

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CLARK M. HOLCOMB, individually and as a former officer of KCD Holdings, Inc., and KCD, Incorporated

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BONNIE L. RICHARDS, individually and as an officer of KCD Holdings, Inc., and KCD, Incorporated

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GERALD E. HATTO, individually and as an officer and principal of Deerfield Corporation

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Attorney for Respondents

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NADINE S. SAMTER  
Counsel for the Federal Trade  
Commission

APPROVED:

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CHARLES A. HARWOOD  
Regional Director  
Seattle Regional Office

[Confidential Appendix A redacted.]



place of business at 2835 Townsgate Road, Suite 110, Westlake Village, California 91361. KCD is a wholly owned subsidiary of KCD Holdings.

3. Respondent Deerfield Corporation ("Deerfield") is a California corporation with its principal office or place of business at 1455 Valley High Avenue, Thousand Oaks, California 91359. Respondent Deerfield is now and has been at all times relevant to this complaint an advertising agency of KCD and KCD Holdings.

4. Respondent Clark M. Holcomb ("Holcomb") was the president, director and a majority shareholder of KCD Holdings and KCD from November 1993 through April 1996. Individually or in concert with others, he has formulated, directed, controlled or participated in the acts and practices of KCD Holdings and KCD, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of KCD Holdings.

5. Respondent Bonnie L. Richards ("Richards") is vice president, secretary, and director of KCD Holdings and KCD. Individually or in concert with others, she formulates, directs, controls or participates in the acts and practices of KCD Holdings and KCD, including the acts and practices alleged in this complaint. Her principal office or place of business is the same as that of KCD Holdings.

6. Respondent Gerald E. Hatto ("Hatto") is an officer and the owner of Deerfield. Individually or in concert with others, he formulates, directs, controls or participates in the acts and practices of Deerfield Corporation, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Deerfield.

7. Respondents have advertised, labeled, offered for sale, sold and distributed products to the public, including SeQuester, an over-the-counter fat reduction and weight-loss tablet. SeQuester is a "food" and/or "drug," within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

8. Since at least May 1994, respondents KCD, KCD Holdings, Holcomb and Richards ("KCD respondents") have advertised, distributed and sold an over-the-counter fat reduction and weight-loss product to the public through, among other means, newspaper and radio advertisements disseminated nationally. The KCD respondents have wholesaled this product to retail drug stores and other retailers for resale to the general public. The product, sold under the name "SeQuester," is a combination of fiber and ox bile extract.

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

10. The KCD respondents have prepared and disseminated or have caused to be disseminated advertisements for SeQuester, including but not necessarily limited to the attached Exhibits A through E. Respondents Deerfield and Hatto have prepared and disseminated or have caused to be disseminated advertisements for SeQuester, including but not necessarily limited to the attached Exhibits A through C and E. These advertisements contain the following statements and depictions:

A.

**THIS  
IS WHAT  
SEQUESTER  
DOES TO  
THE FAT  
IN FOOD  
YOU  
EAT**

Introducing SeQuester - the revolutionary tablet that “shrinks” the amount of dietary fat your body absorbs.

SeQuester is a lab-tested formula that neutralizes fat in the food you eat - safely and naturally - *before* it's absorbed, so it won't wind up on your body.

SeQuester's unique, patented ingredients bind fat molecules to vegetable fiber passing them gently and harmlessly through your digestive tract. It's like you never ate them at all. Shrink fat with SeQuester. Take advantage of introductory savings, and discover the safe, natural approach to fat reduction. It's in the diet section, today.

(Exhibit A -- newspaper advertisement)

B. **THE FAT STOPS HERE**

Dietary fat is a prime cause of overweight, heart disease, high cholesterol, and other major health problems. So imagine a tablet that can “shrink” the amount of fat your body absorbs.

Imagine SeQuester. A revolutionary discovery that lets you “remove” fat from the food you eat before it's absorbed, so it won't wind up on your body. Or in your arteries.

SeQuester is a safe, natural, lab-tested formula, shown to be effective in lowering fat absorption. It's easy. Just take one or more SeQuester tablets 30 minutes before meals. Its unique, patented formula binds fat molecules to natural vegetable fiber (as illustrated), passing it gently and harmlessly through your digestive tract.

SeQuester is intended for use as part of a program of sensible nutrition and exercise. Unlike fad diets that are ineffective at best, unhealthy at worst, SeQuester contributes to a safe, gradual loss of body fat and weight significantly better than what you're likely to accomplish through dieting and exercise alone.

So get control of fat, before fat controls you. Take advantage of our introductory savings on SeQuester, and experience for yourself this patently superior approach to fat reduction. Look for SeQuester in the diet section, today.

(Exhibit B -- newspaper advertisement)

C. For the holidays, don't cut it all out.  
**Just take SeQuester.**

**SEQUESTER REDUCES FAT FROM THE FOOD YOU EAT.**

Don't look now, weight watchers, but the holidays are gaining on us. So many parties, so much good food, so hard to say, "no." So consider your choices:

Either you can cut out all those rich, delicious foods that make life worthwhile.

Or you can cut out this coupon and introduce yourself to SeQuester - a revolutionary discovery that helps your body minimize fat retention from the food you eat.

With SeQuester, you can plan on enjoying reasonable portions of all those great holiday foods, confident that their entire fat content won't be showing up on your scale - or in your arteries - come January 1st.

SeQuester is a safe, natural dietary supplement. Its unique, patented formula helps bind fat molecules to natural vegetable fiber, so they pass gently and effortlessly through the digestive tract. Just take one or more tablets 30 minutes before meals.

This season, make SeQuester the centerpiece of all your holiday meals. You'll find it in better drugstores and supermarkets, everywhere.

*NOTE: SeQuester is intended for use as part of a complete program of sensible nutrition and moderate exercise. By following this program, studies suggest that SeQuester contributes to a safe, gradual loss of body fat and weight significantly more successful than dieting and exercise alone.*

(Exhibit C -- newspaper advertisement)

D. . . . .

**Q. SHOULD I INCREASE MY DOSAGE?**

**A:** After two or three days, increase your dosage to 2 tablets prior to your largest and fattiest meal of the day. If no diarrhea results from 2 tablets at your largest meal, you may choose to use 2 tablets before every meal. Some people will even use 3 or more SeQuester tablets prior to their fattiest meal. If diarrhea occurs, it is controllable. It does not require medication or any treatment. It just means that there is too much fat in your stool to allow a normal bowel movement. This actually is a condition we regard as desirable as it means the fat is leaving your body.

Whatever is appropriate for you depends upon how your body responds to lesser dosages, and upon the advice of your physician.

.....

(Exhibit D -- product package insert)

E. **SeQuester**  
Natural Nutritional Fat Sequestrant\*

\*SeQuester is a specially formulated patented product which, when used as directed, reduces fat and sugar from the foods you eat.

Tests have shown SeQuester effects metabolizable energy, thus increasing fecal energy (calorie) excretion and reduces hunger feelings without increasing total calorie intake.

(Exhibit E -- product package label)

**The KCD Respondents**

11. Through the means described in Paragraph 10, the KCD respondents have represented, expressly or by implication, that:

- A. SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.
- B. SeQuester significantly reduces the body's absorption of sugar from consumed food.
- C. Scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.
- D. Scientific research demonstrates that SeQuester causes significant weight loss.

12. In truth and in fact:

- A. SeQuester does not prevent or significantly reduce the body's absorption of fat from consumed food.
- B. SeQuester does not significantly reduce the body's absorption of sugar from consumed food.
- C. Scientific research does not demonstrate that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.
- D. Scientific research does not demonstrate that SeQuester causes significant weight loss.

Therefore, the representations set forth in Paragraph 11 were, and are, false or misleading.

13. Through the means described in Paragraph 10, the KCD respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 11(A) and(B), at the time the representations were made.

14. In truth and in fact, the KCD respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 11(A) and (B), at the time the representations were made. Therefore, the representation set forth in Paragraph 13 was, and is, false or misleading.

15. Through the means described in Paragraph 10, the KCD respondents have represented, expressly or by implication, that:

- A. SeQuester causes significant weight loss.
- B. Use of SeQuester allows consumers to eat high-fat foods without gaining weight.
- C. SeQuester causes significantly greater loss of weight and body fat than diet and exercise alone.
- D. Use of SeQuester allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet.
- E. SeQuester reduces the risk of high cholesterol, clogged arteries, heart disease, and other health problems associated with a high-fat diet.
- F. Use of SeQuester in amounts sufficient to cause diarrhea is beneficial and safe.

16. Through the means described in Paragraph 10, the KCD respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 15, at the time the representations were made.

17. In truth and fact, the KCD respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 15, at the time the representations were made. Therefore, the representation set forth in Paragraph 16 was, and is, false or misleading.

**Respondents Deerfield and Hatto**

18. Through the means described in Paragraph 10, including but not limited to the advertisements attached as Exhibits A through C and E, respondents Deerfield and Hatto have represented, expressly or by implication, that:

- A. SeQuester causes significant weight loss.

- B. Use of SeQuester allows consumers to eat high-fat foods without gaining weight.
- C. Use of SeQuester allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet.
- D. SeQuester prevents or significantly reduces the body's absorption of fat from consumed food.
- E. SeQuester reduces the risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet.
- F. SeQuester significantly reduces the body's absorption of sugar from consumed food.

19. Through the means described in Paragraph 10, including but not limited to the advertisements attached as Exhibits A through C and E, respondents Deerfield and Hatto have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 18, at the time the representations were made.

20. In truth and in fact, respondents Deerfield and Hatto did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 18, at the time the representations were made. Therefore, the representation set forth in Paragraph 19 was, and is, false or misleading.

21. Through the means described in Paragraph 10, including but not limited to the advertisements attached as Exhibits A through C and E, respondents Deerfield and Hatto have represented, expressly or by implication, that scientific research demonstrates that SeQuester:

- A. Prevents or significantly reduces the body's absorption of fat from consumed food.
- B. Causes significant weight loss.

22. In truth and in fact, scientific research does not demonstrate that SeQuester:

- A. Prevents or significantly reduces the body's absorption of fat from consumed food.
- B. Causes significant weight loss.

Therefore, the representation set forth in Paragraph 21 was, and is, false or misleading.

23. Respondents Deerfield and Hatto knew or should have known that the representations set forth in Paragraphs 18, 19 and 21 were, and are, false or misleading.

24. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of

Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this \_\_\_\_\_ day of \_\_\_\_, 1997, has issued this complaint against respondents.

By the Commission.

Donald S. Clark  
Secretary

SEAL:

[Exhibits A-E attached to paper copies of complaint, but not available in electronic form.]

## **ANALYSIS OF PROPOSED CONSENT ORDERS TO AID PUBLIC COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, agreements to proposed consent orders from KCD, Incorporated (“KCD”) and KCD Holdings, Inc. (“KCD Holdings”), their former officer, Clark M. Holcomb (“Holcomb”), and their current officer, Bonnie L. Richards (“Richards”) (hereinafter “KCD respondents”), their advertising agency, Deerfield Corporation (“Deerfield”), and its owner, Gerald E. Hatto (“Hatto”). The KCD respondents market and sell an over-the-counter weight loss product, known as SeQuester, comprised of fiber and ox bile. The product advertisements have represented that the product reduces the body’s absorption of fat and sugar from consumed food, thereby providing weight loss and cholesterol lowering benefits. Respondents Deerfield and Hatto assisted in the creation and dissemination of the SeQuester advertisements.

The Commission has also accepted, subject to final approval, agreements to proposed consent orders from Interactive Medical Technologies, Ltd. (“IMT”), its wholly owned subsidiary, Effective Health, Inc. (“EHI”), William Pelzer, Jr. (“Pelzer”), a former officer of IMT and EHI, and William E. Shell, M.D. (“Shell”), also a former officer of IMT (hereinafter “IMT respondents”). These respondents marketed and sold an over-the-counter weight loss product, known as Lipitrol, also comprised of fiber and ox bile. The Lipitrol product advertisements represented that the product reduced the body’s absorption of fat from consumed food, thereby providing weight loss and cholesterol lowering benefits. The IMT respondents also provided means and instrumentalities or substantial assistance to the KCD respondents’ marketing and sale of SeQuester.

The proposed consent orders have been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreements and take other appropriate action or make final the proposed orders contained in the agreements.

### The Proposed Complaints

The Commission’s complaint against the KCD respondents, Deerfield and Hatto, charges these respondents with making false and unsubstantiated claims, in advertising and promotional materials, regarding the efficacy of SeQuester as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that the KCD respondents falsely represented, expressly or by implication, that SeQuester prevents or significantly reduces the body’s absorption of fat and sugar from consumed food. The complaint also charges that these respondents failed to possess and rely upon a reasonable basis for these representations. The complaint further alleges that these respondents made false and deceptive

representations that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss.

In addition, the complaint alleges that the KCD respondents have represented that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; causes significantly greater weight loss than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and is beneficial and safe when used in amounts sufficient to cause diarrhea. The complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

The complaint also alleges that Deerfield and Hatto have represented, expressly or by implication, that SeQuester causes significant weight loss; allows consumers to eat high-fat foods without gaining weight; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet; prevents or significantly reduces the body's absorption of fat and sugar from consumed food; reduces the risk of high cholesterol, clogged arteries, heart disease and other problems associated with a high-fat diet; and significantly reduces the body's absorption of sugar from consumed food. The complaint charges that Deerfield and Hatto did not possess and rely upon a reasonable basis for these representations. The complaint further alleges that Deerfield and Hatto falsely represented that scientific research demonstrates that SeQuester prevents or significantly reduces the body's absorption of fat from consumed food and causes significant weight loss. The complaint also charges that respondents Deerfield and Hatto knew or should have known that these representations were false and misleading.

The Commission's complaint against the IMT respondents charges IMT, EHI and Shell, with making false and unsubstantiated advertising claims regarding the efficacy of Lipitrol as a weight loss, fat reduction and cholesterol reduction product. Specifically, the complaint alleges that IMT, EHI and Shell falsely represented, either expressly or by implication, that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, and absorbs approximately 5.9 grams of fat per tablet from consumed food. The complaint also charges that respondents IMT, EHI and Shell failed to possess and rely upon a reasonable basis for these representations. The complaint further alleges that these respondents made false and deceptive representations that scientific research demonstrates that Lipitrol prevents or significantly reduces the body's absorption of fat from consumed food, absorbs approximately 5.9 grams of fat per tablet from consumed food, causes significant weight loss and lowers blood cholesterol levels.

In addition, the complaint alleges that respondents IMT, EHI and Shell have represented that Lipitrol causes significant weight loss; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high

blood pressure, diabetes, breast cancer and heart disease; causes significantly greater weight loss than diet and exercise alone; and is beneficial and safe when taken in amounts sufficient to cause diarrhea. The complaint charges that these respondents did not possess and rely upon a reasonable basis for these representations.

Respondent William Pelzer, Jr. is not included in the above-mentioned allegations because he had no involvement in the advertising, marketing or sale of Lipitrol.

In addition, the complaint charges that the IMT respondents, including respondent Pelzer, provided means and instrumentalities and/or substantial assistance to others who respondents knew or should have known were making false and deceptive or unsubstantiated claims for the product, sold under the name SeQuester. Specifically, the complaint alleges that the respondents licensed to KCD, its holding company, KCD Holdings, those companies' former principal, Holcomb, and current principal, Richards, the exclusive rights to market the product.

The complaint alleges that the IMT respondents knew or should have known that the KCD respondents made false and deceptive or unsubstantiated representations similar to those made for Lipitrol, in advertisements for SeQuester. The complaint charges that despite the fact that respondents knew or should have known that KCD was making the false and deceptive, and/or unsubstantiated representations in the marketing and sale of SeQuester, the IMT respondents nevertheless provided various services and promotional materials to the KCD respondents in furtherance of the KCD respondents' efforts to disseminate these false claims, including providing the KCD respondents with studies purporting to show that SeQuester effectively reduces the body's absorption of fat from consumed food and causes significant weight loss; the licensing rights to market and sell the product to consumers; technical information regarding the product; and various promotional materials and information for marketing the product.

### The Proposed Orders

The Commission has accepted four separate consent orders in this matter. The proposed orders contain provisions designed to remedy the alleged violations. The proposed orders against respondents KCD Holdings, Inc., KCD, Incorporated and Bonnie L. Richards; IMT and EHI; and Shell provide for the payment of consumer redress in installments over a period of one year from the date the proposed orders become final. In the event that consumer redress is not feasible, the proposed orders provide that the funds will be deposited in the United States Treasury. In addition, the proposed order against respondent Shell requires him to post a performance bond of either \$250,000 or \$1,000,000, depending on the circumstances of his activities.

## Proposed Consent Order with the KCD Respondents, Deerfield and Hatto

Part I of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from making representations that SeQuester or any product or program prevents or reduces the body's absorption of fat or sugar from consumed food unless the representation is true at the time it is made and is supported by competent and reliable scientific evidence.

Part II of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from representing that SeQuester or any product or program provides any weight loss benefit; causes greater loss of body fat than diet and exercise alone; allows consumers to eat high-fat foods without increasing their risk of high cholesterol, clogged arteries, heart disease or other health problems associated with a high-fat diet; or reduces, or reduces the risk of, high cholesterol, clogged arteries, heart disease and other health problems associated with a high-fat diet, unless respondents can substantiate these representations with competent and reliable scientific evidence.

Part III of the proposed consent order against the KCD respondents prevents them from representing that SeQuester or any product or program can be used beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless, at the time the representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates the representation, which when appropriate, must be competent and reliable scientific evidence.

Part IV of the proposed consent order against the KCD respondents, Deerfield and Hatto bars them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research. Part V of the proposed consent order against the KCD respondents, Deerfield and Hatto prohibits them from making representations about the benefits, performance, efficacy or safety of SeQuester or any product or program unless competent and reliable evidence substantiates any such representation.

Part VI of the proposed consent order against the KCD respondents provides Deerfield and Hatto with a defense to Parts I, II and V of the order if they neither knew nor had reason to know of an inadequacy of substantiation for any representation covered by those parts of the order; and a defense to Part IV of the order if they neither knew nor had reason to know that the test, study or research did not prove, demonstrate or confirm any representation covered by that part of the order.

Part VII of the proposed order against the KCD respondents requires KCD, KCD Holdings and Richards to pay \$150,000 in consumer redress, in thirteen installments over a period of one year. If consumer redress is impracticable, Part VII provides that these funds will be paid to the United States Treasury. Part VII(C) requires KCD, KCD Holdings and Richards to provide the Commission with a security interest in certain property to insure full payment of the \$150,000 of consumer redress.

Parts VIII and IX of the proposed order against the KCD respondents, Deerfield and Hatto contain provisions permitting certain claims that are approved for labeling by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under any new drug application approved by the FDA.

Parts X, XI, XII, XIII and XIV of the proposed order against the KCD respondents, Deerfield and Hatto contain compliance reporting provisions requiring respondents to: retain records that bear on their compliance with the order; distribute copies of the order to those persons having responsibility with respect to the subject matter of the order; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the order, or any changes in the business affiliations of the individual respondents; and report to the Commission their compliance with the terms of the order.

Part XV of the proposed order against the KCD respondents, Deerfield and Hatto contains a provision automatically terminating the order twenty (20) years from the date that it becomes final.

#### Proposed Consent Order with IMT, EHI, Shell and Pelzer

Part I of the proposed consent order against respondents IMT and EHI bars them from making representations that Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program prevents or reduces the body's absorption of fat from consumed food or absorbs any amount of fat from consumed food unless the representation is true and supported by competent and reliable scientific evidence. Part I of the proposed order against respondent Shell contains the same bar, but covers representations for Lipitrol or any product or program.

Part II of the proposed order against respondents IMT and EHI prohibits them from representing that Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement, provides any weight loss benefit; lowers blood cholesterol levels; reduces, or reduces the risks associated with, high cholesterol, including clogged arteries, high blood pressure, diabetes, breast cancer and heart disease; or can be used, beneficially and safely, in amounts or with frequency sufficient to cause diarrhea, unless respondents can substantiate these representations with competent and reliable scientific evidence. Again, the same prohibition is contained in Part II of the proposed order against respondent Shell, but covers representations for Lipitrol or any product or program.

Part III of the proposed order against respondents IMT and EHI prohibits them from misrepresenting the existence, contents, validity, results, conclusions or interpretations of any test, study or research in connection with Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement. Part IV of the proposed order prohibits respondents IMT and EHI from making representations about the

benefits, performance, efficacy or safety of Lipitrol or any weight loss, fat reduction or cholesterol reduction product or program, or any food, drug or dietary supplement unless competent and reliable scientific evidence substantiates any such representation. Parts III and IV of the proposed order against respondent Shell are the same except that the prohibitions apply to representations for Lipitrol or any product or program.

Part V of the proposed orders against respondents IMT, EHI and Shell, and Part I of the proposed order against respondent Pelzer, bars each of these respondents from providing means and instrumentalities or substantial assistance or support to any person or entity who they know or should know is making any false or misleading or unsubstantiated claim for any weight loss, fat reduction or cholesterol reduction product or program. The proposed orders define “assistance” to include providing: tests, analyses, studies or research to determine the benefits, performance, efficacy or safety of the product or program; licensing or other contractual rights to market any such product or program; technical assistance; or advertising, labeling or promotional materials for the marketing and sale of any such product or program.

Part VI of the proposed orders against respondents IMT, EHI and Shell, and Part II of the proposed order against respondent Pelzer, require these respondents to monitor business practices of certain parties to whom they provide assistance. To the extent that any such party is engaged in the marketing and sale of any weight loss, fat reduction or cholesterol reduction product or program, these respondents must make an effort to determine whether false or misleading or unsubstantiated claims are being made with respect to any such product or program. Specifically, these respondents must review all advertisements and promotional materials and all tests, reports, studies, surveys, demonstrations or other evidence that any such person relies upon in making any claims to consumers. In addition, these respondents are required to terminate their business relationship with any person whom they know or should know is making any false or misleading or unsubstantiated claims.

Part VII of the proposed order against respondents IMT and EHI requires them to pay \$35,000 in consumer redress in three installments over a period of one year. If consumer redress is impracticable, Part VII provides that these funds will be paid into the United States Treasury. Part VII(C) requires IMT and EHI to provide the Commission with a security interest in certain property to insure full payment of the \$35,000 of consumer redress.

Part VII(A)(1) and (2) of the proposed order against respondent Shell requires him to obtain a performance bond for \$1,000,000 before he markets, sells or holds any ownership interest or official position in any business that advertises or sells Lipitrol or any other weight loss, fat reduction or cholesterol reduction product composed of fiber and bile extract. Part VII(A)(3) and (4) of the proposed order also requires respondent Shell to obtain a performance bond of \$250,000 before he markets, sells or holds an ownership interest or official position in any business that advertises or sells any weight loss, fat reduction or cholesterol reduction product or program to consumers, other than his treatment of patients in connection with his private medical practice. Parts VII(B) through (F) require respondent Shell to provide a copy

of the bond to the FTC; prohibit him from disclosing the existence of the bond to any consumer; and describe the period during which the bond must remain effective, the bond's coverage, the bond's potential beneficiaries and certain other administrative requirements.

Part VIII of the proposed order against respondent Shell requires him to pay consumer redress in the amount of \$20,000 in four installments over a period of one year. In the event that consumer redress is impracticable, this Part provides that these funds will be paid into the United States Treasury. Part VIII(C) requires Shell to provide the Commission with a security interest in certain property to insure full payment of the \$20,000 of consumer redress.

Parts VIII and IX of the proposed order against respondents IMT and EHI, Parts IX and X of the proposed order against respondent Shell, and Parts III and IV of the proposed order against respondent Pelzer, contain provisions permitting certain claims that are approved for labels by the FDA, either under the Nutrition Labeling and Education Act, a tentative final or final monograph or under any new drug application approved by the FDA.

Parts X, XI, XII and XIII of the proposed order against respondents IMT and EHI, Parts XI, XII, XIII and XIV of the proposed order against respondent Shell, and Parts V, VI, VII and VIII of the proposed order against respondent Pelzer, contain compliance reporting provisions requiring these respondents to: retain all records that would bear on their compliance with the respective orders; notify the Commission of any changes in the structure of the corporate respondents that may affect their compliance obligations under the orders, or any changes in the business affiliations of the individual respondents relating to the advertising, offering for sale, sale or distribution of any weight loss, fat reduction or cholesterol reduction product or program; distribute copies of the orders to those persons having responsibility with respect to the subject matter of the respective orders; and report to the Commission their compliance with the terms of the respective orders.

Part XIV of the proposed order against respondents IMT and EHI, Part XV of the proposed order against respondent Shell, and Part IX of the proposed order against respondent Pelzer contain a provision automatically terminating the orders twenty (20) years from the date that they become final.

The purpose of this analysis is to facilitate public comment on the proposed orders. It is not intended to constitute an official interpretation of the agreements and proposed orders or to modify their terms in any way.