

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

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IN RE: NEW YORK DIET DRUG LITIGATION

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THIS DOCUMENT APPLIES TO ALL DIET DRUG
CASES VENUED IN NEW YORK COUNTY

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Index No: 700000/98

CASE MANAGEMENT
ORDER NO. 7

February 10, 1999

Uniform Discovery of the "Phentermine" Defendants

Pursuant to Case Management Order No. 1 ("CMO No. 1") entered in these coordinated cases on May 28, 1998, this Court, inter alia, established steering committees, and joint subcommittees, of plaintiffs' and defendants' counsel to develop uniform pleadings and discovery requests to be used in these cases. The Plaintiffs' Discovery Subcommittee has reached agreement regarding written discovery with SmithKline Beecham Corp., Medeva Pharmaceuticals Manufacturing, Inc., Medeva Pharmaceuticals, Inc., Fisons Corporation, Gate Pharmaceuticals, a Division of Teva Pharmaceuticals, USA Inc., Goldline Laboratories Inc., Eon Labs Manufacturing Inc., Shire Richwood Inc., f/k/a Richwood Pharmaceuticals Company, Inc., a division of Rexar Pharmacal, Ion Laboratories, Inc., Jones Medical Industries, f/k/a Abana Pharmaceuticals, Inc., Qualitest Pharmaceuticals Inc., and United Research Laboratories, Inc.

This Order and the matters set forth herein pertaining to the production of documents and responses to interrogatories by the Phentermine Defendants, as defined herein, shall apply to and be binding on all parties in the New York Diet Drug Litigation cases which are presently or hereafter assigned to the undersigned.

A. Documentary Discovery of the Phentermine Defendants

1. For purposes of this Case Management Order, the Phentermine Defendants shall be defined as including the following business entities: SmithKline Beecham Corp., Medeva Pharmaceuticals Manufacturing, Inc., Medeva Pharmaceuticals, Inc., Fisons Corporation, Gate Pharmaceuticals, a Division of Teva Pharmaceuticals, USA Inc., Goldline Laboratories Inc., Eon Labs Manufacturing Inc., Shire Richwood Inc., f/k/a Richwood Pharmaceuticals Company, Inc., a division of Rexar Pharmacal, Ion Laboratories, Inc., Jones Medical Industries, f/k/a Abana Pharmaceuticals, Inc., Qualitest Pharmaceuticals Inc., United Research Laboratories Inc., and any phentermine manufacturers and/or distributors who become subject to jurisdiction of this Court in the NYDDL.

2. The Phentermine Defendants will produce within twenty (20) days of the entry of this order one set of documents which they have already produced in other Diet Drug Litigations (other than any inadvertently produced material) to the Plaintiffs' Steering Committee in the New York Diet Drug Litigation. The Phentermine Defendants shall also produce a log of documents withheld on the basis of privilege or other protection. The Plaintiffs' Steering Committee shall pay the reasonable costs of copying (including copying of any compact disc as set forth herein subject to the terms of paragraph 3, herein). To the extent they have not already received the same document production in other litigations from each Phentermine Defendant, the other defendants to any action shall be entitled to receive the same document production as the Plaintiff's Steering Committee is going to receive and agree to pay the reasonable costs of copying (including copying of any compact disc as described in paragraph 3 herein).

3. Many of their documents being produced pursuant to paragraph A.2. of this Order

have been imaged by Phentermine Defendants in single page TIFF format and stored on compact disc ("CD ROM") in a computer readable form. All documents to be produced pursuant to Paragraph 2 of this Order which have been imaged and stored on CD ROM shall be produced by the Phentermine Defendants to the Plaintiffs' Steering Committee, and to the other Defendants, if applicable, in CD ROM form only. All documents produced by the Phentermine Defendants which are not available in CD ROM form will be produced in hard copy (paper) form. Each Phentermine Defendant will provide any and all necessary information as to the format in which data is stored so as to allow access to documents by plaintiffs. Each defendant shall provide plaintiffs and, if applicable, the other defendants with an index of what is contained on each disc provided to Plaintiffs' Steering Committee, including Bates Number ranges. This obligation may be satisfied by providing objective bibliographic coding which will include, as may be applicable, (i) bates number range, (ii) number of pages, (iii) date, (iv) author, (v) recipients, (vi) copies, (vii) actual title, if any (viii) document type, and (ix) attachment ranges for each document. No Phentermine Defendant is obligated to provide coding except as may be separately agreed to by Plaintiffs' Steering Committee and that particular defendant and as may be separately agreed to by the other defendants and that particular defendant. In the event that a Phentermine Defendant makes objective coding available to the Plaintiffs' Steering Committee, such defendant will make that coding available to other defendants on comparable terms.

4. Any objective coding that is being provided is solely to assist the parties in these cases in reviewing the underlying documents. By producing bibliographic coding for such use by the parties, the Phentermine Defendants do not represent that the coded information is complete and accurate. In addition, neither the provision of the coding or coded information

shall constitute a waiver of any privilege or work product protection for any document, nor shall the provision of such coding constitute an admission of any kind by the Phentermine Defendants. Without limiting the generality of the foregoing, the coding provided shall not be admissible in any case subject to this Order.

B. Interrogatories

1. Within sixty (60) days after entry of this Order, the Phentermine Defendants' responses to interrogatories served by plaintiffs shall be filed in the Master File created for these cases by CMO No. 1 and shall be deemed made in each of the cases to which the **New York State Diet Drug Litigation** Master File and this Order now or hereafter applies. If any additional Phentermine Defendants become subject to the jurisdiction of this Court after the signing of this order, responses to interrogatories served by plaintiffs shall be filed in the Master File within sixty (60) days. Copies of said interrogatories are annexed hereto as Exhibit 1.

2. The entry of this Order is without prejudice to (i) the rights of the parties or any one of them to challenge by appropriate motion the withholding or redaction of such information by the Phentermine Defendants as provided for in paragraph C.3 hereof, or (ii) the rights of the Phentermine Defendants or any of them to oppose any such motion.

C. Other Matters

1. Any and all prior written discovery requests directed to the Phentermine Defendants, including any interrogatories and notices for discovery and inspection, are deemed withdrawn. Notwithstanding anything in this Order to the contrary, the Plaintiffs' Steering Committee reserves its right to serve a demand for a bill of particulars addressed to the Phentermine Defendants' affirmative defenses.

2. The foregoing discovery shall apply to and be binding on all parties in the New York Diet Drug Litigation as the discovery of the Phentermine Defendants in the nature of document requests, interrogatories and the like. If any party desires to propound additional limited, non-repetitive interrogatories pertaining to matters about which discovery cannot be obtained by other means and/or discovery which is specific in nature to New York, such party must first consult with its respective steering committee (to avoid duplicative or otherwise inappropriate requests) and the Phentermine Defendants. Unless such party's respective steering committee and the Phentermine Defendants agree, such additional requests may not be served without leave of the Court for good cause shown on motion made in accordance with CMO No.

1. To the extent the Phentermine Defendants respond or are ordered to respond to any such additional interrogatories or requests for documents, they may do so by reference to documents and are not required to provide specific Bates number ranges.

3. The entry of this Order is without prejudice to the rights of the parties or any one of them to challenge by appropriate motion the withholding or redaction of such information by the Phentermine Defendants. In the event a party wishes to dispute the withholding or redaction of information, such party shall notify the Phentermine Defendants in writing, specifying the nature of the dispute. If the parties are unable to amicably resolve the dispute, the disputing party may apply by motion to the Court for a ruling as to whether the withheld or redacted information may, in accordance with the law of New York, properly be withheld or redacted.

4. Plaintiffs' Liaison Counsel is hereby directed to serve a copy of this Order with

notice of entry on all counsel who have appeared in these actions.

SO ORDERED.

Dated: New York, New York
February 10, 1999



Helen E. Freedman, J.S.C.

SUPREME COURT OF THE STATE OF NEW YORK
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Index No. 700000/98

Exhibit No. 1
Case Management Order No. 7

Hon. Helen E. Freedman,

**Plaintiffs' Steering Committee's Proposed Interrogatories
to the "Phentermine" Defendants.**

DEFINITIONS

Communication The term "communication" is intended to refer to any transmittal of information orally or in writing, excluding communications by and between counsel and their respective clients unless such communications were made in the course of seeking or rendering business rather than legal advice. The term "communication" also excludes individual patient medical records.

Side Effects

The term "side effect" means any adverse effect that is associated with the administration of a therapy or medication. "Adverse" means unfavorable.

Notification

The term notification is meant to encompass any communication in any form (written, mail, electronic, etc.) from the defendant to any other person or entity containing recommendations or advice concerning the usage, prescription or properties of defendant's diet drugs.

Document

The term "document" is intended to encompass the following: Any medium by which information is recorded, stored, communicated or utilized, including papers (of any kind, type or character) and any method or medium by which information may be communicated, recorded or retrieved by people or by computers. The term includes, without limitation, photographs, photostats, x-rays, motion pictures, audiotape, videotape recordings, computer generated material (including e-mail), computer disks, CD-ROMs, computer tapes, and any other form or type of computer stored or retrievable computer data, microfilm and microfiche or any other process by which information is reduced for storage or use. It is not intended to include any written communication between counsel and their respective clients unless such communication was made in the course of rendering business rather than legal advice.

If the document or information is to be produced in a computer-readable form, specify any software, hardware or information such as passwords or user-supplied files that are required in order to examine and use the information contained on the disks.

Fenfluramine, Dexfenfluramine and/or Phentermine Products

The term *fenfluramine, dexfenfluramine and/or phentermine* products is intended to refer to any products containing fenfluramine, dexfenfluramine and/or phentermine, whether used singly or in combination for the treatment of obesity or any other health condition.

Study or Test

The terms *study or test* are intended to include pre-clinical (animal) and clinical (human) testing, tests conducted on tissue or blood samples, and epidemiological investigations. They are

intended to include information and data acquired from such studies or tests regardless of the stated or original purpose of the study or test.

A request for information concerning a test or study that has been completed should be construed as including the following documents: the protocol for the conduct of the test/study, any amendment to the protocol, documents containing the original raw test/study data, documents containing the written test/study report and all attachments thereto, any summary, abstract, analysis, compilation, including evaluation or interpretation of the test/study and all investigators or entities, universities and/or laboratories involved in the testing.

Labeling

The term "labeling" includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. "Label" means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity. 21 CFR §1.3.

Relevant Time Period

The relevant time period for these discovery requests is January 1, 1990, through September 15, 1997, except as otherwise specified in a particular interrogatory.

You or Your, or the Defendant, or Said Defendant

Each of these terms or phrases refers to the defendant to whom the attached "Requests for

Discovery" is addressed and/or on whose behalf the response is being made. Where documents or other materials are requested, those materials are to be produced by you if in your possession, custody or control.

Employed By

Employed By is meant to encompass any relationship by which actions were performed or carried out on your behalf, or for your benefit, concerning the diet drugs in question.

Detail Person

The term detail person includes any and all persons engaged or employed by you for the purposes of direct field communications with physicians or other health care providers about the marketing and/or sale of fenfluramine, dexfenfluramine and/or phentermine. "Physicians or other Health Care Providers" includes, but is not limited to hospitals, clinics, out-patient centers, and diet or weight loss centers, whether these providers or centers are approved or not by any governmental or regulatory agency.

Redaction

If an interrogatory calls for a portion of documents which defendant believes are protected from disclosure pursuant to federal regulations, defendant shall identify by category or type the information redacted and the authority upon which redaction is based. Redactions shall occur in such a manner that the redacted portion is obvious on the face of the document.

INTERROGATORIES

1. When did you first manufacture, develop, distribute, market and or license phentermine in any form, for any use (i.e. animal studies, human clinical trials, etc.)?
 - A. Please identify with specificity when your involvement in each activity began.

2. Did you apply to the FDA for an NDA (New Drug Application), ANDA (abbreviated or amended New Drug Application) or an IND (Investigational New Drug) for phentermine, fenfluramine and/or dexfenfluramine?

3. If yes to interrogatory no. 2 above, please provide the following:
 - A. Date(s) of any such applications.
 - B. Produce with your answers a copy of any and all responses by FDA or other governmental agencies in response to the applications.
 - C. Identify the person(s), employee(s) or officer(s) who was/were responsible for communicating with the FDA about questions related to your IND Application and the NDA for fenfluramine, dexfenfluramine and/or phentermine to the FDA and identify all persons who communicated in writing to the FDA. In this connection, give such individual's name and state whether or not he/she is still employed by the Defendant Company.
 - D. State whether there were any comments, responses or opposition made to any applications for the drugs either in written form or in the form of testimony, from any source, and if so, please identify the objecting party and describe the sum and substance of the objection.
 - E. Please identify and produce with your answer all documents relating to

your response in D above.

4. If the answer to interrogatory no. 2 is yes, have you apprised, notified or advised the FDA that fenfluramine, dexfenfluramine and/or phentermine had any of the following side effects upon:

A. Animals;

B. Humans;

Side Effects:

1. Death;
2. Cardiac arrhythmias;
3. Aortic, mitral, tricuspid or pulmonic valve disease/injury;
4. Aortic, mitral, tricuspid or pulmonic valve regurgitation;
5. Shortness of breath;
6. Pulmonary insufficiency;
7. Pulmonary hypertension;
8. Any cardiac abnormality on echocardiogram, sonogram, doppler, stress tests, catheterization, or chest x-ray;
9. Increase in the left or right atrial and/or left or right ventricular size;
10. Deterioration in, or depressed left ventricular function;
11. Thickening of any valves;
12. Heart Fibrosis, Dilated, Hypertrophic or Restrictive Cardiomyopathy;
13. Mitral valve prolapse, mitral annular calcification;

14. Increased delivery of serotonin to the lungs;
15. Serotonin Dysfunctions or Reductions in serotonin axonal markers;
16. Brain Neurotoxicity;

5. If yes to interrogatory no. 4 above, identify:

- A. The side effects;
- B. If the effect(s) was/were in animals or humans or both;
- C. When the effect was first reported to you;
- D. How you became aware of such effect. (i.e. clinical trial, animal study, literature search, etc.);
- E. The name of anyone employed by you involved in the research, marketing, and/or development of your diet drugs to whom it was first reported, and the name of the person who reported it to you;
- F. The specific document (by date or other identifying means) in which the FDA was advised by you of such an effect;
- G. The specific part or page of that document that contained the first notification of such actual or potential adverse effect;
- H. Any response by FDA or any other governmental agency to such notification by you.

Please produce any and all documents responsive to this interrogatory.

6. At the time you filed any NDA, ANDA or IND, were you aware of any side effects of fenfluramine, dexfenfluramine and/or phentermine that you did not notify, apprise or

advise FDA about? (Answer this interrogatory only as to the side effects listed in Interrogatory No.4)

7. If yes to No. 6 above, for each side effect that you were aware of but did not notify, apprise or advise FDA about in an NDA, ANDA or IND, please specifically set forth the following:

- A. The side effects;
- B. If the effect was in animals or humans or both;
- C. When the effect was first reported to you;
- D. How you became aware of such effect. (i.e. clinical trial, animal study, literature search, etc.);
- E. The name of anyone employed by you involved in the research, marketing, and/or development of your diet drugs to whom it was first reported, and the name of the person who reported it to you;
- F. Any action taken by you in response to the information concerning the side effect that you received.
- G. Attach any and all responsive documents relating to any of your responses to this interrogatory.

8. What warnings or notifications, if any, did you provide to physicians concerning the use of fenfluramine, dexfenfluramine and/or phentermine during the following time periods:

- A. Before FDA approval

B. After FDA approval

Produce copies of any and all such warnings and notifications that relate to any of your responses. In your response, please also identify by year the pre-FDA approval period and the post-FDA approval period.

9. During or after the time that you marketed, sold, distributed or produced the diet drug medication in question, were you aware of any side effects for which you did not provide warnings or notifications to Health Care Providers, consumers, or any governmental agencies? (Answer this interrogatory only as to the side effects listed in Interrogatory No.4)

10. If the answer to interrogatory no. 9 above is yes, please identify:

A. The side effects;

B. If the effect was in animals or humans or both;

C. When the effect was first reported to you;

D. How you became aware of such effect. (i.e. clinical trial, animal study, literature search, etc.);

E. The name of anyone employed by you involved in the research, marketing, and/or development of your diet drugs to whom it was first reported, and the name of the person who reported it to you;

F. The identity of those individual(s) who made the decision whether or not to inform Health Care Providers, consumers, or governmental agencies of these side effects.

11. At any time did you learn that physicians or any prescribing entity in the United States or in any other country were prescribing fenfluramine and phentermine in combination for patients? If yes, please identify:

- A. When you first became aware that physicians were so prescribing these medications;
- B. How you first became aware of this practice;
- C. Any communications from you to any person concerning this practice;
- D. Any communications from any person to you concerning this practice;
- E. The name of the person or persons employed by you responsible for reviewing and evaluating ADEs for Pondimin & Redux during the relevant time period.

12. Have you received any communications (other than lawsuits filed in any jurisdiction or attorney claim letters) whether by letter, telegram, e-mail, telephone or in person from any entity either concerning the safety of fenfluramine, dexfenfluramine and/or phentermine, or seeking information related to any adverse side effects of these drugs?

If yes, please identify by name the individual(s) and/or company(ies) or institutions(s) who communicated with you, and if not in a written or reproducible format, describe the nature of such communication in detail. Produce any communications responsive to this interrogatory.

13. Have you received any communications (other than lawsuits filed in any jurisdiction or attorney claim letters) whether by letter, telegram, e-mail, telephone or in person from any entity stating that the dose and/or duration of use of your fenfluramine, dexfenfluramine and/or phentermine products described in the approved FDA labeling should be

changed or modified?

A. If yes, please identify by name the individual(s) and/or Company(ies) or institution(s) who communicated with you, and if not in a written or reproducible format, describe the nature of such communication in detail. Produce a copy of any communications responsive to this interrogatory.

14. Have you received any communications from any person (except from plaintiffs in lawsuits filed in any court and/or attorney claim letters) at any time since you first marketed, manufactured, sold or distributed these drugs concerning whether the following conditions are associated with the use of fenfluramine, dexfenfluramine and/or phentermine alone or in combination in humans:

- A. Death;
- B. Cardiac arrhythmias;
- C. Aortic, mitral, tricuspid or pulmonic valve disease/injury;
- D. Aortic, mitral, tricuspid or pulmonic valve regurgitation;
- E. Shortness of breath;
- F. Pulmonary insufficiency;
- G. Pulmonary hypertension;
- H. Any cardiac abnormality on echocardiogram, sonogram, doppler, stress tests, catheterization, or chest x-ray.
- I. Cognition, memory, modulation of mood, anxiety, impulsivity, aggression, sleep disturbance, pain, arousal, appetite, release of hormones or neuroendocrine function;

J. Depression, psychosis, exacerbation of pre-existing psychosis;

15. If the answer to interrogatory no. 14 above is yes, please indicate for each of the conditions listed (A-J), if the responsive information is presently unavailable or not in reproducible format:

A. How many communications you have received;

B. The date of each such communication;

C. The identity of the person(s) who made the communication to you;

D. The substance of each such communication;

E. If the responsive information is in written or reproducible format, produce a copy of each such communication;

F. For each communication identified in A-E above, state with specificity any and all actions taken by you in response.

16. Give the name of the person employed by you who supervised or was in charge of the safety and efficacy testing of the drug fenfluramine, dexfenfluramine and/or phentermine:

A. Before FDA approval;

B. After FDA approval;

C. Provide with your answer all organizational charts that reflect the supervisors at any level of the persons named in subparts A and B above.

17. Are you or any person employed by you currently performing any testing or studies on fenfluramine, dexfenfluramine and/or phentermine to determine whether or not these drugs used singly or in combination cause any of the following side effects including but not

limited to the following:

- A. Death;
- B. Cardiac arrhythmias;
- C. Aortic, mitral, tricuspid or pulmonic valve disease/injury;
- D. Aortic, mitral, tricuspid or pulmonic valve regurgitation;
- E. Shortness of breath;
- F. Pulmonary insufficiency;
- G. Pulmonary hypertension;
- H. Any cardiac abnormality on echocardiogram, sonogram, doppler, stress tests, catheterization, or chest x-ray;
- I. If so, please set forth specifically for each such side effect currently under study;
- J. The start date of the study;
- K. The anticipated end-date of the study;
- L. The anticipated publication date of the study;
- M. The anticipated dates for the disclosure to the FDA or others of any preliminary data or results from the study; (please specifically identify those persons or agencies to whom disclosure will be made);
- N. The identity of the source of any funding for the study, in whole or in part, if the study is not wholly funded by you;
- O. If the study does not concern the side effects listed above, specifically identify the side effect under study;
- P. Produce with your answer copies of any protocols, statistical plans, blank

case report forms and any amendments to any of the above documents concerning the studies you identified above;

Q. The basis or bases for the decision to perform such studies;

R. The identity of the persons employed by you who decided that such studies would be performed.

18. List the form (liquid, solid, powder, or injectable) for which your drug phentermine was approved by the FDA and/or offered for sale and use by the public, giving the following information concerning each form.

A. Trade name;

B. Form(s) (liquid, solid, powder, or injectable);

C. Give the dosage/concentration in which each form was packaged by defendant for public sale;

D. Give the FDA approved dosage for each form;

E. Attach to your answers the labeling or a facsimile thereof for each form listed in your answer to this interrogatory;

F. Produce a copy or facsimile thereof of each and every piece of labeling issued or distributed by defendant to the public or to the medical profession with respect to each of the forms of phentermine listed in the answer to this interrogatory;

G. State exactly what, if any, written warranties were made to the public and/or Health Care Providers concerning the manufacture and use of fenfluramine, dexfenfluramine and/or phentermine in each of its forms;

H. Produce or describe the instructions and any warnings disclosed by you to

the public or Health Care Providers with respect to the use of each form of fenfluramine, dexfenfluramine and/or phentermine listed in the answer to this interrogatory.

19. Were the combinations of the drugs fenfluramine, dexfenfluramine and/or phentermine recommended by the detail people, or sales representatives of your company to physicians, nurses, diet doctors, diet clinic personnel, and patients? If so, please:

A. Describe what recommendations were made by you concerning the combinations of these drugs;

B. Produce any document that concern or reference in any way prescribing these diet drugs in combination for patients.

20. State whether you advertised your phentermine products, fenfluramine and/or dexfenfluramine and if so:

A. Identify each advertising firm you engaged to market and/or advertise your phentermine products, fenfluramine and/or dexfenfluramine, including the identity of the manager of your accounts;

B. Produce a specimen copy of all advertisements you ran.

21. Did you provide any information in any form to the public, pharmacists, and health professionals of any kind or the medical profession concerning exceeding the dosage or duration of use described in the approved FDA labeling of fenfluramine, dexfenfluramine and/or

phentermine? If yes, please identify specifically:

- A. What information was provided to the public;
- B. What information was provided to the medical profession;
- C. In each case, how such information was communicated;
- D. Identify the individual(s) responsible for determining the information that would be provided;
- E. Attach to your answer any and all documents that reference, contain or concern any such warnings.

22. Did you at any time become aware that physicians were prescribing the diet drug medications in question in doses or duration of use that exceeded the dosages contained in the FDA approved labeling? If so, please set forth:

- A. When this information (that physicians were so prescribing these medications) was first reported to you;
- B. How you became aware that physicians were so prescribing these medications;
- C. Produce a sample of any communications from you to physicians concerning prescribing these medications in such fashion;
- D. Any communications from physicians to you concerning prescribing these medications in such fashion;
- E. The name of the person or persons employed by you involved in the research, marketing and/or development of your diet drugs to whom it was first reported that these medications were being prescribed in dosages exceeding the recommended doses or

duration of use.

23. Did you report to the FDA the results of any safety and efficacy studies or tests of phentermine, fenfluramine, and/or dexfenfluramine you performed after FDA approval of these drugs? If yes:

A. Produce a copy of each of any and all such report or reports, including any amendments or versions so submitted.

24. Did you, at any time issue a *Dear Doctor* letter to the medical profession (doctors, nurses, physician assistants, diet clinic personnel, pharmacists) or to your detail people and/or to patients in general regarding the use of phentermine, fenfluramine and/or dexfenfluramine? If yes, set forth the following information:

- A. Attach a copy of each such letter to these answers;
- B. Set forth the date of such letter(s) and to whom directed;
- C. Who first suggested the sending of such letter?
- D. Who composed the letter?

25. Identify the individual, committee or group in your company that made the final decision to file an NDA for Phentermine HCL or Phentermine Resin and to market same after NDA approval. If not a single individual, please:

A. Provide the name of such individuals, and state whether or not these persons are still employed by you.

B. Identify the position held by each individual in your company at the time this decision was made.

C. Produce all documents relating to this decision.

26. Identify the individual, committee or group in your company that was concerned or involved in the withdrawal of fenfluramine and dexfenfluramine products from the market. If not a single individual, please:

A. Provide the name of such individuals, and state whether or not these persons are still employed by you.

B. Identify the position held by each individual in your company at the time this withdrawal was made.

C. Produce all internal correspondence, meeting minutes, memoranda and e-mail discussing the withdrawal of dexfenfluramine and fenfluramine from the market.

27. Give the name, official capacity or position of those persons employed or formerly employed by you who were responsible for communicating with the FDA during the FDA approval process for your phentermine product(s).

28. Please provide the following information concerning your detail person(s) or sales representative(s) who were responsible for the sales or marketing of your phentermine product(s) in the state of New York:

A. Name, current address and whether or not still employed by you;

B. What, if any training was provided to these individuals by you concerning

the diet drugs in question;

- C. A copy of the applicable job description for this job position;
- D. Copies of any and all training manuals provided to these individuals;
- E. Copies of any documents and instructions provided to these individuals

concerning the marketing of the diet drugs in question;

F. Copies of any documents provided, if any to these individuals concerning the use of the diet drugs in combination with each other.

29. Give the name, official capacity or position of those persons employed by you or serving in an official capacity or position with your company that have the responsibility to communicate or coordinate with FDA concerning post-approval experience with your phentermine products concerning the following:

- A. Reporting of adverse effects;
- B. Changes in packaging or labeling, including modifications to warning or instructions to physicians or the consuming public;
- C. Prophylactic diagnostic testing (e.g. echocardiograms) of persons who took your phentermine products either alone or in combination with fenfluramine and/or dexfenfluramine, for the purposes of early detection of the possible adverse effects of these diet drugs.

For each, set forth the name, position and identify for each the specific areas of responsibility in A-C above. Also produce each document responsive to this interrogatory.

30. Give the name, official capacity or position of those persons employed by you or serving in an official capacity or position with your company that have the responsibility to communicate or coordinate with New York authorities in any relevant state agency concerning post-approval experience with your phentermine products concerning the following:

- A. Reporting of adverse effects;
- B. Changes in packaging or labeling, including modifications to warning or instructions to physicians or the consuming public;
- C. Prophylactic diagnostic testing (e.g. echocardiograms) of persons who took your phentermine products, either alone, or in combination with fenfluramine and/or dexfenfluramine, for the purposes of early detection of the possible adverse effects of these diet drugs.

For each, set forth the name, position and identify for each the specific areas of responsibility in A-C above. Also produce each document responsive to this interrogatory.

31. Have you at any time agreed to indemnify, (with or without limitation) hold harmless or defend any New York physician, Health Care Provider, clinic, diet center or any other person with regard to the prescription of your phentermine products, either alone, or in combination with fenfluramine and/or dexfenfluramine. If yes, please identify for each such physician or provider:

- A. The name and address of the physician or other with whom the agreement was made;

- B. When the agreement was made;
- C. Produce a copy of each such agreement.

32. Did you at any time receive any communications (other than lawsuits or attorney claim letters) whether by letter, telegram, e-mail, telephone or in person form anyone concerning the warnings or information you provided to physicians and/or the consuming public regarding the use of your phentermine products, either alone or in combination with fenfluramine and/or dexfenfluramine.

A. If yes, please identify by name the individual(s) who communicated with you, and if not written or currently available, describe the nature of such communication in detail;

B. Produce a copy of any document that reflects or was a part of any such communication.

33. Do you have documentation/destruction policies or procedures concerning your diet drugs that apply to safety or marketing documents or records? If yes, please attach a copy of same to your answers and identify the person or persons responsible for implementing the safety and marketing document retention policy.

34. Did you ever meet with or communicate with anyone affiliated with the Mayo Clinic regarding cardiac abnormalities in patients who had taken fenfluramine and/or dexfenfluramine? If so, state the dates and location of each meeting or communication and:

A. Identify who was involved in each meeting or communication;

B. State what was discussed or presented during the meeting or in the communication if not in reproducible form;

C. Produce a copy of all correspondence, memoranda, minutes, or e-mail discussing any such meeting or any such communication.

35. Before Pondimin and Redux were withdrawn from the market, did you meet or communicate with anyone outside your company regarding any alleged association between the diet drugs in question and any abnormal echocardiogram findings in patients who had taken fenfluramine, dexfenfluramine and/or phentermine or any combination of the above? If so, state:

A. The dates of each such meeting or communication;

B. What was discussed or presented in connection with or during each meeting or communication;

C. Produce all documents relating to the meeting or communication.

36. With respect to the findings ultimately published in the New England Journal of Medicine on August 28, 1998 at pp. 581-588,

A. When were you first advised of such findings;

B. What information was told or provided to you on the date identified in (a);

C. What steps did you take to disseminate that information described in (b) to healthcare providers, the FDA, and the consuming public;

D. What information did you actually disseminate;

E. When did you disseminate the information identified in (d) above?

37. With respect to cases of heart valve problems associated with the use of fenfluramine or dexfenfluramine between 1994 and 1996 reported by physicians in Belgium or other European countries,

- A. Were you at any time advised of any of these cases, and if so, when;
- B. What specifically were you told about such cases;
- C. Did you disseminate the information described in (b) to physicians and other prescribers of the drugs, the FDA, and the consuming public? If so:
 - D. When did you disseminate that information;
 - E. What information did you actually disseminate?

As to Defendant Nutri/Systems

1. State whether you (Nutri/System) advertised or marketed your NutriRx program, the Diet Drugs (whether by name or otherwise), or the availability of the Diet Drugs from Nutri/System. If so:

A. Identify each advertising firm that you engaged to market or advertise the NutriRx program, the Diet Drugs (whether by name or otherwise), or the availability of the Diet Drugs from Nutri/System, including the identity of the manager of your account with each such firm;

B. Produce a specimen copy (or, as to radio or other non-written advertising or marketing, a script or transcript) of all advertisements that mention or refer to the NutriRx program, the Diet Drugs (whether by name or otherwise), or the availability of the Diet Drugs from you.

2. State whether you have or have had possession, custody or control of any documents that reflect or relate to the guidelines of any manufacturer of any of the Diet Drugs for the prescription of any of the Diet Drugs. If so, produce copies of any such documents, including but not limited to, package inserts, correspondence between you and any such manufacturer(s), and internal memoranda of Nutri/System regarding such guidelines your implementation of them, or any deviation from them by you.

3. State whether you have maintained any records regarding or relating to persons who participated in the NutriRx program. If so, for each participant produce:

A. Records reflecting the identity, height and weight at the time of registration for the NutriRx program, and the length of time for which any of the Diet Drugs was prescribed.

B. A copy of the patient chart and any other medical record reflecting the physical examination of such participant by you or your agent.

Dated: New York, New York
February _____, 1999

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