COUNTY OF NEW YORK	-X
IN RE: NEW YORK DIET DRUG LITIGATION	Index No. 700000/98
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THIS DOCUMENT APPLIES TO ALL DIET DRUG CASES VENUED IN NEW YORK COUNTY	CASE MANAGEMENT ORDER NO. 3 September 25, 1998
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# Master Pleadings, Confidentiality Order and Inadvertent Production Order

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' Pleadings Subcommittee has developed the attached Master Complaint, and the committees have jointly developed the Verified Complaint by Adoption, Verified Answer by Adoption, Protective Order Concerning Certain Confidential Material and Order Concerning Inadvertently Produced Material. This Order, which adopts these items and contains certain other provisions, applies to all diet drug cases which are presently or hereafter assigned to the undersigned.

# A. Master Complaint

Plaintiffs' Master Complaint, attached hereto as Appendix A and filed as a part of this Order under the index number 700000/98, contains allegations that plaintiffs allege may be suitable for incorporation by reference in individual cases. It is envisioned that, in many cases, there will only be a Verified Complaint by Adoption incorporating by reference

allegations from the Master Complaint. Defendants reserve the right to move against the Master Complaint in all cases which incorporate its allegations by reference. Any party desiring to make such a motion shall first request a conference with the Court to discuss a schedule for the briefing and argument of the motion and, to the extent applicable, a narrowing of the issues. Any such motion shall be served in accordance with CMO No. 1.

# B. <u>Verified Complaint by Adoption</u>

- 1. Allegations in the Master Complaint are not deemed automatically included in any particular case. Plaintiffs wishing to incorporate by reference any or all of the causes of action in the Master Complaint shall do so by listing them on a Verified Complaint by Adoption substantially in the form attached hereto as Appendix B. Multiple unrelated plaintiffs may not appear on the same Verified Complaint by Adoption. Counsel for any plaintiff filing a Verified Complaint by Adoption must sign said notice as required by 22 NYCRR § 130-1.1-a.
- 2. Plaintiffs' Verified Complaint by Adoption shall be served, together with an appropriate Summons, on each named defendant in accordance with the provisions for Service of Process in Section VII of CMO No. 1 or otherwise in accordance with the CPLR.

# C. Amendments to Pending Actions

Within thirty (30) days of the signing of this Order, any plaintiff may amend and serve in accordance with CMO No. 1 any previously filed complaint to add or subtract parties and/or to adopt all or a portion of the allegations contained in the Master Complaint by serving a Verified Complaint by Adoption. Leave to amend a complaint in the manner set forth above is hereby granted without the necessity of filing a motion pursuant to CPLR § 3025.

# D. Master Answers

Any defendant may file in the master file applicable to these cases, a form of Master Answer for that defendant incorporating its defenses to the allegations in the Master Complaint. Master Answers shall thus be filed under the index number 700000/98 and, in addition, shall be served on Defendants' and Plaintiffs' Liaison Counsel. Any defendant filing a Master Answer as set forth above may thereafter incorporate the terms of the Master Answer in any action assigned to this Court in the manner set forth below. The filing of a Master Answer does not prejudice or affect in any way a defendant's right to move against the Master Complaint as it may be made applicable (in accordance with the terms of this Order) to any individual action. Plaintiffs reserve the right to move against any Master Answer. Any such motion shall be served in accordance with CMO No. 1.

# E. Verified Answer by Adoption

- 1. A defendant that has filed a Master Answer may respond to a complaint served upon it by serving a Verified Answer by Adoption substantially in the form annexed hereto as Appendix C or, alternatively, may respond in any other manner it deems appropriate (including, but not limited to, serving a separate Answer or moving against the Complaint).
- 2. Defendant's Verified Answer by Adoption shall be served on the plaintiff and each defendant appearing in the action to which the Notice applies in accordance with the provisions of CMO No. 1.

#### F. <u>Venue</u>

The parties reserve all rights to contest the venue of any case as of right without the obligation to take any action otherwise required by the CPLR (including without limitation service of a demand), subject to further order of the Court.

# G. Order Concerning Inadvertently Produced Material

Attached hereto as Appendix D and made a part hereof is an Order governing the procedures to be followed by the parties in the event of inadvertent disclosure of any attorney-client privileged, work product or other protected material.

# H. Other Matters

- The entry of this Order does not constitute a finding by the Court, or an agreement by the parties, as to the truth, validity, sufficiency or availability of any fact, cause of action, claim for relief, affirmative defense or any other matter stated in the Master Complaint, Verified Complaint by Adoption, any Master Answer or Verified Answer by Adoption.
- 2. Plaintiffs' and Defendants' Liaison Counsel are hereby directed to mail a copy of this Order to all counsel who have appeared in these actions for plaintiffs and defendants, respectively.

SO ORDERED.

Dated:

September 5, 1998 New York, New York

Helen E. Freedman, J.S.C.

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SUPREME COURT OF THE COUNTY OF NEW YORK	•			
IN RE: NEW YORK DIET		INDEX	NO.	700000/98
VARIOUS NAMED INDIVID	==			

Plaintiffs,

MASTER COMPLAINT

-against-

JURY TRIAL DEMANDED

AMERICAN HOME PRODUCTS CORP., WYETH-AYERST LABORATORIES, a division of AMERICAN HOME PRODUCTS CORP., A.H. ROBINS COMPANY, INC., WYETH LABS, INC., INTERNEURON PHARMACEUTICALS, INC., SMITHKLINE BEECHAM CORP., MEDEVA PHARMACEUTICALS, INC., MEDEVA PHARMACEUTICALS MANUFACTURING, INC., FISONS CORPORATION, EON LABS MANUFACTURING, INC., ZENITH GOLDLINE PHARMACEUTICALS, INC., ION LABORATORIES, INC., CAMALL COMPANY, GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS USA, INC., JONES MEDICAL INDUSTRIES, INC., f/k/a ABANA PHARMACEUTICALS, INC., ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICALS COMPANY, INC., a division of REXCAL PHARMACAL, INC. SHIRE RICHWOOD, INC., RUGBY LABORATORIES, INC., SEATRACE PHARMACEUTICALS, INC., ROSEMONT PHARMACEUTICALS, INC., GENEVA PHARMACEUTICALS, INC., KING PHARMACEUTICALS, INC., UNITED RESEARCH LABORATORIES INC., UPJOHN COMPANY, PARMED PHARMACEUTICALS, INC., LABORATOIRES SERVIER, SA, VARIOUS INDIVIDUALLY NAMED PHYSICIANS, HEALTH CARE PROVIDERS, DIET CENTERS, CLINICS AND HEALTH CARE FACILITIES. PHARMACIES AND OTHER PRESCRIBING ENTITIES.

Defendants.

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The plaintiffs as their claim against defendants allege as follows:

#### GENERAL ALLEGATIONS

- Plaintiffs are citizens and residents of the State of New York.
- 2. Plaintiffs are users of defendants' fenfluramine, dexfenfluramine and/or phentermine products, who were injured by such products as were, in specific cases, their spouses or representatives.
- Defendant, AMERICAN HOME PRODUCTS CORPORATION, is a 3. Delaware Corporation, which has its principal place of business in New Jersey; defendant, WYETH-AYERST LABORATORIES, is a division of AMERICAN HOME PRODUCTS CORPORATION, which has its principal place of business in New Jersey; defendant, A.H. ROBINS COMPANY, INCORPORATED is a Delaware corporation whose principal place of business is in Virginia; defendant, WYETH LABS, INC. is a New York Corporation with its principal place of business in New York; defendant, INTERNEURON PHARMACEUTICALS, INC., is a Delaware Corporation, which has its principal place of business in Massachusetts; defendant, SMITHKLINE BEECHAM CORPORATION, is a Pennsylvania Corporation, which has its principal place of business in Pennsylvania; defendant, MEDEVA PHARMACEUTICALS, INC., is a Delaware Corporation, which has its principal place of business in Collegeville, PA; defendant, MEDEVA PHARMACEUTICALS MANUFACTURING, INC., is a Delaware Corporation, which has its principal place of business in Rochester, New York; defendant, FISONS CORPORATION, is a

Massachusetts Corporation, which has its principal place of business in Rochester, New York; defendant, EON LABS MANUFACTURING, INC., is a New York corporation whose principle place of business is in New York; defendant, ZENITH GOLDLINE PHARMACEUTICALS, INC. is a Florida Corporation, which has its principal place of business in Florida; defendant, ION LABORATORIES, INC., is a Texas Corporation, which has its principal place of business in Texas; defendant, CAMALL COMPANY, is a Michigan Corporation, which has its principal place of business in Michigan; defendant, GATE PHARMACEUTICALS, is an unicorporated division of TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, which has its principal place of business in Pennsylvania; defendant, JONES MEDICAL INDUSTRIES, INC., f/k/a ABANA PHARMACEUTICALS, INC., is a Delaware Corporation, which has its principal place of business in Missouri; defendant, ABANA PHARMACEUTICALS, INC., is a Delaware Corporation, which has its principal place of business in Missouri; defendant, RICHWOOD PHARMACEUTICALS COMPANY, INC., a division of REXCAL PHARMACAL, INC., is a Kentucky Corporation, which has its principal place of business in Kentucky; defendant, SHIRE RICHWOOD INC. is a Kentucky Corporation, which has its principal place of business in Kentucky; defendant RUGBY LABORATORIES, INC. is a New York Corporation which has its principal place of business in Georgia; defendant, SEATRACE PHARMACEUTICALS, INC., is an Alabama Corporation, which has its principal place of business in Alabama; defendant ROSEMONT PHARMACEUTICALS, INC., is a Delaware Corporation, which has its

principal place of business in Colorado; defendant, GENEVA
PHARMACEUTICALS, INC., is a Colorado Corporation, which has its
principal place of business in Colorado; defendant, KING
PHARMACEUTICALS, INC., is a Tennessee Corporation, which has its
principal place of business in Tennessee; defendant, PARMED
PHARMACEUTICALS, INC., is a New York Corporation, which has its
principal place of business in New York; defendant, UNITED
RESEARCH LABORATORIES, INC., is a Pennsylvania Corporation,
which has its principal place of business in Pennsylvania;
defendant, UPJOHN COMPANY, is a Michigan Corporation, which has
its principal place of business in Michigan; defendant,
LABORATOIRES SERVIER, SA, is a French company with its principal
place of business in the county of France. The aforementioned
defendants will hereafter, collectively be referred to as
"product defendants."

- 4. At all times relevant hereto, these product defendants were engaged in the business of supplying, manufacturing, labeling, distributing, promoting, developing, testing and selling the drugs Pondimin (fenfluramine), Redux (dexfenfluramine) and/or phentermine. The product defendants do business in New York and, at all times relevant hereto, sold and/or supplied Pondimin (fenfluramine), Redux (dexfenfluramine) and/or phentermine in interstate commerce and in New York.
- 5. These drug products are schedule IV controlled substances pursuant to Federal and New York State laws and regulations.
  - 6. The plaintiffs' lawsuit falls within one of the

enumerated exceptions in article 16 of the CPLR, specifically section 1602.

7. By virtue of the conduct alleged below, plaintiffs sustained serious and permanent physical, mental and emotional pain and suffering, have suffered economic loss, have been damaged in a sum that exceeds the jurisdictional limits of all lower Courts and demand a judgment against the defendants, jointly, severally, and alternatively, for damages plus interest and costs of suit on this cause of action.

# SECTION A. PRODUCT LIABILITY OF MANUFACTURERS, SUPPLIERS AND DISTRIBUTORS

# FIRST CAUSE OF ACTION -- NEGLIGENCE

- 8. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 9. At all times relevant hereto, the product defendants developed, manufactured, labeled, distributed, promoted and sold their respective drug products.
- 10. At all times relevant hereto, the product defendants were negligent in the testing, labeling, promotion and sale of their respective drug products.
- 11. At all times relevant hereto, the product defendants were aware of, and profited from, the facts that their product was being prescribed and used in the various combinations and that such use was dangerous and unsanctioned by the Food and Drug Administration.
- 12. As a result of plaintiffs' use of the said drugs, plaintiffs developed neurological heart and/or lung damage and

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otherwise have been permanently, physically, mentally, and emotionally injured and have suffered economic loss.

- 13. After notice of problems with said drug products and the knowledge that injuries had occurred as a result of the use of said products, the product defendants negligently failed to issue warnings, recall the product, publicize the problem, and otherwise acted properly and timely to alert the public of the drugs' inherent dangers.
- 14. At all times relevant hereto, the product defendants carelessly and negligently sold and promoted their respective drug products as safe and effective; knew that the drug products would not substantially reduce weight or reduce weight for a long period of time; knew that the drug products were and still are associated with serious and potentially fatal side effects; did not warn the plaintiffs that the drug product was a controlled substance; did not warn the plaintiffs that the drug products were not unapproved for use to be prescribed for a long period of time or for use in conjunction with other weight loss drugs; did not warn that the prescribing doctors should be limited to those who specialized in the treatment of obesity; promoted the drug products for cosmetic loss of weight and not limited to morbid obesity; did not warn the plaintiffs that the combination use of the product had not been studied, as to safety, in animals or humans; violated the controlled substance laws; encouraged misuse and overuse while underplaying side effects to doctors and the public in order to make a profit from sales; preyed on the cupidity of doctors and the fears of

overweight members of American society and were otherwise negligent.

- 15. The product defendants were careless, grossly negligent, willful, wanton, malicious and exhibited a deliberate and total disregard for the public health and safety in the design, testing, manufacturing, labeling, promotion, marketing and distribution of their respective drug products alone and/or in combination and in failing to warn the plaintiffs, their prescribing doctors or other dispensing entities, the FDA and the consuming public of the dangers which were well known to the product defendants.
- 16. The product defendants realized the imminence of danger to the plaintiffs and other members of the consuming public but continued their aggressive marketing and promotional tactics with deliberate disregard, complete indifference and lack of concern for the probable consequences of their acts. An award of punitive and exemplary damages is therefore necessary to punish the product defendants and to deter any reoccurrence of this intolerable conduct. Consequently, the plaintiffs are entitled to an award of punitive and exemplary damages.

#### SECOND CAUSE OF ACTION -- STRICT PRODUCT LIABILITY

- 17. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 18. The product defendants' respective drug products were defective because they were not reasonably safe as intended to be used; the defect existed at the time the products left the product defendants' hands; the plaintiffs used the products for

its intended purpose, i.e., weight loss, took the drug products as prescribed and for the purpose for which it was marketed and prescribed; the plaintiffs could not have discovered any defect in the drug products through the exercise of care; and the defect was a substantial factor in causing the injury.

- 19. The fenfluramine, dexfenfluramine and/or phentermine manufactured and/or supplied by defendants was defective in design or formulation in that, when it left the hands of the manufacturers and/or suppliers, the foreseeable risks exceeded the possible benefits associated with the design and/or formulation, especially since any weight loss experienced was transitory.
- 20. Alternatively, the fenfluramine, dexfenfluramine and/or phentermine manufactured and/or supplied by defendants was defective in design or formulation, in that, when it left the hands of the manufacturers and/or suppliers, it was unreasonably dangerous.

#### THIRD CAUSE OF ACTION -- BREACH OF EXPRESS WARRANTY

- 21. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 22. By the conduct as alleged, the product defendants expressly warranted to the injured plaintiffs and their treating physicians that the drugs were merchantable and fit for the purpose intended.
- 23. This warranty was breached when the plaintiffs were injured.

# FOURTH CAUSE OF ACTION -- BREACH OF IMPLIED WARRANTY

- 24. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 25. By the conduct as alleged, the product defendants impliedly warranted to the injured plaintiffs and their treating physicians that the drugs were merchantable and fit for the purpose intended.
- 26. This warranty was breached when the plaintiffs were injured.

#### FIFTH CAUSE OF ACTION -- FRAUD AND MISREPRESENTATION

- 27. Plaintiffs repeat the prior allegations of this complaint as if set forth fully here.
- 28. The product defendants fraudulently, intentionally, and negligently misrepresented the safety and effectiveness of their product and fraudulently, intentionally, and negligently concealed material adverse information regarding the safety and effectiveness of their product.
- 29. The product defendants made these misrepresentations and actively concealed adverse information at a time when the product defendants knew, or should have known, that their drug products had defects, dangers, and characteristics that were other than what the product defendants had represented to the prescribing doctors or other dispensing entities, the FDA and the consuming public, including the plaintiffs herein. Specifically, the product defendants misrepresented to and/or actively concealed from plaintiffs, their prescribing doctors and other dispensing entities, the FDA and the consuming public that:

- (a) it was dangerous to prescribe phentermine and fenfluramine in combination;
- (b) the FDA had not approved the use of these drugs in combination;
- (c) these drugs were not intended for cosmetic weight-loss;
- (d) fenfluramine, dexfenfluramine and/or phentermine used alone and/or in combination carried the risk of serious adverse effects;
- (e) after discontinuing use, most users of the drugs, either alone or in combination, regained any weight lost as a result of their initial ingestion;
- (f) there had been insufficient studies regarding the safety and efficacy of fenfluramine, dexfenfluramine and/or phentermine used alone and/or in combination for use in treating weight loss;
- (g) while knowing that there had been insufficient or inadequate testing of these drugs either alone or in combination, the product defendants marketed, promoted and sold their drug products as if they were fully and adequately tested, safe and effective; and
- (h) prior studies, research and testing had been conducted linking the use of fenfluramine, dexfenfluramine and/or phentermine used alone and/or in combination or chemically similar diet drugs to serious adverse reactions.
- 30. The misrepresentations of and/or active concealment by the product defendants was perpetrated directly and/or

indirectly by the product defendants, their sales representatives, employees, agents and/or detail persons.

- 31. The product defendants misrepresented the safety and efficacy of their drug products in their labeling, advertising, promotional materials, or other marketing efforts.
- 32. The product defendants made these misrepresentations and/or actively concealed this information with the intention and specific desire that the plaintiffs, their prescribing doctors or other dispensing entities and the consuming public would rely on such in selecting treatment for weight-loss.
  - 33. Plaintiffs, their prescribing doctors or other dispensing entities relied on and were induced by the product defendants' misrepresentations and/or active concealment in selecting treatment for weight-loss and suffered damages as a direct and proximate result.

# SIXTH CAUSE OF ACTION - NEGLIGENCE PER SE

- 34. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 35. At all times herein mentioned, product defendants had an obligation not to violate the law, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of their drug products.
- 36. At all times herein mentioned, product defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 301, et seg., related amendments and codes and federal

regulations provided thereunder, New York's Gen.Bus.Law §392-r (1997) (false labels and misrepresentations) and regulations promulgated thereunder and other applicable laws, statutes and regulations.

- 37. Plaintiffs, as purchasers and consumers of the product defendants' drug products, are within the class of persons the statutes described above are designed to protect, and the plaintiffs' injuries are the type of harm these statutes are designed to prevent.
- 38. The product defendants failed to meet the standard of care set by the following regulations, which were intended for the benefit of individuals such as the plaintiffs, making the product defendants negligent per se:
- (a) the labeling lacked adequate information on the use of the fenfluramine and phentermine combination, even though the product defendants were aware of the widespread use of the combination [21 C.F.R. Section 201.56(a) and (d)];
- (b) the labeling lacked adequate information on the approximate kind, degree and duration of expected improvement, alone or in combination in violation of 21 C.F.R. Section 201,57(c)(3)(i);
- (c) the labeling did not state that there was a lack of evidence to support the common belief of the safety and advocacy of fenfluramine and phentermine in combination [21 C.F.R. 201.57(c)(3)(1) and (iv) and (c)(2)];
- (d) the labeling failed to add warnings for pulmonary hypertension, serious heart conditions, serious lung damage, and

serious brain conditions as soon as there was reasonable evidence of their association with the drug products, alone or with the fenfluramine and phentermine combination [21 C.F.R. 201.57(e)];

- (e) there was inadequate information for patients for the safe and effective use of the product defendants' drug products, alone or in the fenfluramine and phentermine combination in violation of C.F.R. 201.57(f)(2);
- (f) there was inadequate information regarding special care to be exercised by the doctor for safe and effective use of the product defendants' drug products and the product defendants' drug products in the fenfluramine and phentermine combination in violation of 21 C.F.R. 201.57(f)(1);
- (g) the labeling was misleading and promotional in violation of 21 C.F.R. 201.56(b).

# SEVENTH CAUSE OF ACTION - VIOLATION OF NEW YORK'S GENERAL BUSINESS LAW

- 39. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 40. The product defendants knew, or in the exercise of reasonable care, should have known that their respective drug products alone or in combination were not reasonably safe as designed, manufactured, tested and marketed.
- 41. The product defendants knew that their respective drug products alone or in combination carried the risk of serious adverse effects including serious heart conditions, serious lung damage, and serious brain conditions to their intended users,

including the plaintiffs herein.

- 42. The product defendants were negligent, careless and reckless in failing to warn their intended users, including plaintiffs herein, of the above unreasonable risks associated with the use of the product defendants' drug products either alone or in combination.
- 43. These acts, representations and/or omissions by the product defendants constitute unconscionable commercial practices in connection with the sale of merchandise and false advertising and deceptive and misleading practices within the meaning of New York's Consumer Protection from Deceptive Acts and Practices Act, General Business Law §§ 349 and 350.

#### EIGHTH CAUSE OF ACTION - CONCERT OF ACTION

- 44. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 45. The product defendants, with concerted action and with a common plan, scheme or design, did jointly and severally research, develop, market, manufacture and distribute, fenfluramine, dexfenfluramine and/or phentermine.
- 46. This concert of action was between and among the product defendants implicitly through their conduct.
- 47. This concert of action was between and among the product defendants by an explicit agreement, imitative behavior and/or conscious parallel behavior.
- 48. This concert of action caused an indivisible injury to the plaintiffs so situated.

#### NINTH CAUSE OF ACTION - ALTERNATE LIABILITY

- 49. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 50. The product defendants, with a common plan, scheme or design, conspired together to manufacture and distribute fenfluramine, dexfenfluramine and/or phentermine.

#### TENTH CAUSE OF ACTION - MARKET SHARE LIABILITY

- 51. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 52. The product defendants , with a common plan, scheme or design, conspired together to manufacture and distribute fenfluramine, dexfenfluramine and/or phentermine.
- 53. Each of the product defendants jointly and/or separately maintained or presently maintain a "substantial share" of the relevant market for fenfluramine, dexfenfluramine and/or phentermine.

# ELEVENTH CAUSE OF ACTION - ENTERPRISE LIABILITY

- 54. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 55. The product defendants, acting in concert, and with a common plan, scheme or design, set an unsafe standard for testing fenfluramine, dexfenfluramine and/or phentermine.
- 56. The product defendants, acting in concert, failed to set a safe standard for testing fenfluramine, dexfenfluramine and/or phentermine.

# TWELFTH CAUSE OF ACTION -INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

57. Plaintiffs repeat the prior allegations of this

Complaint as if set forth fully here.

- 58. The product defendants conduct, either individually or collectively, in designing, manufacturing, selling, distributing, or marketing fenfluramine, dexfenfluramine, and/or phentermine alone and/or in combination was so reckless and/or intentionally outrageous, atrocious, utterly intolerable, and transcending all possible bounds of decency in a civilized society that, as a result, plaintiffs have suffered severe emotional distress.
- 59. The product defendants conduct, either individually or collectively, in failing to correct the defect in their respective products, failing to warn the plaintiffs, their doctors or other prescribing entities, the FDA or the consuming public about the dangerous adverse affects of ingesting fenfluramine, dexfenfluramine, and/or phentermine alone and/or in combination was so reckless and/or intentionally outrageous, atrocious, utterly intolerable, and transcending all possible bounds of decency in a civilized society that, as a result, plaintiffs have suffered severe emotional distress.

# SECTION B. LIABILITY OF DIET CENTERS, CLINICS AND PHARMACIES

- 60. The diet centers and clinic defendants will hereafter collectively be referred to as "diet center defendants."
- 61. The pharmacy defendants will hereafter collectively be referred to as "pharmacy defendants."

# THIRTEENTH CAUSE OF ACTION - NEGLIGENCE OF DIET CENTER DEFENDANTS

62. Plaintiffs repeat the prior allegations of this

Complaint as if set forth fully here.

- 63. The diet center defendants undertook and agreed to render medical care, advice and treatment to plaintiffs.
- 64. Plaintiffs were patients under the professional care and treatment of the diet center defendants, their agents, servants and employees.
- 65. The diet center defendants, their agents, servants and employees, were negligent, reckless and careless in the medical care and treatment rendered to plaintiff.
- 66. The treatment rendered by the diet center defendants, their agents, servants and/or employees was not in accord with good and acceptable standards of medical care.
- 67. The diet center defendants were careless, grossly negligent, willful, wanton, malicious and exhibited a deliberate and total disregard for the public health and safety in the marketing, prescribing, selling, and distribution of fenfluramine, dexfenfluramine and/or phentermine alone and/or in combinations and in failing to warn the plaintiffs of the dangers which were well known to the diet center defendants.
- 68. The diet center defendants realized the imminence of danger to the plaintiffs and other members of the consuming public but continued their aggressive marketing and promotional tactics with deliberate disregard, complete indifference and lack of concern for the probable consequences of their acts. An award of punitive and exemplary damages is therefore necessary to punish the diet center defendants and to deter any reoccurrence of this intolerable conduct. Consequently, the

plaintiffs are entitled to an ward of punitive and exemplary damages.

# FOURTEENTH CAUSE OF ACTION - MEDICAL MALPRACTICE BY DIET CENTER DEFENDANTS

- 69. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 70. At all times relevant hereto, the diet center defendants undertook and agreed to render medical care and treatment to the plaintiffs and did render such care and treatment.
- 71. The diet center defendants were negligent in the services rendered to and on behalf of the plaintiffs, in failing to use reasonable care; in failing to properly examine the plaintiffs and failing to heed the plaintiffs' conditions; in departing from accepted standards in the procedures and treatment performed; in failing to follow appropriate practices; in prescribing and dispensing fenfluramine, dexfenfluramine and/or phentermine alone and/or in combination; in failing to warn the plaintiffs of the risks of said treatment and in all respects were otherwise negligent.
- 72. As a competent producing result of the foregoing, the plaintiffs suffered permanent and serious personal, mental and emotional injuries and has incurred special damages.

#### FIFTEENTH CAUSE OF ACTION - LACK OF INFORMED CONSENT BY DIET CENTER DEFENDANTS

- 73. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully herein.
  - 74. The diet center defendants, their agents servants and

employees failed to properly and adequately advise plaintiff, of the risks, hazards and dangers inherent in the treatment rendered, failed to advise the plaintiffs, of the alternatives thereto, and failed to obtain an informed consent.

- 75. The diet center defendants, their agents, servants, employees and/or others acting within their control failed to disclose to plaintiff, such alternatives to the treatment/diagnosis and reasonably foreseeable risks and benefits involved as reasonable medical practitioners under similar circumstances would have disclosed in a manner permitting the patient to make a knowledgeable evaluation.
- 76. Reasonably prudent persons in the plaintiffs' positions would not have undergone the same treatment if they had been fully informed.
- 77. Reasonably prudent persons in plaintiffs' positions would not have undergone the diet center defendants' prescribed treatment and procedures if they had been fully informed.
- 78. The lack of informed consent is a direct and proximate cause of the injuries and/or conditions for which the plaintiffs are seeking relief.

# SIXTEENTH CAUSE OF ACTION -NEGLIGENCE OF PHARMACY DEFENDANTS

- 79. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 80. The pharmacy defendants undertook and agreed to render medical and pharmaceutical care and treatment to plaintiffs.
  - 81. The pharmacy defendants, their agents, servants and

- employees, were negligent, reckless and careless in the medical and pharmaceutical care and advice rendered to plaintiffs.
  - 82. The attention and advice rendered by the pharmacy defendants, their agents, servants and employees was not in accord with good and acceptable standards of medical care.
- 83. The pharmacy defendants, their agents, servants and employees were obligated under law to issue warnings and provide information, including the dangers and status of prescription drug combinations, off label use and adverse reactions to the plaintiffs.
- 84. The pharmacy defendants were careless, grossly negligent, willful, wanton, malicious and exhibited a deliberate and total disregard for the public health and safety in the selling, and distribution of fenfluramine, dexfenfluramine and/or phentermine alone and/or in combinations and in failing to warn the plaintiffs of the dangers which were well known to the pharmacy defendants.
- 85. The pharmacy defendants realized the imminence of danger to the plaintiffs and other members of the consuming public but continued conduct with deliberate disregard, complete indifference and lack of concern for the probable consequences of their acts. An award of punitive and exemplary damages is therefore necessary to punish the pharmacy defendants and to deter any reoccurrence of this intolerable conduct.

  Consequently, the plaintiffs are entitled to an ward of punitive and exemplary damages.

#### SECTION C. LIABILITY OF PHYSICIANS

86. The physician defendants will hereafter collectively be referred to as "physician defendants."

#### SEVENTEENTH CAUSE OF ACTION - MEDICAL MALPRACTICE

- 87. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 88. At all times relevant hereto, the physician defendants undertook and agreed to render medical care and treatment to the plaintiffs and did render such care and treatment.
- 89. The physician defendants were negligent in the services rendered to and on behalf of the plaintiffs, in failing to use reasonable care; in failing to properly examine the plaintiffs and failing to heed the plaintiffs' conditions; in departing from accepted standards in the procedures and treatment performed; in failing to follow appropriate practices; in prescribing and dispensing fenfluramine, dexfenfluramine and/or phentermine alone and/or in combination; in failing to warn the plaintiffs of the risks of said treatment and in all respects were otherwise negligent.

#### EIGHTEENTH CAUSE OF ACTION - LACK OF INFORMED CONSENT

- 90. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully herein.
- 91. The physician defendants failed to provide the plaintiffs with the information that reasonably prudent medical practitioners should have provided under the circumstances and the physician defendants failed to make plaintiff aware of the risks and benefits of, and the alternatives to, the procedures

employed.

- 92. Reasonably prudent persons, being fully informed, would not have consented to the procedures employed by the physician defendants.
- 93. The procedures employed and the failure to employ appropriate procedures, were the competent producing cause of the injuries suffered by the plaintiff.

#### SECTION D. SPECIAL PLAINTIFFS

#### NINETEENTH CAUSE OF ACTION - LOSS OF CONSORTIUM

- 94. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 95. At all times relevant hereto, the plaintiffs were spouses, as such the spouse plaintiff was entitled to the services and society of the injured plaintiff.
- 96. At all times relevant hereto, the spouse plaintiff was and still is responsible for the care, maintenance and medical expenses of the injured plaintiff.
- 97. At all times relevant hereto, the spouse plaintiff was deprived of the services and society of the injured plaintiff and became liable for any and all expenses incurred on the injured plaintiff's behalf.

# TWENTIETH CAUSE OF ACTION - WRONGFUL DEATH

- 98. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully herein.
- 99. Prior to the commencement of this action, plaintiffs were appointed Administrators of the estates of the deceased by the Surrogate's Court.

- 100. By reason of the injuries sustained by plaintiffs' decedents, and as a result of the defendants' conduct, they died.
- 101. The decedents left surviving next of kin who sustained pecuniary losses by reason of their death.
- 102. By reason of the deaths of decedents, plaintiffs' decedents became obligated for funeral bills and other expenses.
- 103. By reason of the aforesaid wrongful deaths, the above named defendants are liable to plaintiffs for the loss of services, advice and guidance, loss of inheritance, loss of contribution and income.

#### TWENTY-FIRST CAUSE OF ACTION - SURVIVAL ACTION

- 104. Plaintiffs repeat the prior allegations of this Complaint as if set forth fully here.
- 105. Prior to death, plaintiffs' decedents, experienced terror and were inflicted with severe pain and suffering before their lives ceased.

WHEREFORE, plaintiffs demand judgments against the defendants in each pertinent causes of action as follows:

- (a) Awarding plaintiffs compensatory damages against the defendants in an amount sufficient to fairly and completely compensate the plaintiffs for all their damages;
- (b) Awarding plaintiffs punitive damages against the pertinent defendants in an amount sufficient to punish the above named defendants for their wrongful conduct and deter the above named

- defendants and others from similar wrongful conduct in the future;
- (c) Awarding plaintiffs their costs and disbursements, costs of investigations, attorneys' fees and other relief as available under New York law;
- (d) Awarding plaintiffs pre- and post-judgment interest on their awards; and
- (e) Awarding such other and further relief as the court may deem just and proper.

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SUPREME COURT OF THE STATE OF NEW YORK COUNTY OF NEW YORK INDEX NO. IN RE: NEW YORK DIET DRUG LITIGATION Plaintiff(s), VERIFIED COMPLAINT BY ADOPTION -against-AMERICAN HOME PRODUCTS CORP., JURY TRIAL DEMANDED WYETH-AYERST LABORATORIES, a division of AMERICAN HOME PRODUCTS CORP., A.H. ROBINS COMPANY, INC., WYETH LABS, INC., INTERNEURON PHARMACEUTICALS, INC., SMITHKLINE BEECHAM CORP., MEDEVA PHARMACEUTICALS, INC., MEDEVA PHARMACEUTICALS MANUFACTURING, INC., FISONS CORPORATION, EON LABS MANUFACTURING, INC., ZENITH GOLDLINE PHARMACEUTICALS, INC., ION LABORATORIES, INC., CAMALL COMPANY, GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS USA, INC., JONES MEDICAL INDUSTRIES, INC., f/k/a ABANA PHARMACEUTICALS, INC., ABANA PHARMACEUTICALS, INC., RICHWOOD PHARMACEUTICALS COMPANY, INC., a division of REXCAL PHARMACAL, INC. SHIRE RICHWOOD, INC., RUGBY LABORATORIES, INC., SEATRACE PHARMACEUTICALS, INC., ROSEMONT PHARMACEUTICALS, INC., # GENEVA PHARMACEUTICALS, INC., KING PHARMACEUTICALS, INC., UNITED RESEARCH LABORATORIES INC., : UPJOHN COMPANY, ř PARMED PHARMACEUTICALS, INC., LABORATOIRES SERVIER, SA, VARIOUS INDIVIDUALLY NAMED PHYSICIANS, HEALTH CARE PROVIDERS, DIET CENTERS, CLINICS AND HEALTH CARE FACILITIES, PHARMACIES AND OTHER PRESCRIBING

Defendants.

ENTITIES,

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COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM

# COMPLAINT BY ADOPTION

1. Plaintiff(s),, states his/her claims
against the defendants indicated below as follows and
incorporates by reference the relevant portions of the Master
Complaint on file with the New York County Clerk, in the matter
entitled In Re: New York Diet Drug Litigation, now pending in
the Supreme Court of the State of New York, New York County,
before the Hon. Helen E. Freedman, Index No. 700,000/98.
2.Plaintiff,, a citizen and resident
of, claims damages as a result of loss of
consortium.
ALLEGATIONS AS TO INJURIES
3. The plaintiff has suffered injuries as a result of
having ingested defendant products:
FENFLURAMINE
DEXFENFLURAMINE PHENTERMINE
alone and/or in combination. The defendants listed below, one or
more of them, by their actions or inactions, proximately caused
plaintiff's injuries.
4. As a result of the injuries that plaintiff has
sustained, she is entitled to recover compensatory and punitive
damages.
5. That between and the plaintiff
ingested one or more of the above referenced drugs.

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM

- 6. As a result of the Plaintiffs ingestion of the drug(s) Plaintiffs were injured,
- 7. To the extent that this complaint includes a claim for loss of consortium, that plaintiff is entitled to recover compensatory and punitive damages.

# ALLEGATIONS AS TO DEFENDANTS

ļ	o. The following entitles are hamed as defendants herein
and th	he allegations with regard thereto in the Master Complaint
are he	erein adopted by reference.
	AMERICAN HOME PRODUCTS CORP.
	WYETH-AYERST LABORATORIES, a division of AMERICAN HOME PRODUCTS CORP.
	A.H. ROBINS COMPANY, INC. (PONDIMIN)
	WYETH LABS, INC.
	INTERNEURON PHARMACEUTICALS, INC. (DEXFENFLURAMINE)
	SMITHKLINE BEECHAM CORP. (FASTIN)
	MEDEVA PHARMACEUTICALS, INC. (IONAMIN)
	MEDEVA PHARMACEUTICALS MANUFACTURING, INC. (IONAMIN)
	FISONS CORPORATION (IONAMIN)
	EON LABS MANUFACTURING, INC.
	ZENITH GOLDLINE PHARMACEUTICALS, INC.
	ION LABORATORIES, INC.
<del></del>	CAMALL COMPANY
	GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA, INC. (ADIPEX-P)

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM _ TEVA PHARMACEUTICALS USA, INC. (ADIPEX-P) JONES MEDICAL INDUSTRIES, INC. (f/k/a ABANA PHARMACEUTICALS, INC.) _____ ABANA PHARMACEUTICALS, INC. _ RICHWOOD PHARMACEUTICALS COMPANY, INC., a division of REXCAL PHARMACAL, INC. _ SHIRE RICHWOOD, INC. ____ RUGBY LABORATORIES, INC. _____ SEATRACE PHARMACEUTICALS, INC. _____ ROSEMONT PHARMACEUTICALS, INC. _____ GENEVA PHARMACEUTICALS, INC. ____ KING PHARMACEUTICALS, INC. _____ PARMED PHARMACEUTICALS, INC. _____ UNITED RESEARCH LABORATORIES, INC. ____ UPJOHN COMPANY ____ LABORATOIRES SERVIER, SA _____ VARIOUS INDIVIDUALLY NAMED PHYSICIANS HEALTH CARE PROVIDERS, DIET CENTERS, CLINICS AND HEALTH CARE FACILITIES PHARMACIES

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM

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# THEORIES OF RECOVERY

9. The following claims asserted in the Master

Complaint and the allegations with regard thereto in the Master

Complaint are herein adopted by reference:

	SECTION A. PRODUCT L MANUFACTURERS. SUPPLIERS	<del></del>
	FIRST CAUSE OF ACTION Except as to Defendant(s):	NEGLIGENCE
-	SECOND CAUSE OF ACTION Except as to Defendant(s):	STRICT PRODUCT LIABILITY
	THIRD CAUSE OF ACTION Except as to Defendant(s):	BREACH OF EXPRESS WARRANTY
	FOURTH CAUSE OF ACTION Except as to Defendant(s):	BREACH OF IMPLIED WARRANTY
	FIFTH CAUSE OF ACTION Except as to Defendant(s):	FRAUD AND MISREPRESENTATION
	SIXTH CAUSE OF ACTION Except as to Defendant(s):	NEGLIGENCE PER SE
	SEVENTH CAUSE OF ACTION GENERAL BUSINESS LAW Except as to Defendant(s):	VIOLATION OF NEW YORK'S

ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM EIGHTH CAUSE OF ACTION --- CONCERT OF ACTION Except as to Defendant(s): NINTH CAUSE OF ACTION ----ALTERNATE LIABILITY Except as to Defendant(s): TENTH CAUSE OF ACTION ---- MARKET SHARE LIABILITY Except as to Defendant(s): ELEVENTH CAUSE OF ACTION - ENTERPRISE LIABILITY Except as to Defendant(s): TWELFTH CAUSE OF ACTION -- INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS Except as to Defendant(s): SECTION B. LIABILITY OF DIET CENTERS, CLINICS AND PHARMACIES THIRTEENTH CAUSE OF ACTION --- NEGLIGENCE OF DIET CENTER DEFENDANTS FOURTEENTH CAUSE OF ACTION --- MEDICAL MALPRACTICE BY DIET CENTER DEFENDANTS FIFTEENTH CAUSE OF ACTION -- LACK OF INFORMED CONSENT BY DIET CENTER DEFENDANTS SIXTEENTH CAUSE OF ACTION ---- NEGLIGENCE OF PHARMACY DEFENDANTS -- STATE WHAT SPECIFIC ACTS OR OMISSIONS YOU ALLEGE AS TO THE PHARMACY DEFENDANT(S):

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM

		SECTION C. LIABILITY OF PHYSICIANS
	SEVE	NTEENTH CAUSE OF ACTION - MEDICAL MALPRACTICE
	EIGH	TEENTH CAUSE OF ACTION LACK OF INFORMED CONSEN
		SECTION D. SPECIAL PLAINTIFFS
	NINE	TEENTH CAUSE OF ACTION LOSS OF CONSORTIUM
	TWEN	TIETH CAUSE OF ACTION WRONGFUL DEATH
	TWEN	TY-FIRST CAUSE OF ACTION - SURVIVAL ACTION
	10.	Plaintiff(s) assert the following additional
theories	of re	covery against these Defendants:
		PUNITIVE DAMAGES
	11.	If you are making a claim for punitive damages
set forth	whic	h class of defendants you are making the claim
against:		
		PRODUCT DEFENDANTS Except as to Defendant(s):
·	<del></del>	DIET CENTER DEFENDANTS Except as to Defendant(s):
	<u>.</u>	PHARMACY DEFENDANTS Except as to Defendant(s):
		PHYSICIAN DEFENDANTS Except as to Defendant(s):

COUNSEL IS CAUTIONED THAT THEY SHOULD USE PRUDENCE IN CHECKING ONLY THOSE DEFENDANTS AND CAUSES OF ACTION APPLICABLE TO THE FACTS OF THE INDIVIDUAL CLAIM

WHEREFORE, plaintiff(s) pray(s) that he/she(they) will recover from these Defendants to the extent set forth above, as follows:

- (a) For his/her (their) general and compensatory damages in an amount greater than the jurisdictional amount of all lower courts, exclusive of interest and costs;
- (b) For punitive damages as allowed by law;
- (c) For the costs of this litigation; and
- (d) For such other and further damages and relief as this Court may deem appropriate.

Dated:		NY
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[SIGNATURE OF COUNSEL UNDER 22 NYCRR §130-1.1-a: NAME, ADDRESS, PHONE]

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COUNTY OF NEW YORK	K.
IN RE: NEW YORK DIET DRUG LITIGATION :	
Plaintiff(s), : -against- : :	Index No VERIFIED ANSWER BY ADOPTION
Defendant(s). :	
1. Defendant(s)	•
and through their undersigned attorneys, as and for de Verified Complaint by Adoption of the above-reference	ed plaintiff(s) dated
filed by defendant(s) herein with the New York Count	•
New York Diet Drug Litigation, Index No. 700000/98	, now pending in the Supreme Court of
the State of New York, New York County, before the	Honorable Helen E. Freedman, and in
all other respects, deny the allegations made by the pla	aintiff(s).
2. As and for their affirmative defe	enses, said defendant(s), by and through
their undersigned counsel, on information and belief, i	ncorporate the affirmative defenses
listed in defendant(s) Master Answer except:	
3. Defendant(s) herein, by and thro	ugh their undersigned counsel, on
information and belief, allege the following additional	affirmative defenses:

WHEREFORE, the defendant(s)
demand judgment in their favor dismissing the Complaint and each and every cause of act
thereof as against said defendant(s) and denying to plaintiff(s) the relief sought in the
Complaint, and further awarding to defendant(s) herein the fees, costs and disbursements
incurred by said defendant(s) in the defense of this action.
Dated:, New York

⁽Signature under 22 NYCRR § 130-1.1-a, name, address and telephone # of counsel to defendant(s))

## **VERIFICATION**

STATE OF NEW YORK )		
: ss.: COUNTY OF NEW YORK )		
	_, being duly swom, deposes	and says:
I am		, attorneys for the
defendant(s) in the within action. I	have read the foregoing answ	er and know the contents
thereof. The matters set forth therei	n are true to my own knowle	dge, information and belief,
except as to those matters alleged or	information and belief, and	to those matters, I believe
them to be true.		
•		
Sworn to before me this	Name	•
Notary Public		

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PRESENT: HONORABLE HELEN E. FREEDMAN
Justice

SUPREME COURT OF THE STATE OF NET COUNTY OF NEW YORK	W YORK	ζ
	X :	
IN RE: NEW YORK DIET DRUG LITIGATI	ON:	Index No. 700000/98
	:	
w +	X	
THIS DOCUMENT RELATES TO ALL	:	ORDER CONCERNING
DIET DRUG CASES VENUED IN	:	CERTAIN CONFIDENTIAL
NEW YORK COUNTY	:	DISCOVERY MATERIAL
	X	•

- 1. This Order applies to the confidential treatment of documents and other products of discovery, all information derived therefrom and including, but not limited to, all copies, excerpts of summaries thereof, obtained by the plaintiffs or defendants in these cases pursuant to the requirements of any court order, responses to notices for discovery and inspection, responses to requests to admit, interrogatory answers, and depositions and deposition exhibits ("Discovery Material").
- 2. (a) Prior to giving any person access to Discovery Material designated as confidential pursuant to paragraph 3 of this Order, counsel for the party intending to disclose such confidential Discovery Material shall furnish a copy of this Order to the person being given access. The person being given access shall execute a Confidentiality Agreement in the form annexed hereto as Exhibit A. Counsel for the party disclosing confidential material shall retain the executed Confidentiality Agreements during the pendency of this litigation and, upon the termination of this litigation, those Agreements shall be filed under seal with the Court. The requirement to execute a Confidentiality Agreement shall not apply to the

Court, counsel of record for a party, members or employees of counsel's law firm, or in-house counsel for a party.

- (b) The parties have agreed that Discovery Material produced in the New York Diet Drug Litigation designated as confidential under paragraph 3 hereof will be used only for the purposes of this litigation, and any litigation in any other state or federal court relating to the health effects of the Diet Drugs (phentermine, fenfluramine and dexfenfluramine), provided that the court and parties in any such state or federal court litigation agree to be bound with respect to such Discovery Material by the terms of this Order or by the terms of a protective order entered in such state or federal court litigation providing equal or greater protection to Discovery Material.
- 3. Persons producing Discovery Material may designate as confidential Discovery Material, or portions thereof, containing or disclosing trade secrets or other confidential research, development or commercial information ("Confidential Discovery Material"). The information subject to such designation shall be limited to the producing party's:
  - i. Customer names:
- ii. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products, whether previously or currently marketed or under development;
  - iii. Ongoing clinical studies (to the extent produced);
  - iv. Information concerning competitors;
  - v. Production information;

- vi. Financial information not publicly filed with any federal or state regulatory authorities; and
- vii. Information submitted to the FDA or other governmental agency, that under applicable regulations is exempt from disclosure under the Freedom of Information Act.
- 4. Confidential Discovery Material, if a writing, shall have the following language (or similar language provided by the terms of a protective order of comparable scope entered into in the litigation described in paragraph 2(b) hereof) stamped on the face of the writing, or shall otherwise have such language clearly marked:

SUBJECT TO PROTECTIVE ORDER, IN RE NEW YORK DIET DRUG LITIGATION N.Y. County Index No. 700000/98

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SUBJECT TO PROTECTIVE ORDER

MDL NO. 1203 (EDPA)

Such stamping or marking will take place prior to production by the producing person, or subsequent to selection by the receiving party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner as not to obliterate or obscure any written matter. In the case of deposition testimony, confidentiality designations shall be made within thirty (30) days after the transcript has been received by counsel for the deponent, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such 30 day period, the entire text of the deposition, including all testimony therein, shall be treated as confidential under this Order. In the event

that the producing person inadvertently fails to designate Discovery Material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such Discovery Material was produced, in writing as soon as practicable.

After receipt of such notification, the parties to whom production has been made will treat the designated Discovery Material as confidential, subject to their right to dispute such designation in accordance with paragraph 8 hereof.

- 5. In the event that any question is asked at a deposition which a party or nonparty asserts calls for confidential information, such question shall nonetheless be answered by the witness fully and completely, to the extent required by law. Counsel for the deponent shall, either at the deposition or within 30 days after receipt of the transcript thereof by said counsel, notify all counsel on the record or in writing, that the information provided in such answer is confidential.
- 6. Confidential Discovery Material may not be used by any person receiving such Discovery Material for any business or competitive purposes and shall be used solely for the purposes of this litigation, and such other state or federal court litigations as authorized by paragraph 2(b) hereof, and for no other purpose without prior written approval from the Court or the prior written consent of the producing person. All persons receiving or given access to Confidential Discovery Material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.
- 7. (a) Subject to subparagraphs (b), (c) and (d) below, Confidential Discovery

  Material shall not be disclosed to anyone other than the outside and in-house attorneys

  engaged in the conduct of the litigation described in paragraph 2(b) hereof, and to the

employees of such outside attorneys directly involved in the conduct of such litigation.

Notwithstanding anything to the contrary contained in this paragraph, given the fact that co-defendants may be commercial competitors, defense attorneys shall not disclose to their clients, or to any of their clients' employees except in-house counsel, any Discovery Material produced by any other defendant and designated as confidential, without first obtaining the consent of the producing party or leave of Court for good cause shown.

- (b) For purposes of this litigation, outside attorneys may disclose Confidential Discovery Material to retained experts (including persons directly employed by such experts) and to any person expected to testify at trial or at a deposition to the extent that the Discovery Material relates to his/her proposed testimony. When so doing, the disclosing outside attorneys and the recipients of the Confidential Discovery Material shall comply with the terms of paragraph 2(a) hereof.
- (c) For purposes of this litigation outside and in-house counsel may disclose Confidential Discovery Material to agents and employees of services involved in one or more aspects of organization, filing, converting, storing, retrieving or coding Confidential Discovery Material, but only if disclosure is necessary for the performance of such services. When so doing, the disclosing outside attorneys and the recipients of the Confidential Discovery Material shall comply with the terms of paragraph 2(a) hereof.
- (d) All outside and in-house counsel and the employees and assistants of outside counsel receiving discovery shall take all steps reasonably necessary to prevent the disclosure of Confidential Discovery Material other than in accordance with the terms of this Order. Such Confidential Discovery Material shall be made available only to those persons outside counsel deems necessary in the conduct of the litigation.

- (e) Disclosure of Confidential Discovery Material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate.
- 8. (a) If at any time a party wishes for any reason to dispute a designation of Discovery Material as confidential hereunder, such party shall notify the designating party of such dispute in writing, specifying the Discovery Material in dispute and the nature of the dispute. If the parties are unable amicably to resolve the dispute, the disputing party may apply by motion to the Court for a ruling as to whether the designated Discovery Material may, in accordance with the law of New York and this Order, properly be treated as confidential. The designating party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation. Disputed Discovery Material shall continue to be treated as confidential hereunder until such dispute is resolved either amicably by the parties, or by order of the Court.
- (b) All Discovery Material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:
- (i) The producing party agrees in writing, that the material is no longer confidential and subject to the terms of this Order; or
- (ii) This Court enters an Order that the matter shall not be entitled to confidential status and that Order is not timely appealed.
- 9. The parties shall negotiate in good faith before filing any motion relating to this Order.

- of information or documents obtained from some source other than Discovery Material produced in the New York Diet Drug Litigation without the restrictions of this Order if the information or documents are lawfully in their possession and/or lawfully obtained through discovery in this litigation or in any other litigation in which such information was not designated as "confidential" or subject to confidential treatment.
- pleading, motion or other paper filed with the Court containing or disclosing any such Confidential Discovery Material shall be filed under seal and shall bear the legend: "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION COVERED BY A CONFIDENTIALITY ORDER OF THE COURT AND IS SUBMITTED UNDER SEAL PURSUANT TO THAT ORDER. THE CONFIDENTIAL CONTENTS OF THIS DOCUMENT MAY NOT BE DISCLOSED WITHOUT EXPRESS ORDER OF THE COURT." Said Confidential Discovery Material and/or other papers shall be kept under seal and maintained by the Clerk of the Court separate from the public records in this litigation until further order of the court; however, said Confidential Discovery Material and other papers filed under seal shall be available to the Court and counsel of record, and to all other persons entitled to receive the confidential information contained therein under the terms of this Order.
- 12. (a) Nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any Discovery Material produced or provided by that party.

- (b) Nothing shall prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not timely appealed.
- (c) No disclosure pursuant to this paragraph 12 shall waive any rights or privileges of any party granted by this Order.
- 13. This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that Discovery Material designated as confidential under the terms of this Order is properly discoverable, relevant or admissible in this or any other litigation. Without limiting the generality of the foregoing, this order is without prejudice to the right of the producing party to object to the production of the information or to withhold information on the ground that it constitutes highly confidential trade secrets that should not be produced even pursuant to the protections contained in this Order. In the event a party withholds documents or other information on the ground that it constitutes a highly confidential trade secret, the party withholding information shall produce a log specifying in reasonable detail what has been withheld and the basis therefor and the requesting party reserves the right to challenge by appropriate motion the withholding of such information.
- 14. The entry of this Order shall be without prejudice to the rights of the parties, or any one of them, or of any non-party to assert or apply for additional or different protection at their discretion.
- 15. All counsel of record in this litigation shall make a good faith effort to comply with the provisions of this Order and to ensure that their clients do so. In the event

of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

16. The terms of this Order shall survive and remain in effect after the termination of In re New York Diet Drug Litigation and all lawsuits which now or hereafter are consolidated therein. The parties shall take such measures as are necessary and appropriate to prevent the public disclosure of Confidential Discovery Material, through inadvertence or otherwise, after the conclusion of such litigation.

17. This Order does not restrict or limit the use of Confidential Discovery Material at any hearing or trial. Nothing in this Order, however, shall prevent any party from seeking an appropriate protective order to govern such use of Confidential Discovery Material at a hearing or trial.

IT IS SO ORDERED

	ENTER:
DATED;	
	Honorable Helen E. Freedman  Justice of the Supreme Court

The undersigned agrees:

PRESENT: HONORABLE HELEN E. FREEDMAN

I hereby attest to my understanding that information or documents designated confidential are provided to me subject to the Order Concerning Certain Confidential Material, dated _______, 1998 (the "Confidentiality Order"), in the above-captioned litigation; that I have been given a copy of and have read the Confidentiality Order, and that I agree to be bound by its terms. I also understand that my execution of this Confidentiality Agreement, indicating my agreement to be bound by the Confidentiality Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Confidentiality Order.

I further agree that I shall not disclose to others, except in accord with the Confidentiality Order, any Confidential Discovery Material, as defined therein, or any information contained in such Confidential Discovery Material, in any form whatsoever, and

that such Confidential Discovery Material and the information contained therein may be used only for the purposes authorized by the Confidentiality Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such Discovery Material and information will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Confidentiality Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the Supreme Court of the State of New York, New York County, for the purposes of any proceedings relating to enforcement of the Confidentiality Order.

I further agree to be bound by and to comply with the terms of the Confidentiality Order as soon as I sign this Agreement, whether or not the Confidentiality Order has yet been signed by the Court.

Date:			
	By:	-	
Subscribed and sworn to before me this day of, 1998			
Notary Public	-		

COUNTY OF NEW YORKX	RK
IN RE: NEW YORK DIET DRUG LITIGATION:	Index No. 700000/98
:	
THIS DOCUMENT RELATES TO ALL DIET DRUG CASES VENUED IN NEW YORK COUNTY	ORDER CONCERNING INADVERTENTLY PRODUCED MATERIAL
: X	

- 1. This Order applies to all documents and other information media exchanged by the parties in the course of this litigation, including but not limited to products of discovery, all information derived therefrom and including, but not limited to, all copies, excerpts of summaries thereof, obtained by the plaintiffs or defendants in these cases pursuant to the requirements of any court order, responses to notices for discovery and inspection, responses to requests to admit, interrogatory answers, and depositions and deposition exhibits.
- 2. The inadvertent production or disclosure of an attorney-client privileged, work product or other protected document or information medium shall not be deemed either a general waiver of privilege, work product or other protection by the producing party or a waiver of privilege, work product or other protection as to the document or other information medium inadvertently produced or disclosed. In the event of inadvertent disclosure of an attorney-client privileged, work product or other protected document or information medium, promptly upon discovery of such inadvertent disclosure, the producing party may move the Court for a protective order with respect thereto. Upon finding that the document or information medium is privileged or otherwise protected and that its production was

inadvertent, the Court may direct the return of the document or information medium and all copies thereof to the producing party, preclude the use of the document or information medium and any information contained therein for any purpose in this litigation, and order such other relief as the Court deems necessary and appropriate. Before making application to the Court for such relief, the producing party shall confer with the Plaintiffs' and Defendants' Steering Committees in an attempt consensually to resolve any dispute regarding the inadvertent production. Upon notification by the producing party that a document or information medium is privileged or otherwise protected and that its production was inadvertent, the recipient of the document or information medium shall not use the document in any litigation, nor permit the document or information medium to be copied or distributed to any other party until the dispute regarding its inadvertent production is resolved either amicably by the parties, or by order of the Court.

3. All counsel of record in this litigation shall make a good faith effort to comply with the provisions of this Order and to ensure that their clients do so. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

IT IS SO ORDERED

	ENTER:
DATED:	
	Honorable Helen E. Freedman  Justice of the Supreme Court