0610217

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Deborah Platt Majoras, Chairman**
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

In the Matter of	)	
BARR PHARMACEUTICALS, INC.	)	**Docket No. C-**
a corporation.	)	

DECISION AND ORDER
[Public Record Verrsion]

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Barr Pharmaceuticals, Inc. of PLIVA d.d., and Respondent having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets (attached to this Order as Appendix I), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission

hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Barr Pharmaceuticals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

2. PLIVA d.d. is a corporation organized, existing and doing business under and by virtue of the laws of the Republic of Croatia, with its headquarters address at Ulica Graden Vukovara 49, 10000 Zagreb, Croatia, and the address of the principal place of business of its United States subsidiaries at 72 Eagle Rock Avenue, P.O. Box 371, East Hanover, New Jersey 07936.

3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in the Order, the following definitions shall apply:

A. "Barr" means Barr Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Barr (including, but not limited to, Barr Laboratories, Inc.) and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Barr shall include PLIVA.

B. "PLIVA" means PLIVA d.d., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by PLIVA (including, but not limited to, its United States subsidiaries, *i.e.*, PLIVA, Inc., PLIVA USA, and Odyssey Pharmaceuticals, Inc.), and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

C. "Respondent" means Barr.

D. "Commission" means the Federal Trade Commission.

E. "Acquisition" means the Respondent's acquisition of fifty percent (50%) or more of the voting securities of PLIVA.

F. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, but is not limited to, the United States Food and Drug Administration ("FDA").

G. "Apotex" means Apotex, Inc., a corporation organized, existing, and doing business under and by virtue of the laws of Canada, with its headquarters address at 200 Barmac Drive, Toronto ON M9L2Z7 and its United States subsidiary Apotex Corp, a corporation organized, existing, and doing business under and by virtue of the laws of State of Delaware.

H. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA") means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND") for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondent and the FDA related thereto.

I. "Banner" means Banner Pharmacaps Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 4125 Premier Drive, High Point, NC 27265-8144.

J. "Cardinal" means Cardinal Health, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Ohio, with its headquarters address at 7000 Cardinal Place, Dublin, OH 43017.

K. "Categorized Assets" means the following assets related to the specified Divestiture Product(s):

1. all Product Intellectual Property related to such Divestiture Product(s);

2. perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold, imported, or exported the Divestiture Product(s) within the specified Geographic Territory;

3. all Product Registrations related to such Divestiture Product(s);

4. all Product Manufacturing Technology related to such Divestiture Product(s);

5. all Product Marketing Materials related to such Divestiture Product(s);

6. a list of all of the NDC Numbers related to such Divestiture Product(s), and rights, to the extent permitted by Law:

    a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;

    b. to prohibit Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s);

    c. to seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondent of any such cross-referencing that is discovered by Respondent);

    d. to seek cross-referencing from a customer of those NDC Numbers with the relevant Commission-approved Acquirer's NDC Numbers related to the Divestiture Product(s);

    e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;

    f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such numbers by Respondent prior to such notification(s) being disseminated to the customer(s);

7. all rights to all of Respondent's Applications related to such Divestiture Product(s);

8. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);

9. for each Divestiture Product that is a medical device, all rights to all of Respondent's or PLIVA's (whichever party is relevant to such Divestiture Product(s)) Premarket Approvals and Premarket Notifications related to such Divestiture Product(s);

10. for each Divestiture Product that is a medical device, all rights to all of Respondent's or PLIVA's (whichever party is relevant to such Divestiture Product(s)) medical device

reports, *i.e.*, all submissions to and correspondence from the FDA related to the Divestiture Product made pursuant to 21 C.F.R. § 803;

11. all Product Development Reports related to such Divestiture Product(s);

12. at the relevant Commission-approved Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Commission-approved Acquirer on or before the Closing Date);

13. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;

14. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);

15. a list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of such Divestiture Products on behalf of the High Volume Account and his or her business contact information;

16. at the relevant Commission-approved Acquirer's option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to such Divestiture Product(s);

17. copies of all unfilled customer purchase orders for such Divestiture Product(s) as of the Closing Date, to be provided to the relevant Commission-approved Acquirer not later than two (2) days after the Closing Date;

18. at the relevant Commission-approved Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Divestiture Products; and

19. all of the Respondent's or PLIVA's (whichever party is relevant to such Divestiture Product(s)) books, records, and files directly related to the foregoing or to such Divestiture Product(s);

provided, however, that "Categorized Assets" shall not include documents relating to Respondent's or PLIVA's general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products;

provided further, the "Categorized Assets" shall not include administrative, financial, and accounting records;

provided further, Respondent may exclude from the "Categorized Assets" quality control records that are determined by the Interim Monitor or the Commission-approved Acquirer not to be material to the manufacture of the Divestiture Product(s);

provided further, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such Divestiture Product(s) and to other Products or businesses of the Respondent or PLIVA and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Divestiture Product(s); or (2) for which the relevant party has a legal obligation to retain the original copies, the relevant party shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the relevant Commission-approved Acquirer, the relevant party shall provide such Commission-approved Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondent provides the relevant Commission-approved Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

L. "cGMP" means current Good Manufacturing Practice as set forth in the United States Federal, Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

M. "Closing Date" means, as to each Divestiture Product, the date on which Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to a Commission-approved Acquirer pursuant to this Order.

N. "Commission-approved Acquirer" means the following:

1. an entity specified by name in this Order to acquire particular assets or rights that Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's

determination to make this Order final; or

2. an entity approved by the Commission to acquire particular assets or rights that Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

O. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent or PLIVA that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Order regarding the use, conveyance, provision or disclosure of "Confidential Business Information" shall not apply to the following:

1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondent;

2. information related to the Nimodipine (Barr) Products, Trazodone Hydrochloride Products, the Triamterene and Hydrochlorothiazide Products or the ViaSpan Products that PLIVA can demonstrate it obtained without the assistance of Respondent prior to the Acquisition;

3. information related to the Custodiol Products or the Nimodipine (PLIVA) Products that Respondent can demonstrate it obtained without the assistance of PLIVA prior to the Acquisition;

4. information related to the Trazodone Hydrochloride Tablets USP 300 mg;

5. information that is required by Law to be publicly disclosed;

6. information that does not directly relate to the Divestiture Product(s);

7. information relating to Respondent or PLIVA's general business strategies or practices relating to research, development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or

8. information specifically excluded from the Categorized Assets.

P. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondent or a Designee to a Commission-approved Acquirer.

Q. "Custodiol Product(s)" means all Products that contain Histidine, Tryptophan, Potassium hydrogen 2-Ketoglutarate and Mannitol, researched, Developed, in Development, manufactured, marketed or sold by PLIVA on or before the Effective Date. The term "Custodiol Products" includes, but is not limited to, all Products in Development, manufactured, marketed or sold by PLIVA on or before the Effective Date that are planned to be marketed for use in the preservation or cleansing of human organs during transplantation and/or for use in cardioplegia.

R. "Custodiol Product Assets" means all of PLIVA's rights, title and interest in and to all assets related to PLIVA's business within the United States of America (including all of the territories within its jurisdiction or control) and Canada related to the Custodiol Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Custodiol Products, including, without limitation, the Categorized Assets related to the Custodiol Products.

S. "Custodiol Product Divestiture Agreements" means the "Asset Purchase Agreement" by and between Odyssey Pharmaceuticals, Inc. and New Custodiol LLC dated as of August 2, 2006, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Custodiol Products that have been approved by the Commission to accomplish the requirements of this Order. The Custodiol Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.B.

T. "Designee" means any entity other than Respondent or PLIVA that will manufacture a Divestiture Product for a Commission-approved Acquirer.

U. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.

V. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Commission-approved Acquirer for its use of any of Respondent's employees' labor shall not exceed the average hourly wage rate for such employee.

W. "Divestiture Product(s)" means the following Products: the Custodiol Products, the Nimodipine (Barr) Products, the Nimodipine (PLIVA) Products, the Trazodone

Hydrochloride Products, the Triamterene and Hydrochlorothiazide Products, and the ViaSpan Products, individually and collectively.

X. "Divestiture Product Core Employees" means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

Y. "Divestiture Product Releasee(s)" means the Commission-approved Acquirer for the assets related to a particular Divestiture Product or any entity controlled by or under common control with such Commission-approved Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Commission-approved Acquirer, or of such Commission-approved Acquirer-affiliated entities.

Z. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.

AA. "Domain Name" means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. "Domain Name" shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

BB. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

CC. "Effective Date" means the date on which the Acquisition occurs.

DD. "Expiration Date" means the earliest of the following days:

1. the day on which Respondent withdraws its tender offer for the voting securities of PLIVA;

2. the day on which Respondent's tender offer for the voting securities of PLIVA expires without extension or amendment by Respondent;

3. the day on which an entity other than Respondent acquires fifty (50) percent or more of the voting securities of PLIVA; or

4. the day six (6) months after the day on which this Order becomes final.

EE. "Generic Divestiture Product Agreement(s)" means the "Asset Purchase Agreement" between Barr Laboratories, Inc. and Apotex Corp. dated as of October 2, 2006, and all amendments, exhibits, attachments, agreements, and schedules thereto and the "Interim Supply Agreement" between Barr Laboratories, Inc. and Apotex Corp. dated as of October 2, 2006, and all amendments, exhibits, attachments, agreements, and schedules thereto,

related to the Trazodone Hydrochloride Product Assets, and the Triamterene and Hydrochlorothiazide Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.A.

FF. "Geographic Territory" shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.

GG. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

HH. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from the Respondent or PLIVA (whichever party is relevant to such Divestiture Product) was, is, or is projected to be among the top twenty highest of such purchase amounts by Respondent's or PLIVA's (whichever party is relevant to such Divestiture Product) U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

II. "Interim Monitor" means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.

JJ. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

KK. "NDC Numbers" means the National Drug Code number(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

LL. "New Custodiol" means New Custodiol LLC, a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at c/o Francis X. Wentworth, Jr., 1776 On The Green, 67 Park Place East, 8th Floor, Morristown, NJ 07960.

MM. "Nimodipine (Barr) Product(s)" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following of Respondent Barr's ANDAs:

1. ANDA No. 77-811; and

2. any supplements, amendments, or revisions thereto.

NN. "Nimodipine (Barr) Product Assets means all of Respondent Barr's rights, title and interest in and to all assets related to Respondent Barr's business within the Geographic Territory related to the Nimodipine (Barr) Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Nimodipine (Barr) Products, including, without limitation, the Categorized Assets related to the Nimodipine (Barr) Products.

OO. "Nimodipine (PLIVA) Product(s)" means all of the following: all Products in Development, manufactured, marketed or sold by PLIVA pursuant to the following of PLIVA's ANDAs:

1. ANDA No. 76-740; and

2. any supplements, amendments, or revisions thereto.

PP. "Nimodipine (PLIVA) Product Agreement" means the "Amended and Restated Joint Venture Agreement" by and between Sidmak Laboratories, Inc. and Banner Pharmacaps, Inc. dated as of May 30, 2002, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Nimodipine (PLIVA) Product Agreement is attached to this Order and contained in non-public Appendix III.1.

QQ. "Nimodipine (PLIVA) Product Assets means all of PLIVA's rights, title and interest in and to all assets related to PLIVA's business within the Geographic Territory related to the Nimodipine (PLIVA) Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Nimodipine (PLIVA) Products, including, without limitation, the Categorized Assets related to the Nimodipine (PLIVA) Products.

RR. "Nimodipine (PLIVA) Product Divestiture Agreement(s)" means the "Asset Purchase Agreement" by and between PLIVA, Inc. and Banner Pharmacaps Inc., dated as of August 2, 2006, and the "Transition Services Agreement" by and between PLIVA, Inc. f/k/a Sidmak Laboratories, Inc. and Banner Pharmacaps Inc., dated as of August 2, 2006, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Nimodipine (PLIVA) Products that have been approved by the Commission to accomplish the requirements of this Order. The Nimodipine (PLIVA) Product Divestiture Agreements are attached to this Order and contained in non-public Appendix III.1.

SS. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders. The Order to Maintain Assets is attached to this Order and contained in Appendix I.

TT. "Ownership Interest" means any and all rights, present or contingent, of Respondent to hold any voting or nonvoting stock, share capital, equity or other interests or beneficial ownership in an entity.

UU. "Paragraph II Divestiture Products" means the following Products: (1) the Trazodone Hydrochloride Products; (2) the Triamterene and Hydrochlorothiazide Products; and (3) the Divestiture Products and the assets related to such Divestiture Products that Respondent divests in accordance with and pursuant to Paragraph II.B., *i.e.*, either the Custodiol Products or the ViaSpan Products.

VV. "Paragraph III Divestiture Products" means the Divestiture Products and the assets related to such Divestiture Products that Respondent divests in accordance with and pursuant to Paragraph III.A., *i.e.*, either the Nimodipine (Barr) Products, or the Nimodipine (PLIVA) Products.

WW. "Patents" means all patents, patent applications, including provisional patent applications, and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondent or PLIVA as of the Closing Date (*except* where this Order specifies a different time).

XX. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

YY. "Premarket Approval(s)" means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. § 814, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent(s) and the FDA related thereto. The term "Premarket Approval(s)" includes all orders of approval and all reports and documents submitted to the FDA under postapproval requirements.

ZZ. "Premarket Notification(s)" means a premarketing submission for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. § 807, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, all information submitted with or incorporated by reference, and all correspondence between Respondent(s) and the FDA related thereto, to demonstrate that a device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to Premarket Approval. The term "Premarket Notification(s)" includes all notices of registration and all reports and documents required to be submitted to the FDA related to the marketing of such Product.

AAA. "Product" means:

1. any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient; and/or

2. any medical device, *i.e.*, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

   a. recognized in the official National Formulary of the United States, or the United States Pharmacopoeia, or any supplement to them,

   b. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

   c. intended to affect the structure or any function of the body of man, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

BBB. "Product Assumed Contracts" means all of the following contracts or agreements (copies of each such contract to be provided to the Commission-approved Acquirer on or before the relevant Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product(s) from Respondent or PLIVA (whichever party is relevant to such Divestiture Product) unless such contract applies generally to the divesting entity's sales of Products to that Third Party;

2. pursuant to which Respondent or PLIVA (whichever party is relevant to such Divestiture Product) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);

3. relating to any clinical trials involving the Divestiture Product(s);

4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;

5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);

6. pursuant to which a Third Party manufactures the Divestiture Product(s) on behalf of Respondent or PLIVA (whichever party is relevant to such Divestiture Product);

7. pursuant to which a Third Party provides the Product Manufacturing Technology or related equipment related to the Divestiture Product(s) to Respondent or PLIVA (whichever party is relevant to such Divestiture Product);

8. constituting confidentiality agreements involving the Divestiture Product(s);

9. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);

10. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Divestiture Products to Respondent or PLIVA (whichever party is relevant to such Divestiture Product) including, but not limited to, consultation arrangements; and/or

11. pursuant to which any Third Party collaborates with Respondent or PLIVA (whichever party is relevant to such Divestiture Product) in the performance of research, Development, marketing, distribution or selling of the Divestiture Product(s) or the Divestiture Product(s) business;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), Respondent shall assign the Commission-approved Acquirer all such rights under the contract or agreement as are related to the Divestiture Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

CCC. "Product Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all raw data relating to clinical trials of the Divestiture Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; customer information, promotional and marketing materials, the

Divestiture Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Commission-approved Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all data contained in laboratory notebooks relating to the Divestiture Product(s) or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the FDA.

DDD. "Product Development Reports" means:

1. Pharmacokinetic study reports related to the specified Divestiture Product(s);

2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);

3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product(s);

4. all correspondence to the Respondent or PLIVA (whichever party is relevant to such Divestiture Product) from the FDA and from the Respondent or PLIVA (whichever party is relevant to such Divestiture Product) to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent or PLIVA (whichever party is relevant to such Divestiture Product) related to the specified Divestiture Product;

5. annual and periodic reports related to the above-described Application(s), including any safety update reports;

6. FDA approved Product labeling related to the specified Divestiture Product(s);

7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);

8. FDA approved patient circulars and information related to the specified Divestiture Product(s);

9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);

10. summary of Product complaints from physicians related to the specified Divestiture

Product(s);

11. summary of Product complaints from customers related to the specified Divestiture Product(s); and

12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

EEE. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by the Law:

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondent within ninety (90) days of the execution date of any Remedial Agreement);

2. with respect to each such employee, the following information:

    a. the date of hire and effective service date;

    b. job title or position held;

    c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondent may provide the employee's most recent performance appraisal;

    d. the base salary or current wages;

    e. the most recent bonus paid, aggregate annual compensation for Respondent's last fiscal year and current target or guaranteed bonus, if any;

    f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and

    g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

3. at the Commission-approved Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

FFF. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;

2. Product Copyrights;

3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and

4. rights to obtain and file for patents and copyrights and registrations thereof;

provided, however, "Product Intellectual Property" does not include the names or trade dress of "Barr", "PLIVA", or the names or trade dress of any other corporations, companies, or brands owned or sold by Respondent or PLIVA or the related logos to the extent used on Respondent's or PLIVA's Retained Products.

GGG. "Product Licensed Intellectual Property" means the following:

1. Patents that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by either Respondent or PLIVA (whichever party is relevant to such Divestiture Product) for a Retained Product(s) that:

   a. has been marketed or sold on an extensive basis by Respondent or PLIVA (whichever party is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or

   b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by Respondent or PLIVA; and

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in any jurisdiction to limit the use or disclosure thereof, that are related to a Divestiture Product and that Respondent or PLIVA can demonstrate have been routinely used, prior to the Effective Date, by either Respondent or PLIVA (whichever party is relevant to such Divestiture Product) for a Retained Product(s) that:

   a. has been marketed or sold on an extensive basis by either Respondent or PLIVA (whichever party is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or

b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by Respondent or PLIVA;

provided however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Commission-approved Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Commission-approved Acquirer; *provided further, however*, that in such cases, Respondent may take a license back from the Commission-approved Acquirer for such intellectual property for use in connection with the Retained Products.

HHH. "Product Manufacturing Employees" means all salaried employees of Respondent or PLIVA who have directly participated in the planning, design, implementation or use of the Product Manufacturing Technology of the specified Divestiture Product(s) (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

III. "Product Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Product(s) (including, for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Commission-approved Acquirer's option, all such equipment used to manufacture the Divestiture Product(s)), including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists.

JJJ. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (e.g., detailing reports, vendor lists, sales data), marketing information (e.g., competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchases information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational

materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product(s); provided however, "Product Marketing Materials" excludes the pricing of each of the Divestiture Products to customers *except* for the Custodiol Products and the ViaSpan Products.

KKK. "Product Registrations" means all registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, or sale of the Product within the Geographic Territory, including all Applications in existence for the Product as of the Closing Date.

LLL. "Product Research and Development Employees" means all salaried employees of Respondent or PLIVA who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

MMM. "Product Trade Dress" means the current trade dress of the Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

NNN. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Product(s).

OOO. "Proposed Acquirer" means an entity proposed by Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent pursuant to this Order.

PPP. "Remedial Agreement(s)" means the following:

1. any agreement between Respondent and a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

2. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of a Commission-approved Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final;

3. any agreement between Respondent and a Commission-approved Acquirer (or between a Divestiture Trustee and a Commission-approved Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of a Commission-approved Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

QQQ. "Retained Product" means any Product(s) other than a Divestiture Product.

RRR. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

SSS. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit.

TTT. "Third Party(ies)" means any private entity other than the following: (1) Respondent; (2) PLIVA or (3) the relevant Commission-approved Acquirer for the affected assets, rights and Divestiture Product(s).

UUU. "Trazodone Hydrochloride Product(s)" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following of Respondent Barr's ANDAs:

1. ANDA No. 71-196 (Trazodone Hydrochloride Tablets USP 100 mg, 150 mg, 300 mg);

2. ANDA No. 71-258 (Trazodone Hydrochloride Tablets USP 50 mg); and

3. any supplements, amendments, or revisions thereto.

VVV. "Trazodone Hydrochloride Product Assets" means all of Respondent Barr's rights, title and interest in and to all assets related to Respondent Barr's business within the Geographic Territory related to the Trazodone Hydrochloride Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Trazodone Hydrochloride Products, including, without limitation, the Categorized Assets related to the Trazodone Hydrochloride Products; *provided*, *however*, Respondent may receive a non-exclusive license from the Commission-approved Acquirer to market Trazodone Hydrochloride Tablets USP 300 mg.

WWW. "Triamterene and Hydrochlorothiazide Product(s)" means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following of Respondent Barr's ANDAs:

1. ANDA No. 71-251 (Triamterene/Hydrochlorothiazide Tablets USP 37.5 mg/25 mg); and

2. any supplements, amendments, or revisions thereto.

XXX. "Triamterene and Hydrochlorothiazide Product Assets" means all of Respondent Barr's rights, title and interest in and to all assets related to Respondent Barr's business within the Geographic Territory related to the Triamterene and Hydrochlorothiazide Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Triamterene and Hydrochlorothiazide Products, including, without limitation, the Categorized Assets related to the Triamterene and Hydrochlorothiazide Products.

YYY. "ViaSpan Product(s)" means all of the Products in Development, manufactured, marketed or sold by Respondent Barr pursuant to the following Premarket Notification:

1. 510(k) No. K944866; and

2. any supplements, amendments, or revisions thereto;

The term "ViaSpan Products" also includes all Products in Development, manufactured, marketed or sold by Barr on or before the Effective Date that are planned to be marketed for use in the preservation of human organs during transplantation and/or for use in cardioplegia.

ZZZ. "ViaSpan Product Assets" means all of Respondent Barr's rights, title and interest in and to all assets related to Respondent Barr's business within the Geographic Territory related to the ViaSpan Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the ViaSpan Products,

including, without limitation, the Categorized Assets related to the ViaSpan Products.

AAAA. "Website" means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by Respondent; *provided, however*, "Website" shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondent can convey its rights, if any, therein; or (2) content unrelated to the Product(s).

II.

IT IS FURTHER ORDERED that:

A. Not later than ten (10) days after the Effective Date, Respondent shall divest the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets, absolutely and in good faith, to Apotex pursuant to, and in accordance with, the Generic Divestiture Product Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Apotex or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets, respectively, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets to Apotex prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Apotex is not an acceptable purchaser of the Trazodone Hydrochloride Product Assets, or the Triamterene Product Assets then Respondent shall immediately rescind the transaction with Apotex, in whole or in part, as directed by the Commission, and shall divest the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets, as is relevant, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer(s) and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent has divested the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets to Apotex prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a

Divestiture Trustee, to effect such modifications to the manner of divestiture of the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets to Apotex (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

B. Respondent either:

1. not later than ten (10) days after the Effective Date, shall divest the Custodiol Product Assets, absolutely and in good faith, to New Custodiol pursuant to, and in accordance with, the Custodiol Product Divestiture Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of New Custodiol or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes the Remedial Agreement related to the Custodiol Product Assets, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondent has divested the Custodiol Product Assets to New Custodiol prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that New Custodiol is not an acceptable purchaser of the Custodiol Product Assets then Respondent shall immediately rescind the transaction with New Custodiol, in whole or in part, as directed by the Commission, and shall divest either the Custodiol Product Assets or the ViaSpan Product Assets within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission;

provided further that if Respondent has divested the Custodiol Product Assets to New Custodiol prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Custodiol Product Assets to New Custodiol (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order; or

2. not later than ninety (90) days from the date on which this Order becomes final, shall divest the ViaSpan Product Assets, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission.

C. Any Remedial Agreement related to the Paragraph II Divestiture Products shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such

Remedial Agreement shall constitute a failure to comply with this Order. Respondent shall include in each Remedial Agreement related to each of the Paragraph II Divestiture Products a specific reference to this Order, and the remedial purpose thereof.

D. Respondent shall do the following and, in addition, include the following among the provisions in the Remedial Agreement(s) related to each of the Paragraph II Divestiture Products:

1. upon reasonable notice and request from the Commission-approved Acquirer to Respondent, Respondent shall provide in a timely manner at no greater than Direct Cost the following:

   a. assistance and advice to enable the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all necessary permits and approvals from any Agency or Government Entity to manufacture and sell the relevant Divestiture Products;

   b. assistance to the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to manufacture the relevant Divestiture Product(s) in substantially the same manner, quality, and quantity(ies) employed or achieved by either Respondent or PLIVA for the relevant Divestiture Product(s); and

   c. consultation with knowledgeable employees of Respondent and training, at the request of the Commission-approved Acquirer and at a facility chosen by the Commission-approved Acquirer, until the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) obtains all FDA approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the relevant Divestiture Product(s) independently of Respondent and PLIVA and sufficient to satisfy management of the Commission-approved Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Product(s);

   d. personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the assets related to the Divestiture Products;

   e. the foregoing provisions, II.D.1.a. - e., shall remain in effect until the relevant Commission-approved Acquirer (or the Designee(s) of such Commission-approved Acquirer) is: (1) approved by the FDA to manufacture each of the relevant Divestiture Products, and (2) able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and PLIVA;

2. provide an organized, comprehensive, complete, useful, timely, and meaningful transfer

of information related to the Product Manufacturing Technology, and, as a part of such transfer, shall designate employees of Respondent knowledgeable with respect to such Product Manufacturing Technology and experienced in such transfers to a committee for the purposes of communicating directly with the Commission-approved Acquirer and the Interim Monitor (if applicable) for the purposes of effecting such transfer;

3. include in the Remedial Agreement a representation from the relevant Commission-approved Acquirer that such Commission-approved Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product and to have any such manufacture to be independent of Respondent and PLIVA, all as soon as reasonably practicable;

4. upon reasonable notice and request from the Commission-approved Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist the Commission-approved Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to the relevant Divestiture Product(s);

5. for any patent infringement suit in which Respondent or PLIVA is a party prior to the Closing Date or for which Respondent or PLIVA has prepared or is preparing as of the Closing Date to be a party, and where such a suit would have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Product(s), Respondent shall:

    a. cooperate with the Commission-approved Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation involving a Divestiture Product;

    b. waive conflicts of interest, if any, to allow Respondent's or PLIVA's outside legal counsel to represent the Commission-approved Acquirer in any ongoing patent litigation involving a Divestiture Product; and

    c. permit the transfer to the Commission-approved Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondent's or PLIVA's outside counsel relating to such Divestiture; and

6. Respondent shall not seek pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

E. Respondent shall do the following and, in addition, shall include the following among the provisions in the Remedial Agreement(s) related to each of the following Divestiture Products: Trazodone Hydrochloride Product(s) and Triamterene and Hydrochlorothiazide Product(s):

1. upon reasonable notice and request from the Commission-approved Acquirer to Respondent, Respondent shall Contract Manufacture and deliver to the Commission-approved Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the relevant Divestiture Products at Respondent's Supply Cost, for a period of time sufficient to allow the Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the relevant finished drug product independently of Respondent and PLIVA and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components specified in the Respondent's Application(s) for the Product from entities other than Respondent or PLIVA; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, Supply Cost shall be determined as specified in such Remedial Agreement;

2. Respondent shall make representations and warranties to the Commission-approved Acquirer that the Product(s) supplied through Contract Manufacture pursuant to the Remedial Agreement meet the relevant Agency-approved specifications. For the Product(s) to be marketed or sold in the Geographic Territory, Respondent shall agree to indemnify, defend and hold the Commission-approved Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Commission-approved Acquirer pursuant to the Remedial Agreement by Respondent to meet cGMP. This obligation may be made contingent upon the Commission-approved Acquirer giving Respondent prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order; *provided, however*, that Respondent may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondent's responsibilities to supply the ingredients and/or components in the manner required by this Order; *provided further* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Commission-approved Acquirer or for any representations and warranties, express or implied, made by the Commission-approved Acquirer that exceed the representations and warranties made by Respondent to the Commission-approved Acquirer; *provided further* that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits

on Respondent's aggregate liability resulting from the failure of the Products supplied to the Commission-approved Acquirer pursuant to such Remedial Agreement by Respondent to meet cGMP;

3. Respondent shall make representations and warranties to the Commission-approved Acquirer that Respondent shall hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver the Products in a timely manner as required by the Remedial Agreement unless Respondent can demonstrate that its failure was entirely beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent; *provided, however*, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondent's aggregate liability for such a breach; and

4. during the term of the Contract Manufacture between Respondent and the Commission-approved Acquirer, upon request of the Commission-approved Acquirer or Interim Monitor (if any has been appointed), Respondent shall make available to the Commission-approved Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date.

The foregoing provisions, II.E.1. - 4., shall remain in effect until the relevant Commission-approved Acquirer (or the Designee(s) of such Commission-approved Acquirer) is: (1) approved by the FDA to manufacture each of the relevant Divestiture Products, and (2) able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and PLIVA.

F. Respondent shall:

1. submit to the Commission-approved Acquirer, at Respondent's expense, all Confidential Business Information related to the relevant Divestiture Product(s);

2. deliver such Confidential Business Information as follows:

   a. in good faith;

   b. as soon as practicable, avoiding any delays in transmission of the respective information; and

   c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the Commission-approved Acquirer, provide the Commission-approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Product(s) that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondent's obligations to the Commission-approved Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or

   c. applicable Law;

5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer; and

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products.

G. Respondent shall not enforce any agreement against a Third Party or the Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Commission-approved Acquirer to acquire the Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

H. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Commission-approved Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to the Commission-approved Acquirer for the relevant assets.

I. Respondent shall:

1. for each Paragraph II Divestiture Product, for a period of at least twelve (12) months from the relevant Closing Date or upon the hiring of ten (10) Divestiture Product Core Employees by the relevant Commission-approved Acquirer, whichever occurs earlier, provide the relevant Commission-approved Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Paragraph II Divestiture Products and assets acquired by such Commission-approved Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Employee Access Period(s)"; and

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Commission-approved Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Employee Access Period(s) with respect to that employee in an amount equal to the delay.

J. Respondent shall:

1. during the Divestiture Product Employee Access Period(s), not interfere with the hiring or employing by the relevant Commission-approved Acquirer of the Divestiture Product Core Employees related to the particular Divestiture Products and assets acquired by such Commission-approved Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with the relevant Commission-approved Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent or PLIVA (whichever party is relevant to such Divestiture Product) that would affect the ability or incentive of those individuals to be employed by the relevant Commission-approved Acquirer. In addition, Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Commission-approved Acquirer;

provided, however, that this Paragraph II.J.1 shall not prohibit Respondent or PLIVA from continuing to employ any Divestiture Product Core Employee during the Divestiture Product Employee Access Period (subject to the conditions of continued employment prescribed in this Order);

2. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product(s) consistent with past practices and/or as may be

necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent or PLIVA (whichever party is relevant to such Divestiture Product) until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that nothing in this Order requires or shall be construed to require Respondent to terminate the employment of any employee or prevent Respondent from continuing to employ the Divestiture Product Core Employees (other than those conditions of continued employment prescribed in this Order) in connection with the Acquisition; and

3. for a period of one (1) year from the relevant Closing Date, not:

   a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commission-approved Acquirer with any amount of responsibility related to a Divestiture Product ("Divestiture Product Employee") to terminate his or her employment relationship with the relevant Commission-approved Acquirer; or

   b. hire any Divestiture Product Employee; *provided, however,* Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the relevant Commission-approved Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided, however, Respondent may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

K. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to the relevant Commission-approved Acquirer(s), and/or to permit such Commission-approved Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Paragraph II Divestiture Products;

provided, however, Respondent may satisfy this requirement by certifying that the relevant Commission-approved Acquirer has executed all such agreements directly with each of the relevant Third Parties.

L. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondent and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Paragraph II Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

M. Not later than thirty (30) days after the Effective Date, Respondent shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Paragraph II Divestiture Products by Respondent's personnel to all of Respondent's employees who:

1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;

2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition; and/or

3. may have Confidential Business Information related to the Divestiture Products.

Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondent shall provide a copy of such notification to the Commission-approved Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's corporate headquarters and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

N. Upon reasonable notice and request by the Commission-approved Acquirer(s), Respondent shall make available to the Commission-approved Acquirer(s), at no greater than Direct Cost (or, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, then at such cost as may be provided therein) such personnel, assistance and training as the Commission-approved Acquirer(s) might reasonably need to transfer the assets related to the Divestiture Product(s) and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer(s), until the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is: (1) approved by the FDA to

manufacture each of the relevant Divestiture Products, and (2) able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and PLIVA.

O. Pending divestiture of the assets required to be divested pursuant to Paragraphs II.A. and II.B. of this Order, Respondent shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with such assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of these assets until after their respective transfer to the relevant Commission-approved Acquirer in a manner that ensures that there is no disruption, delay, or impairment of the regulatory approval processes related to such assets. Respondent shall not sell, transfer, encumber or otherwise impair such assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the above-described businesses.

P. Respondent shall maintain manufacturing facilities necessary to manufacture the Trazodone Hydrochloride Product(s) and Triamterene and Hydrochlorothiazide Product(s) in finished form (suitable for sale to the ultimate consumer/patient) until the relevant Commission-approved Acquirer (or the Designee of the Commission-approved Acquirer) is: (1) approved by the FDA to manufacture each of the relevant Divestiture Products, and (2) able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and PLIVA;

provided, however, the Commission may eliminate, or limit the duration of, Respondent's obligation under this provision if the Commission determines that the relevant Commission-approved Acquirer is not using commercially reasonable efforts to secure the FDA approvals necessary to manufacture in commercial quantities each such Divestiture Product in finished form in a facility that is independent of Respondent and PLIVA and to enable itself to manufacture such quantities of each such Divestiture Product independently of Respondent and PLIVA.

Q. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant Commission-approved Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Paragraph II Divestiture Product(s) under the following:

1. any Patent owned or licensed by Respondent or PLIVA as of the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the respective Divestiture Product, or that claims a device relating to the use thereof;

2. any Patents owned or licensed at any time after the Effective Date by Respondent that claim any aspect of the research, Development, manufacture, use, import, export,

distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;

if such suit would have the potential to interfere with the relevant Commission-approved Acquirer's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Paragraph II Divestiture Products. Respondent shall also covenant to the relevant Commission-approved Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the relevant Commission-approved Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with the relevant Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Paragraph II Divestiture Products.

Respondent shall include the above-described covenants in the Remedial Agreement(s) with the relevant Commission-approved Acquirer.

R. Respondent shall not, in the Geographic Territory:

1. use the Product Trademarks related to the Divestiture Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;

2. attempt to register such Product Trademarks;

3. attempt to register any mark confusingly similar to such Product Trademarks;

4. challenge or interfere with the Commission-approved Acquirer(s)'s use and registration of such Product Trademarks; or

5. challenge or interfere with the Commission-approved Acquirer(s)'s efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that nothing in this Order shall preclude Respondent from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

S. The purpose of the divestiture of either the Custodiol Product Assets or the ViaSpan Product Assets is: (1) to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Custodiol Product or the ViaSpan Products, respectively; (2) to create a viable and effective competitor in the relevant markets alleged in the Commission's Complaint who is independent of the Respondent and PLIVA;

and, (3) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

T. The purpose of the divestiture of the Trazodone Hydrochloride Product Assets, and the Triamterene Product Assets is: (1) to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Trazodone Hydrochloride Products and the Triamterene Products, respectively; (2) to create a viable and effective competitor in the relevant markets alleged in the Complaint who is independent of Respondent and PLIVA; and, (3) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

III.

IT IS FURTHER ORDERED that:

A. Respondent either:

1. Not later than ten (10) days after the Effective Date, shall divest the Nimodipine (PLIVA) Product Assets (to the extent such assets are not already owned, controlled, or in the possession of Banner), absolutely and in good faith, to Banner pursuant to and in accordance with the Nimodipine (PLIVA) Product Divestiture Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of Banner or to reduce any obligations of Respondent under such agreements), and such agreement, if it becomes the Remedial Agreement related to the Nimodipine (PLIVA) Products is incorporated by reference into this Order and made a part hereof;

provided however, that if Respondent has divested the Nimodipine (PLIVA) Product Assets to Banner prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of the divestiture to Banner (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order; or

2. Not later than sixty (60) days from the Effective Date, shall divest the Nimodipine (Barr) Product Assets (to the extent that such assets are not already owned, controlled, or in the possession of Cardinal), absolutely and in good faith, at no minimum price, to Cardinal and only in a manner that receives the prior approval of the Commission.

B. Any Remedial Agreement related to the Paragraph III Divestiture Products shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order. Respondent shall include in each such Remedial Agreement a specific reference to this Order, and the remedial purpose thereof.

C. Upon reasonable notice and request from the Commission-approved Acquirer of assets pursuant to Paragraph III.A. ("Paragraph III.A. Commission-approved Acquirer"), Respondent shall provide, in a timely manner at no greater than Direct Cost, assistance and advice of knowledgeable employees of Respondent as such Commission-approved Acquirer might reasonably need to transfer the assets divested pursuant to Paragraph III.A., and shall continue providing such personnel, assistance and training, at the request of such Commission-approved Acquirer, until such assets are fully transferred to such Commission-approved Acquirer.

D. At the Paragraph III.A. Commission-approved Acquirer's request, Respondent shall provide, in a timely manner, at no greater than Direct Cost or Supply Cost (whichever is relevant), such assistance and services as may be necessary for such Commission-approved Acquirer to obtain any approvals that were planned or pending prior to the Acquisition related to any Application or planned or pending Application related to the Paragraph III Divestiture Products.

E. After the Closing Date for the divestiture required pursuant to Paragraph III.A., Respondent shall not receive any payment or other compensation from the Paragraph III.A. Commission-approved Acquirer that is:

1. based on the actual amount of sales or profits of the Paragraph III Divestiture Products realized at any time after the Closing Date, or

2. due upon the realization of any aggregate amount of sales or profits of such Divestiture Products.

F. Respondent shall:

1. submit to the Paragraph III.A. Commission-approved Acquirer, at Respondent's expense, all Confidential Business Information related to the Paragraph III Divestiture Products;

2. deliver such Confidential Business Information as follows:

   a. in good faith;

   b. as soon as practicable, avoiding any delays in transmission of the respective

information; and

c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

3. pending complete delivery of all such Confidential Business Information to the Paragraph III.A. Commission-approved Acquirer, provide such Commission Approved Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Paragraph III Divestiture Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Paragraph III Divestiture Products other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondent's obligations to the Paragraph III.A. Commission-approved Acquirer under the terms of any Remedial Agreement related to the Paragraph III Divestiture Products; or

   c. applicable Law;

5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Paragraph III.A. Commission-approved Acquirer; and

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales related to the Paragraph III Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications as the Paragraph III Divestiture Products.

G. Respondent shall not enforce any agreement against a Third Party or the Paragraph III.A. Commission-approved Acquirer to the extent that such agreement may limit or otherwise impair the ability of such Commission-approved Acquirer to acquire all Confidential Business Information related to the Paragraph III Divestiture Products. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each such Third Party that allows the Third Party to provide all such Confidential Business Information within the Third Party's possession or control to such Commission-approved Acquirer. This includes, but is not limited to, such releases as may be necessary to permit the transfer to such Commission-approved Acquirer of any attorney work-product related to the Product

Intellectual Property related to the Paragraph III Divestiture Products in the possession of Respondent's outside counsel. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to such Commission-approved Acquirer.

H. Until all of Respondent's rights to enforce restrictions on the use, disclosure, conveyance or provision of Confidential Business Information related to the Paragraph III Divestiture Products are fully assigned or conveyed to the Paragraph III.A. Commission-approved Acquirer, Respondent shall enforce any agreement against a Third Party to the extent that such agreement prevents or limits the ability of the Third Party to provide any such Confidential Business Information to any person or entity other than: (1) such Commission-approved Acquirer or (2) any Third Party Consultant authorized by such Commission-approved Acquirer to receive such information.

I. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against the Paragraph III.A. Commission-approved Acquirer(s) or the related Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Paragraph III Divestiture Product(s) under the following:

1. any Patent owned or licensed by Respondent or PLIVA as of the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the respective Divestiture Product, or that claims a device relating to the use thereof;

2. any Patents owned or licensed at any time after the Effective Date by Respondent that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;

if such suit would have the potential to interfere with the Paragraph III.A. Commission-approved Acquirer's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the Paragraph III Divestiture Products. Respondent shall also covenant to the Paragraph III.A. Commission-approved Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Paragraph III.A. Commission-approved Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with the Paragraph III.A. Commission-approved Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution, or sale of the Paragraph III Divestiture Products.

Respondent shall include the above-described covenants in the Remedial Agreement(s) with the Paragraph III.A. Commission-approved Acquirer.

J. Pending divestiture of the assets required to be divested pursuant to Paragraph III.A. of this Order, Respondent shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with such assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of these assets until after their respective transfer to the Paragraph III.A. Commission-approved Acquirer in a manner that ensures that there is no disruption, delay, or impairment of the regulatory approval processes related to such assets. Respondent shall not sell, transfer, encumber or otherwise impair such assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the above-described businesses.

K. The purpose of the divestiture required by Paragraph III is: (1) to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Paragraph III Divestiture Products; (2) to create a viable and effective competitor in the relevant markets alleged in the Complaint who is independent of Respondent and PLIVA; and, (3) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

IV.

IT IS FURTHER ORDERED that:

A. If Respondent does not acquire fifty (50) percent or more of the voting securities of PLIVA on or before the Expiration Date, then Respondent shall divest, absolutely and in good faith, all of its Ownership Interest in PLIVA on the Croatian Stock Exchange, or such other securities exchange as the voting securities of PLIVA are registered to be traded on, within one (1) year of the Expiration Date.

B. Pending the divestiture described in Paragraph IV.A., Respondent shall not, directly or indirectly:

1. exercise dominion or control over, or otherwise seek to influence, the management, direction or supervision of the business of PLIVA including, but not limited to, any participation in the formulation, determination or direction of any business decisions of PLIVA;

2. propose corporate action requiring the approval of PLIVA shareholders;

3. nominate, or any other way seek to or obtain representation on the Board of Directors of PLIVA;

4. have any of its directors, officers or employees serve simultaneously as an officer or

director of PLIVA;

5. exercise any voting rights attached to any Ownership Interest in PLIVA, *provided, however*, that in any matter to be voted on by the shareholders of PLIVA, Respondent shall cast the votes related to its Ownership Interest in each class of PLIVA stock in an amount and manner proportional to the vote of all other votes cast by other PLIVA shareholders entitled to vote on such matter;

6. seek or obtain access to any confidential, proprietary, or other non-public information of PLIVA relating to the research, Development, manufacture, distribution, sale, and marketing of Products that are approved by the FDA for the same or similar indications as Products researched, Developed, manufactured, distributed, sold, or marketed by Respondent, *provided however*, that this shall not be construed to prohibit Respondent from seeking or obtaining discovery in any litigation or other proceeding to resolve a claim between Respondent and PLIVA in accordance with the procedures of the forum before which the dispute is pending. With respect to any such discovery, Respondent shall enter into a protective order to prevent any information from being used for any purpose other than providing legal representation or evidence as to the particular dispute and to prevent any information from being disclosed to any person(s) not necessary to the resolution of such dispute; or

7. take any action or omit to take any action in a manner that would be incompatible with the status of Respondent as a passive investor in PLIVA.

The requirements of this Paragraph IV.B. shall continue and remain in effect so long as Respondent retains any Ownership Interest in PLIVA.

C. The purpose of the requirements of Paragraph IV is to ensure that, if the Acquisition does not occur, Respondent will not seek to exert, or exert influence upon, the business operations of PLIVA and shall divest itself of all of its Ownership Interest in PLIVA.

V.

IT IS FURTHER ORDERED that:

A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in

writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.

3. The Interim Monitor shall serve until the later of:

   a. the completion by Respondent of:

      (1) the divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of this Order; and

      (2) notification by each of the relevant Commission-approved Acquirers to the Interim Monitor that such Commission-approved Acquirer is: (1) approved by the FDA to manufacture the Trazodone Hydrochloride Products and the Triamterene Products, and (2) able to manufacture such Divestiture Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent and PLIVA; and

   b. the completion by Respondent of the last obligation under the Orders pertaining to the Interim Monitor's service;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement. Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials

and information received in connection with the performance of the Interim Monitor's duties.

F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.

H. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

VI.

IT IS FURTHER ORDERED that:

A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. In the event that the Commission or the Attorney General brings an action pursuant to § 5(*l*) of the Federal Trade Commission Act, 15 U.S.C. § 45(*l*), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(*l*) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; and, *provided further, however*, that Respondent shall select such entity

within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.

8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.

PUBLIC
APPENDIX I
ORDER TO MAINTAIN ASSETS

NON-PUBLIC APPENDIX II.A.
GENERIC DIVESTITURE PRODUCT AGREEMENTS

[Redacted From the Public Record Version But Incorporated By Reference]

NON-PUBLIC APPENDIX II.B.
AGREEMENTS RELATED TO THE
CUSTODIOL PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

NON-PUBLIC APPENDIX III.1
AGREEMENTS RELATED TO THE
NIMODIPINE (PLIVA) PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]

NON-PUBLIC APPENDIX III.2.
AGREEMENTS RELATED TO THE
NIMODIPINE (BARR) PRODUCTS

[Redacted From the Public Record Version But Incorporated By Reference]