# UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

0610139

COMMISSIONERS:	Deborah Platt Majoras, Chairman Pamela Jones Harbour Jon Leibowitz William E. Kovacic J. Thomas Rosch	
	3. Thomas Rosen	)
In the Matter of		) )
WATSON PHARMACEUTICALS, INC. a corporation;		) )
_		Docket No. C-4172
and		) )
ANDRX CORPO	RATION	)
a corporation.		) )

## ORDER TO MAINTAIN ASSETS

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Respondent Watson Pharmaceuticals, Inc. ("Watson") of Respondent Andrx Corporation ("Andrx"), hereinafter referred to as "Respondents," and Respondents 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 Respondents 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

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders ("Consent Agreement"), containing an admission by Respondents 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 Respondents 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 to accept the executed Consent Agreement and to place 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 issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

- 1. Respondent Watson is a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- 2. Respondent Andrx 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 8151 Peters Road, Plantation, Florida 33324.
- 3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

## **ORDER**

I.

**IT IS ORDERED** that, as used in the Order to Maintain Assets, the following definitions shall apply:

- A. "Watson" means Watson Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Watson (including, but not limited to, Watson Laboratories, Inc. and Water Delaware, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Watson shall include Andrx.
- B. "Andrx" means Andrx Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Andrx (including, but not limited to, Andrx Pharmaceuticals, Inc., and Andrx Pharmaceuticals, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. "Respondents" means Watson and Andrx, individually and collectively.
- D. "Commission" means the Federal Trade Commission.
- E. "Acquirer" means:

- 1. An entity identified by name in the Decision and Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, terminate, or otherwise convey pursuant to the Decision and Order and that has been approved by the Commission to accomplish the requirements of the Decision and Order in connection with the Commission's determination to make the Decision and Order final; or
- 2. An entity approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, terminate, or otherwise convey pursuant to the Decision and Order.
- F. "Acquirer Employees" means any of an Acquirer's employees with any amount of responsibility related to the Divestiture Products.
- G. "Acquisition" means the acquisition contemplated by The Agreement and Plan of Merger dated March 12, 2006, by and among Watson Pharmaceuticals, Inc., Water Delaware, Inc., and Andrx Corporation, and all amendments, exhibits, attachments, agreements, and schedules thereto.
- H. "Acquisition Date" means the earlier of the following dates:
  - 1. The date Respondents close on the Acquisition; or
  - 2. The date the merger contemplated by the Acquisition is consummated by filing the certificate of merger related to the Acquisition with the Secretary of State of the State of Delaware.
- I. "Actavis" means Actavis Elizabeth LLC, a limited liability company, organized, existing and doing business under and by virtue of the law of the State of Delaware, with its headquarters address at 990 Riverview Drive, Totowa, New Jersey 07512.
- J. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approvals, clearances, qualifications, licenses, or permits for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. This term includes, but is not limited to, the United States Food and Drug Administration ("FDA").
- K. "Anda" means Anda, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its headquarters address at 2915 Weston Road, Weston, Florida 33331.

- L. "Anda Pharmaceuticals" means Anda Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its headquarters address at 6500 Adelaide Court Groveport, OH 43125.
- M. "Andrx Manufactured Generic Oral Contraceptive Products" means:
  - 1. norgestimate/ethinyl estradiol 0.25 mg/0.035 mg tablets;
  - 2. norgestimate/ethinyl estradiol 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg tablets;
  - 3. norethindrone/ethinyl estradiol 1 mg/0.035 mg tablets; and
  - 4. norethindrone/ethinyl estradiol 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, 1 mg/0.035 mg tablets.
- N. "Andrx-Pfizer Agreement" means the Supply Agreement by and between Andrx Pharmaceuticals, Inc., and Pfizer, Inc., dated September 4, 2003, and all amendments, exhibits, attachments, agreements, and schedules related thereto. The Andrx-Pfizer Agreement is attached to the Decision and Order and contained in non-public Appendix II.
- O. "Andrx-Teva Agreement" means the Marketing and Distribution Agreement by and among Teva Pharmaceuticals USA, Inc., Novapharm Limited, Andrx Pharmaceuticals, Inc. and Andrx Pharmaceuticals, LLC, dated March 10, 2003, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Andrx-Teva Agreement is attached to the Decision and Order and contained in non-public Appendix III.
- P. "Andrx-Teva Amendments" means Amendments No. 1 and 2 to the Andrx-Teva Agreement by and among Teva Pharmaceuticals USA, Inc., Novopharm Limited, and Andrx Pharmaceuticals, LLC, dated March 12, 2006, and October 3, 2006, respectively, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Andrx-Teva Amendments are attached to the Decision and Order and contained in non-public Appendix IV.
- Q. "Applications" means the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Parts 312 and 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all related correspondence between Respondents and the FDA. This term includes, but is not limited to, Investigational New Drug

Application ("IND"), New Drug Application ("NDA"), Abbreviated New Drug Application ("ANDA"), Supplemental New Drug Application ("SNDA"), and Marketing Authorization Application ("MAA") for a Product filed or to be filed with the FDA and all supplements, amendments, and revisions thereto, any preparatory work, drafts, and data necessary for the preparation thereof, and all related correspondence between Respondents and the FDA.

- R. "Assumed Contracts" means all of the following contracts or agreements:
  - 1. That make specific reference to the Divestiture Products and pursuant to which any Third Party is obligated to purchase, or has the option to purchase with no further negotiation on price, the Divestiture Products from Respondents unless such contracts apply generally to the divesting Respondents' sales of generic Products to that Third Party;
  - 2. Pursuant to which Respondents purchase the active pharmaceutical ingredients or had planned to purchase the active pharmaceutical ingredients from any Third Party for use in connection with the manufacture of the Divestiture Products;
  - 3. Relating to any clinical trial involving the Divestiture Products;
  - 4. With universities or other research institutions for the use of the Divestiture Products in scientific research;
  - 5. Relating to the particularized marketing of the Divestiture Products or educational matters relating solely to the Divestiture Products;
  - 6. Pursuant to which a Third Party manufactures the Divestiture Products on behalf of the Respondents except for the Andrx-Pfizer Agreement;
  - 7. Pursuant to which a Third Party provides the Manufacturing Technology or related equipment to the Respondents;
  - 8. Constituting confidentiality agreements involving the Divestiture Products;
  - 9. Involving any royalty, licensing, or similar arrangement involving the Divestiture Products to which Respondents are party, except for any agreement relating to the Generic Oral Contraceptive Royalties;
  - 10. Pursuant to which a Third Party provides any specialized services necessary to the research, Development, or manufacture of the Divestiture

Products to Respondents, including consultation arrangements; and

11. Pursuant to which any Third Party collaborates with the Respondents in the performance of research, Development, marketing, distribution or selling of the Divestiture Products or the Divestiture Products business;

*PROVIDED, HOWEVER*, that where any such contract or agreement also relates to Retained Products, Respondents shall assign to an Acquirer all such rights under the contract or agreement as are related to the Divestiture Products, but concurrently may retain similar rights for the purposes of the Retained Products;

*PROVIDED FURTHER*, *HOWEVER*, that Respondents shall provide copies of each contract or agreement to an Acquirer on or before the related Closing Date and segregated in a manner that clearly identifies the purpose of each contract or agreement.

- S. "Categorized Assets" means the following assets related to the Divestiture Products:
  - 1. All Intellectual Property;
  - 2. A perpetual, fully paid-up and royalty-free license with rights to sublicense to all Licensed Intellectual Property solely within the field of use 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 Products within the specified Geographic Territory;
  - 3. All Product Registrations;
  - 4. All Manufacturing Technology;
  - 5. All Marketing Materials;
  - 6. A list of all NDC Numbers and rights, to the extent permitted by Law, related to the Divestiture Products:
    - a. To require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustment for Divestiture Products sold prior to the Acquisition Date;
    - b. To prohibit Respondents from seeking from any customer any type

- of cross-referencing of those NDC Numbers with any Retained Products;
- To seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Products (including the right to receive notification from Respondents of any such crossreferencing that is discovered by Respondents);
- d. To seek cross-referencing from a customer of those NDC Numbers with the relevant Acquirer's NDC Numbers related to the Divestiture Products;
- e. To approve the timing of Respondents' 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 Acquisition Date, provided that Respondents may provide the minimum notice required by contract or law;
- f. To approve any notification from Respondents to any customer regarding the use or discontinued use of such numbers by Respondents prior to such notification being disseminated to the customer, provided that Respondents may provide the minimum notice required by contract or law;
- 7. All rights to all of Respondents' relevant Applications;
- 8. Rights of Reference or Use to the Drug Master Files related to the Applications including, but not limited to, the pharmacology and toxicology data contained in all Applications;
- 9. All Development Reports;
- 10. At an Acquirer's option, all Assumed Contracts;
- 11. All strategic safety programs submitted to the FDA that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
- 12. All patient registries, 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;

- 13. Lists of all customers and/or targeted customers, net sales (in either units or dollars) 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 names of employees for the High Volume Accounts that are or have been responsible for the purchase of such Divestiture Products on behalf of the High Volume Accounts and their business contact information;
- 14. At an Acquirer's option, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods;
- 15. Copies of all unfulfilled customer purchase orders as of the Closing Date, to be provided to the relevant Acquirer not later than two (2) days after the Closing Date;
- 16. At an Acquirer's option, subject to any rights of the customer, all unfulfilled customer purchase orders; and
- 17. All of the Respondents' books, records, and files directly related to the foregoing or to the Divestiture Products;

*PROVIDED*, *HOWEVER*, that this term shall not include (1) documents relating to Respondents' general business strategies or practices relating to research, development, manufacture, marketing or sale of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products, and (2) administrative, financial and accounting records;

PROVIDED FURTHER, HOWEVER, Respondents may exclude from this term quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Divestiture Products;

PROVIDED FURTHER, HOWEVER, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relate to both the Divestiture Products and other Products or businesses of Respondents and cannot be segregated in a manner that preserves the usefulness of the information related to the Divestiture Products; or (2) for which the Respondents have a legal obligation to retain the original copies, the Respondents 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 an Acquirer, the Respondents shall provide such 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 the Respondents provide an Acquirer with the above-described information without requiring the Respondents to completely divest themselves of information that, in content, also relates to Products and businesses other than the Divestiture Products.

- T. "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.
- U. "Closing Date" means the date on which the Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, terminate or otherwise convey assets or rights related to the Divestiture Products or the Interpharm Product to an Acquirer pursuant to the Decision and Order.
- V. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents 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 Products or Interpharm Product; *PROVIDED*, *HOWEVER*, that the restrictions contained in this Order and the Decision and 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 Respondents;
  - 2. Information related to the Interpharm Product that Respondent Andrx can demonstrate it obtained without the assistance of Respondent Watson prior to the Acquisition;
  - 3. Information related to the Divestiture Products that Respondent Watson can demonstrate it obtained without the assistance of Respondent Andrx prior to the Acquisition;
  - 4. Information that is required by law to be publicly disclosed;
  - 5. Information that does not directly relate to the Divestiture Products or the Interpharm Product;
  - 6. Information relating to Respondents' general business strategies or

practices relating to research, Development, manufacture, marketing or sale of generic pharmaceutical Products that does not discuss with particularity the Divestiture Products or the Interpharm Product; and

- 7. Information specifically excluded from the Categorized Assets.
- W. "Copyrights" means rights to all original works of authorship of any kind directly related to the Divestiture Products and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, all the following:
  - 1. Promotional materials for healthcare providers;
  - 2. Promotional materials for patients;
  - 3. Educational materials for the sales force;
  - 4. Copyrights in all preclinical, clinical and process development data and reports relating to research and Development, including raw data relating to clinical trials, case report forms relating thereto, statistical programs developed (or modified in a manner material to use or function thereof) to analyze clinical data, market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research;
  - 5. Customer information, promotional and marketing materials, sales forecasting models, medical education materials, sales training materials, and advertising and display materials;
  - 6. Records relating to employees who accept employment with an Acquirer (excluding any personnel records transfer of which is prohibited by law);
  - 7. Records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists;
  - 8. Data contained in laboratory notebooks;
  - 9. Adverse experience reports and files related thereto (including source documentation), periodic adverse experience reports, and data contained in electronic databases relating thereto;
  - 10. Analytical and quality control data; and

- 11. All correspondence with the FDA.
- X. "Development" means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, 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.
- Y. "Development Reports" means the following documents related to the Divestiture Products in Respondents' possession or in which Respondents have a right to access:
  - 1. Pharmacokinetic study reports;
  - 2. Bioavailability study reports (including reference listed drug information);
  - 3. Bioequivalence study reports (including reference listed drug information);
  - 4. All correspondence between Respondents and the FDA relating to the Applications submitted by, on behalf of, or acquired by Respondents;
  - 5. Annual and periodic reports related to the Applications, including any safety update reports;
  - 6. FDA approved Product labeling;
  - 7. Currently used product package inserts (including historical change of controls summaries);
  - 8. FDA approved patient circulars and information;
  - 9. Adverse event/serious adverse event summaries;
  - 10. Summary of Product complaints from physicians;
  - 11. Summary of Product complaints from customers; and
  - 12. Product recall reports filed with the FDA.

- Z. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent they are directly incurred to provide the relevant assistance or service; *PROVIDED*, *HOWEVER*, that Direct Cost shall not exceed the average hourly wage rate of Respondents' employees used by an Acquirer.
- AA. "Divestiture Products" means the Glipizide ER Products and the Generic Oral Contraceptive Products, individually and collectively.
- BB. "Divestiture Products Core Employees" means the Research and Development Employees and the Manufacturing Employees.
- CC. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to Paragraph VII. of the Decision and Order.
- DD. "Domain Name" means the domain names (universe resource locators), and registrations thereof, issued by any entity or authority that issues and maintains the domain name registration; *PROVIDED*, *HOWEVER*, this term shall not include any trademark or service mark rights to such domain names other than the rights to the Trademarks required to be divested.
- EE. "Drug Master Files" means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- FF. "Employee Information" means, as related to the Divestiture Products Core Employees, and to the extent permitted by law:
  - 1. A complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondents within ninety (90) days of the execution of any Remedial Agreements);
  - 2. The following information for each such employee:
    - a. The date of hire and effective service date;
    - b. Job title or position held;
    - c. A specific job description of the employee's responsibilities related to the Divestiture Products; *PROVIDED*, *HOWEVER*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal;

- d. The base salary and current wages;
- e. The most recent bonus paid, aggregate annual compensation for the Respondents' last fiscal year and current target or guaranteed bonus, if any;
- f. Employment status (*i.e.*, active, on leave, on disability, and full or part time);
- 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 Acquirer's option, copies of all applicable employee benefit plans and summary plan descriptions.
- GG. "Generic Oral Contraceptive Assets" means, within the Geographic Territory and to the extent legally transferrable, all of Respondent Andrx's rights, title and interest in all assets related to:
  - 1. The Generic Oral Contraceptive Products;
  - 2. Respondent Andrx's business related to the Generic Oral Contraceptive Products;
  - 3. The research, Development, manufacture, distribution, marketing and sale of the Generic Oral Contraceptive Products;
  - 4. The Categorized Assets related to the Generic Oral Contraceptive Products; and
  - 5. The Generic Oral Contraceptive Royalties.

*PROVIDED, HOWEVER*, Respondents may retain any asset necessary to fulfill their obligations under the Generic Oral Contraceptive Supply Agreement.

- HH. "Generic Oral Contraceptive Products" means:
  - 1. All Products in Development, manufactured, marketed or sold by Respondent Andrx pursuant to the following of Respondent Andrx's ANDAs:
    - a. ANDA No. 76-334 (norgestimate/ethinyl estradiol 0.25 mg/0.035

- mg tablets);
- b. ANDA No. 76-335 (norgestimate/ethinyl estradiol 0.18 mg/0.035 mg, 0.215 mg/0.035 mg, 0.25 mg/0.035 mg tablets);
- c. ANDA No. 76-337 (norethindrone/ethinyl estradiol 1 mg/0.035 mg tablets);
- d. ANDA No. 76-338 (norethindrone/ethinyl estradiol 0.5 mg/0.035 mg, 0.75 mg/0.035 mg, 1 mg/0.035 mg tablets);
- e. ANDA No. 76-675 (desogestrel/ethinyl estradiol 0.15mg/0.03 mg tablets);
- f. ANDA No. 76-681 (desogestrel/ethinyl estradiol and ethinyl estradiol 0.15mg/0.02 mg and 0.01 mg tablets);
- g. ANDA No. 77-075 (norethindrone acetate/ethinyl estradiol and ferrous fumarate 1.5 mg/0.030 mg/75 mg tablets);
- h. ANDA No. 77-077 (norethindrone acetate/ethinyl estradiol and ferrous fumarate 1 mg/0.020 mg/75 mg tablets);
- i. ANDA No. 77-099 (levonorgestrel and ethinyl estradiol 0.1 mg/0.02 mg tablets);
- j. ANDA No. 77-502 (levonorgestrel/ethinyl estradiol 0.05 mg/0.03 mg, 0.075 mg/0.04 mg, and 0.125 mg/0.03 mg tablets); and any supplements, amendments, or revisions thereto; and
- 2. All Products in Development, manufactured, marketed or sold by Respondent Andrx related to norethindrone/ethinyl estradiol 0.4 mg/0.035 mg tablets.

*PROVIDED, HOWEVER*, this term *excludes* any Products that are bought or sold by Anda, Anda Pharmaceuticals or Valmed.

- II. "Generic Oral Contraceptive Divestiture Agreement" means:
  - 1. The Andrx-Teva Amendments; or
  - 2. Any agreement that receives the prior approval of the Commission

between Respondents and an Acquirer for the divestiture of the Generic Oral Contraceptive Assets entered into pursuant to Paragraph II.A. of the Decision and Order, and any attachments, agreements, and schedules related thereto.

- JJ. "Generic Oral Contraceptive Royalties" means any financial payment or other consideration from Teva related to the Andrx-Teva Amendments that is either of the following:
  - 1. Based on the actual amount of sales or profits of the Generic Oral Contraceptive Products realized at any time after the Acquisition Date; or
  - 2. Due upon the realization of any aggregate amount of sales or profits on the Generic Oral Contraceptive Products at any time after the Acquisition Date.
- KK. "Generic Oral Contraceptive Supply Agreement" means:
  - 1. The Andrx-Teva Amendments; or
  - 2. Any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the supply of Andrx Manufactured Generic Oral Contraceptive Products entered pursuant to Paragraph II.B. of the Decision and Order, and any attachments, agreements, and schedules related thereto.
- LL. "Geographic Territory" means the United States of America, including all of the territories within its jurisdiction or control unless otherwise specified.
- MM. "Glipizide ER Assets" means, within the Geographic Territory and to the extent legally transferrable, all of Respondent Andrx's rights, title and interest in all assets related to:
  - 1. The Glipizide ER Products;
  - 2. Respondent Andrx's business related to the Glipizide ER Products;
  - 3. The research, Development, manufacture, distribution, marketing and sale of the Glipizide ER Products; and
  - 4. The Categorized Assets related to the Glipizide ER Products.
- NN. "Glipizide ER Divestiture Agreement" means:

- 1. The Asset Purchase Agreement by and between Andrx Corporation, Andrx Pharmaceuticals, LLC, Andrx Pharmaceuticals, Inc., and Actavis, Inc., dated October 3, 2006, and all amendments, exhibits, attachments, agreements, and schedules related thereto. This agreement is attached to the Decision and Order and contained in non-public Appendix V.; or
- 2. Any agreement that receives the prior approval of the Commission between Respondents and an Acquirer for the divestiture of the Glipizide ER Assets entered into pursuant to Paragraph III.A. of the Decision and Order, and any attachments, agreements, and schedules related thereto
- OO. "Glipizide ER Products" means all Products in Development, manufactured, marketed or sold by Respondent Andrx pursuant to the following of Respondent Andrx's ANDAs:
  - 1. ANDA No. 76-159;
  - 2. ANDA No. 76-621; and

any supplements, amendments, or revisions thereto.

*PROVIDED, HOWEVER*, this term *excludes* any Products that are bought or sold by Anda, Anda Pharmaceuticals or Valmed.

- PP. "Glipizide ER Supply Agreement" means:
  - 1. The Andrx-Pfizer Agreement; or
  - 2. Any agreement entered into by Respondents and an Acquirer for the supply of Glipizide ER Products entered pursuant to Paragraph III.B. of the Decision and Order, and any attachments, agreements, and schedules related thereto.
- QQ. "High Volume Accounts" means any of Respondents' customers whose annual and/or projected annual aggregate purchase amounts, in units or in dollars, on a company-wide level of the Divestiture Products in the United States was, is, or is projected to be among the top twenty highest of such purchase amounts by Respondents' 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 Acquisition 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 Date and/or the Closing Date.

- RR. "Intellectual Property" means all of the following related to the Divestiture Products:
  - 1. Patents:
  - 2. Copyrights;
  - 3. Trademarks, 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*, this term does not include the names or trade dress of "Watson," "Andrx," or the names or trade dress of any other corporation, companies, or brands owned or sold by Respondents or related logos to the extent used on Respondents' Retained Products.

- SS. "Interim Monitor" means any monitor appointed pursuant to Paragraph III. of this Order to Maintain Assets or Paragraph VI. of the Decision and Order.
- TT. "Interpharm" means Interpharm Holdings, 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 75 Adams Avenue, Hauppauge, New York 11788.
- UU. "Interpharm Product" means the Product that is subject to the Watson-Interpharm Agreement. *PROVIDED*, *HOWEVER*, this term *excludes* any Products that are bought or sold by Anda, Anda Pharmaceuticals or Valmed.
- VV. "Interpharm Product Termination Agreement" means:
  - 1. The Termination and Release Agreement by and between Interpharm, Inc. and Watson Laboratories, Inc., dated October 4, 2006, and all amendments, exhibits, attachments, agreements, and schedules related thereto. This agreement is attached to the Decision and Order and contained in non-public Appendix VI.; or
  - 2. Any agreement that receives the prior approval of the Commission between Respondents and Interpharm to terminate the Watson-Interpharm Agreement pursuant to Paragraph IV. of the Decision and Order.

# WW. "Licensed Intellectual Property" means:

- 1. Patents that are related to the Divestiture Products that Respondents can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Products:
  - a. That have been marketed or sold on an extensive basis by the Respondents 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 Retained Products on an extensive basis by Respondents; 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 the Divestiture Products and that Respondents can demonstrate have been routinely used, prior to the Acquisition Date, by Respondents for Retained Products:
  - a. That have been marketed or sold on an extensive basis by the Respondents 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 Retained Products on an extensive basis by Respondents;

*PROVIDED, HOWEVER*, that, Respondents may take a paid-up, royalty-free, irrevocable, non-exclusive, with a right to sublicense, license back from the Acquirer for such intellectual property for use in connection with Retained Products;

PROVIDED FURTHER, HOWEVER, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Products collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Products collectively, the above described intellectual property shall be considered, at the Acquirer's option, to be Intellectual Property and, thereby, subject to assignment to the Acquirer.

XX. "Manufacturing Employees" means all Respondents' salaried employees who

have directly participated in the planning, design, implementation or use of the Manufacturing Technology of the Divestiture Products (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;

*PROVIDED, HOWEVER*, Respondents *may exclude* from this term those employees that are determined by the Interim Monitor or an Acquirer not to be material to the planning, design, implementation or use of the Manufacturing Technology of the Divestiture Products.

- YY. "Manufacturing Technology" means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the Divestiture Products (including, for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture the Divestiture Products), including, but not limited to, 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 Applications conformance and cGMP compliance, labeling, all other information related to the manufacturing process, and supplier lists.
- ZZ. "Marketing Materials" means all marketing materials used specifically in the marketing or sale of the Divestiture Products 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, 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 Products; *PROVIDED*, *HOWEVER*, this term *excludes* the pricing information of the Divestiture Products.
- AAA. "NDC Numbers" means the National Drug Codes numbers, including both the labeler codes assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

- BBB. "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 the Decision and 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 Respondents as of the Closing Date (*except* where the Decision and Order specifies a different time).
- CCC. "Pfizer" means Pfizer, 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 235 East 42<sup>nd</sup> Street, New York, New York 10017.
- DDD. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- EEE. "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.

## FFF. "Remedial Agreements" means:

- 1. Any agreement related to the Generic Oral Contraceptive Assets entered into pursuant to Paragraph II. of the Decision and Order;
- 2. Any agreement related to the Glipizide ER Assets entered into pursuant to Paragraph III. of the Decision and Order;
- 3. The Interpharm Product Termination Agreement entered into pursuant to Paragraph IV. of the Decision and Order; and
- 4. Any agreement entered into by a Divestiture Trustee pursuant to Paragraph VII. of the Decision and Order.
- GGG. "Research and Development Employees" means all Respondents' salaried employees who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the Divestiture Products (irrespective of the portion of working time involved, unless such participation

consisted primarily of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date;

*PROVIDED*, *HOWEVER*, Respondents *may exclude* from this term those employees who are determined by the Interim Monitor or an Acquirer, in consultation with Commission staff, not to be material to the research, Development, or regulatory approval process, or clinical studies of the Divestiture Products.

- HHH. "Retained Products" means any Product other than the Divestiture Products or the Interpharm Product.
- III. "Rights of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of Applications, including the ability to make available the underlying raw data from the investigation for FDA audit.
- JJJ. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost of manufacturing the Divestiture Products for the twelve (12) month period immediately preceding the Acquisition Date; *PROVIDED*, *HOWEVER*, that the Supply Cost for the Glipizide ER Products shall be the transfer price as determined under the Andrx-Pfizer Agreement; *PROVIDED FURTHER*, *HOWEVER*, this term shall *exclude* any intracompany business transfer profit.
- KKK. "Teva" means Teva Pharmaceutical Industries Limited, a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its headquarters address at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel.
- LLL. "Third Party" means any private entity other than the following: (1) Respondents; or (2) an Acquirer.
- MMM. "Trade Dress" means the current trade dress of the Divestiture Products, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- NNN. "Trademarks" 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.
- OOO. "Valmed" means Valmed Pharmaceutical, Inc., a/k/a VIP, a corporation

- organized, existing and doing business under and by virtue of the laws of the State of New York, with its headquarters address at 3000 Alt Boulevard, Grand Island, New York 14072.
- PPP. "Watson-Interpharm Agreement" means the Manufacturing and Supply Agreement by and between Interpharm, Inc. and Watson Laboratories, Inc., dated October 14, 2003, and all amendments, exhibits, attachments, agreements, and schedules related thereto. The Watson-Interpharm Agreement is attached to the Decision and Order and contained in non-public Appendix VII.
- QQQ. "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 Respondents; *PROVIDED*, *HOWEVER*, this term shall not include the following: (1) content owned by Third Parties and other Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey their rights, if any, therein; or (2) content unrelated to the Divestiture Products.

II.

# **IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final:

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product, and shall prevent the destruction, removal, wasting, deterioration, sale, disposition, transfer, or impairment of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product except for ordinary wear and tear.
- B. Respondents shall not solicit any current customer of the Interpharm Product for the supply of Products similar to the Interpharm Product for a period of six (6) months after the Closing Date.
- C. Respondents shall maintain the operations of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such businesses) and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors, including, but not limited to, the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product. Respondents' responsibilities shall include, but are not

## limited to, the following:

- 1. Providing the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product with sufficient capital to operate at least at current rates of operation, to meet all capital calls with respect to such businesses and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product;
- 2. Continuing, at least at their scheduled pace, any additional expenditures for Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing and sales expenditures;
- 3. Provide such resources as may be necessary to respond to competition against the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product and/or prevent any diminution of sales of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product, prior to divestiture;
- 4. Provide such resources as may be necessary to maintain the competitive strength and positioning of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product at the High Volume Accounts;
- 5. Making available for use by the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product;
- 6. Providing the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product with such funds as are necessary to maintain the viability, marketability, and competitiveness of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product;
- 7. Providing such support services to the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product as were being provided to these businesses by Respondents as of the date of the Consent

## Agreement; and

- 8. Cooperate with the Interim Monitor in the performance of his or her obligations pursuant to Paragraph III. of this Order to Maintain Assets.
- D. Pending divestiture of the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the execution of the Interpharm Product Termination Agreement, Respondents shall:
  - 1. Not use, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing, or sale of the Divestiture Products or the Interpharm Product other than to comply with (1) the requirements of the Orders, (2) Respondents' obligations under the Remedial Agreements, or (3) applicable law;
  - 2. Not disclose or convey any Confidential Business Information, directly or indirectly, to any person except an Acquirer;
  - 3. Not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products or the Interpharm Product to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications; and
  - 4. Promptly after the date the Agreement Containing Consent Orders is signed, develop and implement procedures to ensure that Respondents' employees, associated with the Retained Products that are approved by the FDA for the same or similar indications to the Divestiture Products or the Interpharm Product, do not:
    - a. Provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order; and
    - b. Solicit, access or use any Confidential Business Information that they are prohibited under this Order from receiving for any reason or purpose.
- E. Not later than thirty (30) days after the Acquisition Date, Respondents shall, with respect to all of Respondents' employees who have access to Confidential Business Information:
  - 1. Provide written notification of the restrictions on the use of the

Confidential Business Information by Respondents' personnel. At the same time, if not earlier, Respondents 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. *PROVIDED*, *HOWEVER*, Respondents shall provide a copy of the form of such notification to an Acquirer, the Interim Monitor, and the Commission; and

2. Obtain from each employee an agreement to abide by the applicable restrictions;

*PROVIDED, HOWEVER*, Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters, and provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide an Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

## F. Respondents shall:

- 1. For a period of at least six (6) months after the Closing Date ("Employee Access Period"), provide an Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees; and
- 2. Provide an Acquirer with the Employee Information no later than the earlier of the following dates:
  - a. Ten (10) days after notice by staff of the Commission to Respondents to provide the Employee Information; or
  - b. Ten (10) days after the Closing Date.

*PROVIDED*, *HOWEVER*, failure by Respondents to provide the Employee Information within the time provided herein shall extend the Employee Access Period with respect to any such employee in an amount equal to the delay.

## G. Respondents shall:

1. During the Employee Access Period, not interfere with the hiring or employing of the Divestiture Product Core Employees by an Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with an Acquirer, including,

but not limited to, any non-compete or non-disclosure provision of employment that would affect the ability or incentive of those individuals to be employed by an Acquirer. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from an Acquirer;

*PROVIDED, HOWEVER*, that this paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee during the Employee Access Period (subject to the condition 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 Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Products and to ensure successful execution of the pre-Acquisition plans for such Divestiture Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date for the divestiture of the Divestiture Products 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 Respondents to terminate the employment of any employee or prevents Respondents from continuing the employment of 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 Closing Date, not:
  - a. Directly or indirectly, solicit or otherwise attempt to induce any Acquirer Employees to terminate his or her employment relationship with an Acquirer; or
  - b. Hire any Acquirer Employee; *PROVIDED*, *HOWEVER*, Respondents may hire any Acquirer Employee whose employment has been terminated by an Acquirer, or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the non-solicitation requirements contained herein:

*PROVIDED*, *HOWEVER*, Respondents may do the following: (1) Advertise for employees in newspapers, trade publications or other media not targeted specifically at the Acquirer Employees; or (2) hire a Acquirer Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

- H. Respondents shall adhere to and abide by the Remedial Agreements incorporated by reference into this Order to Maintain Assets and made a part hereof.
- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Generic Oral Contraceptive Assets, the Glipizide Assets, and the Interpharm Product, to minimize any risk of loss of competitive potential for the Generic Oral Contraceptive Assets, the Glipizide ER Assets, and the Interpharm Product, and to prevent the destruction, removal, wasting, deterioration, or impairment of the assets to be divested except for ordinary wear and tear.

III.

#### **IT IS FURTHER ORDERED** that:

- A. Francis J. Civille of Califon, New Jersey, shall serve as the monitor ("Interim Monitor") in this matter to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order to Maintain Assets, the Decision and Order (collectively, "Orders"), and the Remedial Agreements.
- B. If Mr. Civille fails to serve, or if a new Interim Monitor must be selected, the Commission shall select the Interim Monitor, subject to the consent of Respondent Watson, which consent shall not be unreasonably withheld. If Respondent Watson 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 Watson of the identity of any proposed Interim Monitor, Respondents 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, Respondents 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 Respondents' compliance with the relevant requirements of the Orders and in a manner consistent with the purposes of the Orders.

- D. If an Interim Monitor is appointed, Respondents 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 Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, 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 Orders 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 Respondents of:
      - (1) The divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of the Decision and Order; and
      - (2) Notification by each Acquirer to the Interim Monitor that such 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; or
    - b. The completion by Respondents 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 Respondents' 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 Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents

- 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 Respondents' compliance with the Orders;
- 5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents 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 Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities;
- 6. Respondents 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. Respondents shall report to the Interim Monitor in accordance with the requirements of the Orders 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 Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under the Orders 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 Respondents of their obligations under the Orders; and
- 8. Respondents 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 Orders.
- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

#### IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II., III., IV., and V. of the Decision and Order (*i.e.*, have assigned, licensed, divested, transferred, delivered, terminated or otherwise conveyed all relevant assets or rights to an Acquirer in a manner that fully satisfies the requirements of the Decision and Order), Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order to Maintain Assets and the Decision and Order; *PROVIDED*, *HOWEVER*, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph IX. of the Decision and Order.

V.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of such Respondents; (2) acquisition, merger or consolidation of Respondents; or (3) any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

## VI.

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondents made to their principal United States offices or headquarters address, Respondents shall, without restraint or interference, permit any duly

authorized representative of the Commission:

- A. Access, during business office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondents related to compliance with this Order, which copying services shall be provided by Respondents at the request of authorized representative(s) of the Commission; and
- B. To interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

#### VII.

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the divestiture and transfer of the Generic Oral Contraceptive Assets, the Generic Oral Contraceptive Royalties, the Glipizide ER Assets, and the Interpharm Product, as described in and required by the attached Decision and Order, is completed and the Interim Monitor, in consultation with Commission staff and an Acquirer, notifies the Commission that an Acquirer's transition is complete.

By the Commission, Commissioner Rosch recused.

Donald S. Clark Secretary

**SEAL** 

ISSUED: October 31, 2006