

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

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In the Matter of )

WATSON PHARMACEUTICALS, INC. )  
a corporation; )

and )

ANDRX CORPORATION )  
a corporation. )

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Docket No. C-4172

**DECISION AND ORDER**  
**[Public Record Version]**

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 (“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 that it had reason to believe that Respondents have 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 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, 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 this Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, terminate, 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 Respondents are required to assign, grant, license, divest, transfer, deliver, terminate, or otherwise convey pursuant to this 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 this 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., Novopharm 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 this 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 this 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;

- c. 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 cross-referencing 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 this 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 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 this 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 this 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 this 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 Elizabeth LLC, dated October 3, 2006, and all amendments, exhibits, attachments, agreements, and schedules related thereto. This agreement is attached to this 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 this 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 that receives the prior approval of the Commission between Respondents and an Acquirer for the supply of Glipizide ER Products entered pursuant to Paragraph III.B. of this 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 VI. of this Order or Paragraph III. of the Order to Maintain Assets.

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 this 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 this 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 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 Respondents as of the Closing Date (*except* where this 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 this Order;
  2. Any agreement related to the Glipizide ER Assets entered into pursuant to Paragraph III. of this Order;
  3. The Interpharm Product Termination Agreement entered into pursuant to Paragraph IV. of this Order; and
  4. Any agreement entered into by a Divestiture Trustee pursuant to Paragraph VII. of this 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 this 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:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Generic Oral Contraceptive Assets, absolutely and in good faith, to Teva pursuant to, and in accordance with, the Generic Oral Contraceptive Divestiture Agreement (which agreement 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 Teva or to reduce any obligations of Respondents under such agreement);

*PROVIDED, HOWEVER*, that if Respondents have divested the Generic Oral Contraceptive Assets to Teva prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Oral Contraceptive Assets to Teva (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.

*PROVIDED FURTHER, HOWEVER*, that Respondents may not modify or amend the Generic Oral Contraceptive Divestiture Agreement without receiving the prior approval of the Commission. *PROVIDED FURTHER, HOWEVER*, that such

prior approval shall not be required for modifications or amendments that do not relate directly or indirectly, in whole or in part, to the Generic Oral Contraceptive Products.

- B. At Teva's option and upon reasonable notice, Respondents shall enter into a Generic Oral Contraceptive Supply Agreement with the Acquirer for the supply of Andrx Manufactured Generic Oral Contraceptive Products for a time sufficient to allow the Acquirer, or a Third Party affiliated with the Acquirer, to obtain all the relevant Agency approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the Andrx Manufactured Generic Oral Contraceptive Products independently of Respondents and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, and other ingredients specified in Respondents' Applications for the Andrx Manufactured Generic Oral Contraceptive Products from entities other than Respondents.

*PROVIDED, HOWEVER*, that the Generic Oral Contraceptive Supply Agreement shall not exceed a term of five (5) years.

*PROVIDED FURTHER, HOWEVER*, that Respondents may not modify or amend the Generic Oral Contraceptive Supply Agreement without receiving the prior approval of the Commission. *PROVIDED FURTHER, HOWEVER*, that such prior approval shall not be required for modifications or amendments that do not relate directly or indirectly, in whole or in part, to the Generic Oral Contraceptive Products.

- C. The Generic Oral Contraceptive Supply Agreement shall require Respondents to:
1. Deliver, in a timely manner and under reasonable terms and conditions, a supply of Andrx Manufactured Generic Oral Contraceptive Products at a price not to exceed Supply Cost;
  2. Represent and warrant to the Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Andrx Manufactured Generic Oral Contraceptive Products in a timely manner as required by the Generic Oral Contraceptive Supply Agreement unless Respondents can demonstrate that their failure was entirely beyond the reasonable control of Respondents and in no part the result of negligence or willful misconduct by Respondents;
  3. Represent and warrant to the Acquirer that the Andrx Manufactured Generic Oral Contraceptive Products supplied under the Generic Oral Contraceptive Supply Agreement meet the Agency-approved

specifications. For Andrx Manufactured Generic Oral Contraceptive Products to be marketed or sold in the Geographic Territory, Respondents shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged that result from the failure of the Andrx Manufactured Generic Oral Contraceptive Products to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim.

*PROVIDED, HOWEVER*, that Respondents 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 Respondents' responsibilities to supply the ingredients in the manner required by this Order; *PROVIDED FURTHER, HOWEVER*, that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer;

4. Make available to the Acquirer and the Interim Monitor all records that relate to the manufacture of the Andrx Manufactured Generic Oral Contraceptive Products that are generated or created after the Closing Date;
5. Include in the Andrx Manufactured Generic Oral Contraceptive Supply Agreement a representation from the Acquirer that such 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, the Andrx Manufactured Generic Oral Contraceptive Products and to do so independently of Respondents as soon as reasonably practicable;
6. Not seek, pursuant to any dispute resolution mechanism incorporated in the Generic Oral Contraceptive Supply Agreement, a result that would be inconsistent with the terms or the remedial purposes of this Order.

*PROVIDED, HOWEVER*, the Andrx-Teva Amendments, if approved by the Commission, shall satisfy the requirements of this Paragraph.

### III.

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

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Glipizide ER Assets, absolutely and in good faith, to Actavis pursuant to and in accordance with the Glipizide ER Divestiture Agreement (which agreement 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 Actavis or to reduce any obligations of Respondents under such agreement);

*PROVIDED, HOWEVER,* that if Respondents have divested the Glipizide ER Assets to Actavis prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Actavis is not an acceptable purchaser of the Glipizide ER Assets then Respondents shall immediately rescind the transaction with Actavis and shall divest the Glipizide ER Assets within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer and only in a manner that receives the prior approval of the Commission;

*PROVIDED FURTHER, HOWEVER,* that if Respondents have divested the Glipizide ER Assets to Actavis prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Glipizide ER Assets to Actavis (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. Not later than ten (10) days after the Acquisition Date, Respondents shall enter into a Glipizide ER Supply Agreement by:
1. Assigning the Andrx-Pfizer Agreement to the Acquirer of the Glipizide ER Products; or
  2. Entering into a supply agreement with the Acquirer for the supply of Glipizide ER Products under Respondent Watson's ANDA No. 76-467, under terms and conditions no less favorable in the aggregate to the Andrx-Pfizer Agreement, for a period not to exceed thirty (30) months.

- C. The Glipizide ER Supply Agreement shall require Respondents to:
1. Deliver, in a timely manner and under reasonable terms and conditions, a supply of Glipizide ER Products at a price not to exceed Supply Cost;
  2. Represent and warrant to the Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Glipizide ER Products in a timely manner as required by the Glipizide ER Supply Agreement unless Respondents can demonstrate that their failure was entirely beyond the reasonable control of Respondents and in no part the result of negligence or willful misconduct by Respondents;
  3. Represent and warrant to the Acquirer that the Glipizide ER Products supplied under the Glipizide ER Supply Agreement meet the Agency-approved specifications. For Glipizide ER Products to be marketed or sold in the Geographic Territory, Respondents shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged that result from the failure of the Glipizide ER Products to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. *PROVIDED, HOWEVER*, that Respondents 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 Respondents' responsibilities to supply the ingredients in the manner required by this Order; *PROVIDED FURTHER, HOWEVER*, that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer;
  4. Make available to the Acquirer and the Interim Monitor (if applicable) all records that relate to the manufacture of the Glipizide ER Products that are generated or created after the Closing Date;
  5. Include in the Glipizide ER Supply Agreement a representation from the Acquirer that such 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, the Glipizide ER Products and to do so independently of Respondents as soon as reasonably practicable;

6. Not seek, pursuant to any dispute resolution mechanism incorporated in the Glipizide ER Supply Agreement, a result that would be inconsistent with the terms or the remedial purposes of this Order.

*PROVIDED, HOWEVER*, if Respondents enter into a Glipizide ER Supply Agreement pursuant to Paragraph III.B.1 of this Order, then the Andrx-Pfizer Agreement shall satisfy the requirements of this Paragraph.

#### **IV.**

**IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall terminate their rights to the Interpharm Product, absolutely and in good faith, pursuant to the Interpharm Product Termination Agreement (which agreement 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 Interpharm or to reduce any obligations of Respondents under such agreements);

*PROVIDED, HOWEVER*, that if Respondents have terminated their rights to the Interpharm Product prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the termination was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of termination of such rights to the Interpharm Product (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. For a period of six (6) months after the Closing Date, Respondents shall not solicit any current customer of the Interpharm Product for the supply of Products similar to the Interpharm Product.

#### **V.**

**IT IS FURTHER ORDERED** that:

- A. After the Closing Date for the assets related to the Divestiture Products or Interpharm Product, Respondents shall not receive any payment or other compensation from an Acquirer that is:

1. Based on the actual amount of sales or profits of the Divestiture Products or Interpharm Product realized at any time after the Closing Date, or
2. Due upon the realization of any aggregate amount of sales or profits of the Divestiture Products or Interpharm Product after the Closing Date;

*PROVIDED, HOWEVER,* Respondents may receive payments from an Acquirer based on units of Divestiture Products supplied to an Acquirer pursuant to the Generic Oral Contraceptive Supply Agreement and the Glipizide ER Supply Agreement.

- B. At an Acquirer's option, and upon reasonable notice, Respondents shall provide, for a period of five (5) years after the Closing Date, the following technical assistance:
1. 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 Respondents knowledgeable with respect to such Product Manufacturing Technology and experienced in such transfers to a committee for the purposes of communicating directly with an Acquirer and the Interim Monitor for the purposes of effecting such transfer; and
  2. In a timely manner and at Direct Cost:
    - a. Assistance and advice to enable an Acquirer to obtain all necessary permits and approvals from any Agency to manufacture and sell the Divestiture Products;
    - b. Assistance to an Acquirer to manufacture the Divestiture Products in substantially the same manner, quality, and quantity(ies) employed or achieved by Respondent Andrx for the Divestiture Products;
    - c. Consultation with Respondents' employees with relevant knowledge, and training at a facility chosen by an Acquirer, sufficient to satisfy management of an Acquirer that its personnel are adequately trained in the manufacture of the Divestiture Products; and
    - d. Personnel, assistance and training as an Acquirer might reasonably need to transfer the assets related to the Divestiture Products.

- C. Respondents shall:
1. At an Acquirer's option and upon reasonable notice, provide, in a timely manner and at no greater than Direct Cost, assistance of Respondents' employees with knowledge to assist an Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Intellectual Property related to the relevant Divestiture Products;
  2. For any patent infringement suit in which Respondents are parties or are preparing to be parties to prior to the Closing Date, and where such a suit would have the potential to interfere with an Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of the relevant Divestiture Products:
    - a. Cooperate with an Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving the Divestiture Products;
    - b. Waive conflicts of interest, if any, to allow Respondents' outside legal counsel to represent an Acquirer in any ongoing patent litigation involving the Divestiture Product; and
    - c. Permit the transfer to an Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to the Divestiture Products; and
  3. Not join, file, prosecute or maintain any suit, in law or equity against an Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Products, if such suit would have the potential to interfere with an Acquirer's freedom to practice the research, Development, manufacture, use, import, export, distribution, or sale of the relevant Divestiture Products, under:
    - a. Any Patent owned or licensed by Respondents as of the Acquisition Date that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Products, or that claims a device relating to the use thereof; and
    - b. Any Patents owned or licensed at any time after the Acquisition Date by Respondents 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 Acquisition Date;

*PROVIDED, HOWEVER,* Respondents shall also covenant to an 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 covenant not to sue an Acquirer under such Patents if Respondents were prohibited from bringing such suit.

- D. As related to the Divestiture Products and the Interpharm Product, Respondents shall:
1. Submit and deliver to an Acquirer, at Respondents' expense, in good faith and as soon as practicable, in a manner that ensures its completeness and accuracy, all Confidential Business Information;
  2. Provide an Acquirer and the Interim Monitor with access to all Confidential Business Information and to employees who possess or are able to locate or identify the books, records, and files that contain Confidential Business Information pending complete delivery of all the Confidential Business Information;
  3. 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 the requirements of this Order;
  4. Not disclose or convey any Confidential Business Information, directly or indirectly, to any person except an Acquirer; and
  5. 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.
- E. Not later than thirty (30) days after the Acquisition Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information by Respondents' personnel to all of Respondents' employees who:

1. Are, or were, directly involved in the research, Development, manufacturing, distribution, sale or marketing of the Divestiture Products or the Interpharm Product;
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 the Divestiture Products or Interpharm Product prior to the Acquisition; and/or
3. May have Confidential Business Information.

*PROVIDED, HOWEVER*, 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. 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 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 Respondents, the direct supervisor of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor, sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information as strictly confidential, including the non-disclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).
- G. 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.

H. 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 Employee to terminate his or her employment relationship with an Acquirer; or
  - b. Hire any Acquirer Employees; *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.

- I. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and/or to permit an Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products; *PROVIDED, HOWEVER*, Respondents may satisfy this requirement by certifying that an Acquirer has executed all such agreements directly with each of the relevant Third Parties.
- J. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of an Acquirer:
  1. To acquire the Product Manufacturing Technology related to the Divestiture Products, the related equipment, or the use of such 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; and/or
  2. To acquire all Confidential Business Information related to the Interpharm Product. Until all of Respondent Watson's rights to enforce restrictions on the use, disclosure, conveyance or provision of Confidential Business Information related to the Interpharm Product are fully assigned or conveyed to Interpharm, Respondents 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) Interpharm or (2) any Third Party authorized by Interpharm to receive such information.

- K. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that:
1. Is subject to an agreement as described in Paragraph V.J.1. that allows the Third Party to provide the relevant Product Manufacturing Technology and/or the related equipment or use thereof, to an Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to an Acquirer for the relevant assets; and
  2. Allows the Third Party to provide all such Confidential Business Information within the Third Party's possession or control to Interpharm. This includes, but is not limited to, such releases as may be necessary to permit the transfer to Interpharm of any attorney work-product related to the intellectual property connected to the Interpharm Product in the possession of Respondent Watson's outside counsel. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to Interpharm.

L. Respondents shall not, in the Geographic Territory:

1. Use the Trademarks related to the Divestiture Products or any mark confusingly similar to such Trademarks, as a trademark, trade name, or service mark;
2. Attempt to register Trademarks related to the Divestiture Products;
3. Attempt to register any mark confusingly similar to Trademarks related to the Divestiture Products;
4. Challenge or interfere with an Acquirer's use and registration of Trademarks related to the Divestiture Products; or
5. Challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in Trademarks related to the Divestiture Products against Third Parties;

*PROVIDED, HOWEVER*, that nothing in this Order shall preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Acquisition Date.

- M. The Remedial Agreements shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of the Remedial Agreements shall constitute a failure to comply with this Order. Respondents shall include in each Remedial Agreement a specific reference to this Order and the remedial purpose thereof. The Remedial Agreements entered into pursuant to Paragraph II., III., and IV. are attached to this Order and contained in non-public Appendices II., IV., V., and VI.
- N. Pending divestiture of the assets required to be divested pursuant to this Order, Respondents 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 an Acquirer in a manner that ensures that there is no disruption, delay, or impairment of the regulatory approval processes related to such assets. Respondents 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.
- O. Respondents shall maintain manufacturing facilities necessary to manufacture the Divestiture Products in finished form until Respondents have completed their obligations under Paragraphs II. and III. of this Order.
- P. The purpose of Paragraphs II. through V. is: (1) to ensure the continued use of such assets in the research, Development, manufacture, distribution, sale and marketing of the Divestiture Products and the Interpharm Product; (2) to create a viable and effective competitor in the relevant markets alleged in the Complaint who is independent of Respondents; 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.

## **VI.**

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

- A. Francis J. Civile of Califon, New Jersey, shall serve as the monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.
- B. If Mr. Civile 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 Order in a manner consistent with the purposes of the Order.
- D. 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 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 Respondents of:
      - (1) The divestiture of all Divestiture Assets in a manner that fully satisfies the requirements of this 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 Order, 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 Order;
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 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 Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' 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 Respondents of their obligations

under the Order; 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 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.

## **VII.**

**IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with their obligations under Paragraphs II. through V. of 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, Respondents 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 Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Watson, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Watson 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 Watson of the identity of any proposed Divestiture Trustee, Respondents 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, Respondents 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, Respondents 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. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents 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 Respondents' 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 Respondents from among those approved by the Commission; and, *PROVIDED FURTHER, HOWEVER*, that Respondents 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 Respondents, 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 Respondents, 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 Respondents, 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. Respondents 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 Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture; and
  9. Respondents 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.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## VIII.

**IT IS FURTHER ORDERED** that, in any instance wherein Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) either retain unredacted copies of documents or other materials provided to an Acquirer or access original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to an Acquirer, Respondents shall assure that Respondents' counsel do so only in order to do the following:

- A. Comply with the Remedial Agreements, this Order, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. Defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture, the Divestiture Assets or the Interpharm Product, and businesses associated with the Divestiture Assets or the Interpharm Product;

*PROVIDED, HOWEVER*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement; and

*PROVIDED FURTHER, HOWEVER*, that pursuant to this Paragraph VIII, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with an Acquirer (but shall not be deemed to have violated this requirement if an Acquirer withholds such agreement unreasonably); and (2) use its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

## **IX.**

**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with Paragraphs II., III., IV., and V. of this 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 Order), Respondents shall:
  - 1. 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;
  - 2. At the same time, submit a copy of their verified report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed; and

3. In their verified reports, include, among other things, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all persons contacted, copies of all written communications to and from such persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- C. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission that includes information regarding any modifications or amendments to the Generic Oral Contraceptive Divestiture Agreement or the Generic Oral Contraceptive Supply Agreement that Respondents entered without the prior approval of the Commission, and sets forth in detail the manner and form in which they have complied and are complying with the Order.

#### **X.**

**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.

#### **XI.**

**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.

**XII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on December 6, 2016.

By the Commission, Commissioner Rosch recused.

Donald S. Clark  
Secretary

SEAL  
ISSUED: December 6, 2006

**PUBLIC APPENDIX I**  
**ORDER TO MAINTAIN ASSETS**

**NON-PUBLIC APPENDIX II.  
THE GLIPIZIDE ER SUPPLY AGREEMENT  
THE ANDRX-PFIZER AGREEMENT**

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

**NON-PUBLIC APPENDIX III.  
THE ANDRX-TEVA AGREEMENT**

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

**NON-PUBLIC APPENDIX IV.  
THE GENERIC ORAL CONTRACEPTIVE DIVESTITURE AND SUPPLY  
AGREEMENTS  
THE ANDRX-TEVA AMENDMENTS NO. 1 AND 2**

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

**NON-PUBLIC APPENDIX V.  
THE GLIPIZIDE ER DIVESTITURE AGREEMENT  
THE ACTAVIS PURCHASE AGREEMENT**

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

**NON-PUBLIC APPENDIX VI.  
THE INTERPHARM PRODUCT TERMINATION AGREEMENT**

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

**NON-PUBLIC APPENDIX VII.  
THE WATSON-INTERPHARM AGREEMENT**

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