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UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: Edith Ramirez, Chairwoman
Julie Brill
Maureen K. Ohlhausen
Joshua D. Wright
Terrell McSweeny

In the Matter of	)	
AKORN, INC., a corporation.	)	Docket C-4479

DECISION AND ORDER
[Public Record Version]

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 Akorn is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Louisiana, with its headquarters address located at 1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045.

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

ORDER

I.

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

A. "Akorn" means Akorn, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Akorn, Inc. (including, without limitation, Akorn Enterprises, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Akorn shall include VersaPharm.

B. "VersaPharm" means VersaPharm Incorporated, its directors, officers, employees, agents, representatives, successors, and assigns, and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by VersaPharm Incorporated, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

C. "Actavis" means Actavis plc, a corporation organized, existing and doing business under and by virtue of the laws of Ireland, with its world headquarters located in Dublin, Ireland, and its United States headquarters address located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

D. "Watson" means Watson Laboratories, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson Laboratories, Inc. is a wholly owned subsidiary of Actavis plc.

E. "Respondent" means Akorn.

F. "Commission" means the Federal Trade Commission.

G. "Acquirer(s)" means the following:

1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the

Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

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

H. "Acquisition" means Respondent's acquisition of the voting securities of VersaPharm. Respondent entered into the *Agreement and Plan of Merger* between Akorn, Inc., Akorn Enterprises II, Inc., VPI Holdings Corp., and Tailwind Management LP, dated as of May 9, 2014, that was submitted to the Commission.

I. "Acquisition Date" means the date on which the Acquisition is consummated.

J. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").

K. "Akorn Rifampin Product" means the Product in Development, manufactured, owned or controlled by Respondent pursuant to ANDA No. 206736 filed with the FDA on December 27, 2013, and any supplements, amendments, or revisions thereto.

L. "Akorn Rifampin Product Assets" means all rights, title and interest in and to all assets related to the Business within the Geographic Territory of Respondent related to the Akorn Rifampin Product, to the extent legally transferable, including, without limitation, the following assets and rights of Respondent, as such assets and rights are in existence as of the date Respondent signs the Consent Agreement in this matter and as are maintained by Respondent in accordance with the Order to Maintain Assets until the Closing Date:

1. all rights to all of the Applications related to the Akorn Rifampin Product;
2. all Product Intellectual Property related to the Akorn Rifampin Product that is not Product Licensed Intellectual Property;
3. all Product Approvals related to the Akorn Rifampin Product;
4. all Product Manufacturing Technology related to the Akorn Rifampin Product that is not Product Licensed Intellectual Property;
5. all Product Marketing Materials related to the Akorn Rifampin Product;
6. all Product Scientific and Regulatory Material related to the Akorn Rifampin Product;
7. all Website(s) related exclusively to the Akorn Rifampin Product;
8. the content related exclusively to the Akorn Rifampin Product that is displayed on any Website that is not dedicated exclusively to the Akorn Rifampin Product;

9. a list of all of the NDC Numbers related to the Akorn Rifampin Product, and rights, to the extent permitted by Law, and to the extent they are assigned to the Respondent:

    a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the Akorn Rifampin Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;

    b. to prohibit Respondent from seeking from any customer any type of cross-referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;

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

    d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to the Akorn Rifampin Product with the Acquirer's NDC Numbers related to the Akorn Rifampin Product;

    e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of the Akorn Rifampin Product *except* for returns, rebates, allowances, and adjustments for the Akorn Rifampin Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and

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

10. all Product Development Reports related to the Akorn Rifampin Product;

11. at the option of the Acquirer of the Akorn Rifampin Product, all Product Assumed Contracts related to the Akorn Rifampin Product (copies to be provided to that Acquirer on or before the Closing Date);

12. all patient registries related to the Akorn Rifampin Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Akorn Rifampin Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA); and

13. all of the Respondent's books, records, files directly related to the foregoing;

PROVIDED, HOWEVER, that "Akorn Rifampin Product Assets" shall not include: (i) documents relating to Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the Akorn Rifampin Product; (ii) administrative, financial, and accounting records; and (iii) quality control records that are determined not to be material to the manufacture of the Akorn Rifampin Product by the Monitor or the Acquirer of the Akorn Rifampin Product; (iv) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Licensed Intellectual Property;

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

M. "Akorn Rifampin Product Divestiture Agreements" means the following:

1. The Asset Purchase Agreement between Akorn, Inc. and Watson Laboratories, Inc., dated as of July 21, 2014; and

2. The Manufacturing Supply Agreement attached as an exhibit to the above-described Asset Purchase Agreement to be executed as of the Closing Date;

all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Akorn Rifampin Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Akorn Rifampin Product Divestiture Agreements are contained in Non-Public Appendix A.

N. "Application(s)" means "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 *et seq*., and all supplements, amendments, and revisions thereto, any post-approval work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term "Application" also includes an

"Investigational New Drug Application" ("IND") filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.

O. "Business" means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.

P. "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.

Q. "Clinical Trial(s)" means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.

R. "Closing Date" means the date on which Respondent (or a Divestiture Trustee) consummates the transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to the Akorn Rifampin Product to an Acquirer pursuant to this Order.

S. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the conduct of the Business related to the Akorn Rifampin Product. The term "Confidential Business Information" *excludes* the following:

1. information relating to Respondent's general business strategies or practices that does not discuss with particularity the Akorn Rifampin Products;
2. information specifically excluded from the Akorn Rifampin Product Assets conveyed to the Acquirer; and
3. information that is protected by the attorney work product, attorney-client, joint defense, or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

T. "Contract Manufacture" means:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
2. to manufacture, or to cause to be manufactured, a Product that is the therapeutic equivalent (as that term is defined by the FDA) and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product on behalf of an Acquirer; and
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finishing, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

U. “Contract Manufacture Product(s)” means :

1. the Akorn Rifampin Product; and
2. any ingredient, material, or component used in the manufacture of the Akorn

4. to have the Akorn Rifampin Products made anywhere in the world for distribution or sale within, or imported into, the Geographic Territory;

PROVIDED, HOWEVER, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by the Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent.

Y. "Divestiture Product Releasee(s)" means the following Persons:

1. the Acquirer for the assets related to the Akorn Rifampin Product;
2. any Person controlled by or under common control with the Acquirer; and
3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer or Acquirer-affiliated entities.

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

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

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

CC. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

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

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

FF. "Manufacturing Designee" means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.

GG. "Monitor" means any monitor appointed purs

KK. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

LL. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosure, certificates of invention, and applications for certificates of invention and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, 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.

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

NN. “Product(s)” means any pharmaceutical, biological or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient and/or that is the subject of an Application.

OO. “Product Approval(s)” means any approval, registrations, permits, licenses, consents, authorization, and other approval, and pending applications and requests therefor, required by applicable Agencies related to the Research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation all approval, registrations, licenses or authorization, granted in connection with any Application related to that Product.

PP. “Product Assumed Contracts” means all contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1.

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

6. pursuant to which a Third Party manufacturers the Akorn Rifampin Product on behalf of Respondent;

7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the Akorn Rifampin Product on behalf of Respondent;

8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Akorn Rifampin Product to Respondent;

9. pursuant to which a Third Party is licensed by Respondent to use the Product Manufacturing Technology;

10. constituting confidentiality agreements involving the Akorn Rifampin Product;

11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Akorn Rifampin Product;

12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, distribution of the Akorn Rifampin Product to the Respondent including, but not limited to, consultation arrangements; and/or

13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the Akorn Rifampin Product or the Business related to the Akorn Rifampin Product;

PROVIDED, HOWEVER, that where any such contract or agreement also relates to a Retained Product(s), Respondent shall grant the Acquirer all such rights under the contract or agreement as are related to the Akorn Rifampin Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

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

materials, sales training materials, and advertising and display materials; all records relating to employees of Respondent who accept employment with the Acquirer (excluding any personnel records

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

1. Patents that are related to the Akorn Rifampin Product that the Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date; and

2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other

production of packaging components, television masters, and other similar materials related to the Akorn Rifampin Product.

WW. "Product Scientific and Regulatory Materials" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.

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

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

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

1. any agreement between Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to the Akorn Rifkamin Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in TD 0 T

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

AAA. "Retained Product" means any Product other than the Akorn Rifampin Product.

BBB. "Supply Cost" means a cost not to exceed the Respondent's average direct per unit cost in United States dollars of manufacturing the Akorn Rifampin Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *PROVIDED, HOWEVER*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for the Akorn Rifampin Product.

CCC. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, co

Akorn Rifampin Product in commercial quantities and to meet all Agency-approved specifications for the Akorn Rifampin Product; and

c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the Akorn Rifampin Product.

DDD. "Third Party(ies)" means any non-governmental Person other than the Respondent, or the Acquirer.

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

II.

IT IS FURTHER ORDERED that:

A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Akorn Rifampin Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Watson pursuant to, and in accordance with, the Akorn Rifampin Product Divestiture

modifications to the manner of divestiture of the Akorn Rifampin Product Assets to Watson (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. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer and to permit the relevant Acquirer to continue the Business of the Akorn Rifampin Product;

PROVIDED, HOWEVER, Respondent may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

C. Respondent shall:

1. submit to the Acquirer, at Respondent's expense, all Confidential Business Information related to the Akorn Rifampin Product being acquired;

2. deliver all Confidential Business Information related to the Akorn Rifampin Product being acquired:

   a. in good faith;

   b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and

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

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

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Akorn Rifampin Product other than as necessary to comply with the following:

   a. the requirements of this Order;

   b. Respondent's obligations to the Acquirer under the terms of the Remedial Agreement; or

   c. applicable Law;

5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the Akorn Rifampin Product, (ii) other Persons specifically authorized by the Acquirer to receive such Information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and

6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Akorn Rifampin Product to the marketing or sales employees associated with the Business related to those Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Akorn Rifampin Product.

D. Until the Acquirer (or the Manufacturing Designee of the Acquirer) (i) obtains all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished dosage product independently of Respondent, and (ii) identifies sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the Application(s) of Respondent for the Akorn Rifampin Product, Respondent shall:

1. provide, or cause to be provided to the Acquirer all correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the Akorn Rifampin Product in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner; and

2. cooperate with, and assist, Acquirer in responding to all correspondence, submissions, notifications, communications, registrations, or other filings received from, or otherwise conducted with the FDA relating to the Application(s) related to the Akorn Rifampin Product in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner, with copies and notice to the Monitor and the Acquirer of such contacts with the FDA in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner.

E. Respondent shall provide, or cause to be provided to the Acquirer in a manner consistent with the Technology Transfer Standards the following:

1. all Product Manufacturing Technology (including all related intellectual property) related to the Akorn Rifampin Product; and

2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to Respondent related to the Akorn Rifampin Product.

Respondent shall obtain any consents from Third Parties required to comply with this provision. Respondent 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 that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Akorn Rifampin Product acquired by the Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturi

PROVIDED, HOWEVER, that Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order;

PROVIDED FURTHER, HOWEVER, that this obligation shall not require Respondent 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 Respondent to the Acquirer in an agreement to Contract Manufacture;

PROVIDED FURTHER, HOWEVER, that in each instance where: (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for an Akorn Rifampin Product, each such agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

4. give priority to supplying a Contract Manufacture Product to the Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;

5. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

   PROVIDED, HOWEVER, that in each instance where (i) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (ii) such agreement becomes a Remedial Agreement for an Akorn Rifampin Product, each such agreement may contain limits on Respondent's aggregate liability for such a failure;

6. during the term of any agreement to Contract Manufacture, upon the written request of the Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

7. during the term of any agreement to Contract Manufacture, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);

8. in the event (i) Respondent becomes unable to supply or produce a Contract Manufacture Product from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer, and (ii) that Product is the subject of an ANDA, then Respondent shall provide a therapeutically equivalent (as that term is defined by the FDA) Product from another of Respondent's facility or facilities in those instances where such facilities are not being used or have previously been used, and are able to be used, by Respondent to manufacture such Product;

9. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture; and

10. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling

disputed product or service until such payment of all overdue and outstanding undisputed amounts are made.

H. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Akorn Rifampin Product within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of the Retained Products that are the therapeutic equivalent (as that term is defined by the FDA) of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

I. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of their employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acqui

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

K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to the Akorn Rifampin Product to the Acquirer,

1. Respondent shall take actions as are necessary to:

   a. maintain the full economic viability and marketability of the Businesses associated with the Akorn Rifampin Product;

   b. minimize any risk of loss of competitive potential for that Business;

   c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Akorn Rifampin Product;

   d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product; and

   e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and

2. Respondent shall not sell, transfer, encumber, or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses associated with the Akorn Rifampin Product.

L. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against the Acquirer or the Divestiture Product Releasee(s) of the Acquirer under the following:

1. any Patent owned by or licensed to Respondent on or as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or

2. any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Akorn Rifampin Product for the purposes of marketing, sale or offer for sale within the United States of America of the Akorn Rifampin Product; or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Akorn Rifampin Product. Respondent shall also

requirements of this Order and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of: (i) the date the Acquirer of the Akorn Rifampin Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Akorn Rifampin Product and able

Respondent has filed its final report pursuant to Paragraph IV.B, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent.

H. Respondent may require the Monitor and each of the 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 Monitor from providing any information to the Commission.

I. The Commission may, among other things, require the Monitor and each of the 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 Monitor's duties.

J. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after the notice by the staff of the Commission to Respondent of the identity of any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.

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

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

L. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.

IT IS FURTHER ORDERED that:

A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Rifampin Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5 of the Federal Trade Commission Act, 15

U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

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

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

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

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

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

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall

cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *PROVIDED, HOWEVER*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall give to the acquiring Person selected by Respondent from among those approved by the Commission; *PROVIDED FURTHER, HOWEVER*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the

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 Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

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

9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *PROVIDED, HOWEVER,*

B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Akorn Rifampin Products or the Assets and Businesses associated with the Akorn Rifampin Products;

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

PROVIDED FURTHER, *HOWEVER*, that pursuant to this Paragraph V, Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confid

VII.

IT IS FURTHER ORDERED that:

A.

IX.

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 Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

A. access, during business office hours of Respondent 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 Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and

B. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

X.

NON-PUBLIC APPENDIX A
AGREEMENTS RELATED TO THE DIVESTITURE

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

PUBLIC APPENDIX B
MONITOR AGREEMENT

NON-PUBLIC APPENDIX C
MONITOR COMPENSATION

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