

UNITED STATES OF AMERICA  
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman  
J. Thomas Rosch  
Edith Ramirez  
Julie Brill

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<b>In the Matter of</b>	)	
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	)	
<b>VALEANT PHARMACEUTICALS INTERNATIONAL, INC.,</b>	)	<b>Docket No. C-</b>
<b>a corporation.</b>	)	
	)	

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

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, 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 Valeant is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Johnson & Johnson is a corporation organized, existing and doing business under and by virtue of the laws of New Jersey, with its headquarters address located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and the address of its wholly owned subsidiary, Janssen Pharmaceuticals, Inc., located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
3. 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. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “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.
- D. “Acquisition” means Respondent’s acquisition of the rights, titles and interests of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson. The acquisition is contemplated pursuant to an Asset Purchase Agreement, by and among Janssen Pharmaceuticals, Inc., Valeant

International (Barbados) SRL, and Valeant Pharmaceuticals North America LLC, dated as of July 15, 2011, submitted to the Commission.

- E. “Acquisition Date” means the date on which the Acquisition is consummated.
- F. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- G. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between 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, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.
- H. “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.
- I. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to the Acquirer pursuant to this Order.
- J. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent 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 each of the Refissa Products;

*provided, however,* that the restrictions contained in this Order regarding the Respondent’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

- a. 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 the Respondent;

- b. information that is required by Law to be publicly disclosed;
  - c. information relating to the Respondent's general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Refissa Products;
  - d. information specifically excluded from the Refissa Product Assets; and
  - e. 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.
- K. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.
- L. "Divestiture Product Releasee(s)" means the following Persons:
- 1. the Acquirer for the assets related to a particular Divestiture Product;
  - 2. any Person controlled by or under common control with that Acquirer; and
  - 3. any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- M. "Divestiture Products" means the Refissa Products.
- N. "Divestiture Trustee" means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- O. "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. "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.
- P. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

- Q. “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.
- R. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- S. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- T. “Order Date” means the date on which this Decision and Order becomes final and effective.
- U. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- V. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention 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, 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, related to any Product of or owned by the Respondent as of the Closing Date (*except* where this Order specifies a different time).
- W. “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.
- X. “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.
- Y. “Product Assumed Contracts” means all of the following 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. that make specific reference to the Refissa Products and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Refissa Products from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. relating to any Clinical Trials involving the Refissa Products;
  3. relating to the particularized marketing of the Refissa Products or educational matters relating solely to the Refissa Products(s);

4. constituting confidentiality agreements involving the Refissa Products;
5. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Refissa Products;
6. pursuant to which a Third Party manufactures the specified Divestiture Product on behalf of the Respondent;
7. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Refissa Products to the Respondent including, but not limited to, consultation arrangements; and/or
8. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the Refissa Products or the business related to the Refissa Products;

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

- Z. “Product 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, the following: 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 such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture 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 references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the Divestiture Products sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to such Divestiture Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse

experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

AA. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

*provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

BB. “Product 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 purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Products.

CC. “Product 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.

DD. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all

common law rights, and the goodwill symbolized thereby and associated therewith, for the Divestiture Product(s);

*provided, however*, “Product Trademarks” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

- EE. “Refissa Co-Marketing Agreement” means the “Co-Marketing Agreement” by and between Valeant Pharmaceuticals North America and Spear Pharmaceuticals, Inc., dated February 28, 2010, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Refissa Co-Marketing Agreement is attached to this Order and contained in Non-Public Appendix I.
- FF. “Refissa Product(s)” means all products that are the subject of the Refissa Co-Marketing Agreement. “Refissa Products” includes all products marketed under the ANDA No. 76-498.
- GG. “Refissa Product Assets” means all rights, title and interest in and to all assets related to the research, Development, manufacture, distribution, marketing, and sale of the Refissa Products that are owned or controlled by, or licensed to Respondent on or before the Acquisition Date, to the extent legally transferable, including, without limitation, the following:
1. all rights, economic benefits, or other interests conveyed to Respondent pursuant to the Refissa Co-Marketing Agreement;
  2. all Product Intellectual Property related to the Refissa Products;
  3. all Product Marketing Materials related to the Refissa Products;
  4. all Website(s) related exclusively to the Refissa Products;
  5. the content related exclusively to the Refissa Products that is displayed on any Website that is not dedicated exclusively to the Refissa Products;
  6. at the option of Spear, all Product Assumed Contracts related to the Refissa Products;
  7. a list of all customers and targeted customers for the Refissa Products and a listing of the net sales (in either units or dollars) of the Refissa Products to such customers on either an annual, quarterly, or monthly basis;
  8. a list of all physician sales calls related to Refissa Product made pursuant to the Refissa Product Co-Marketing Agreement;



9. a list of all prescribers of the Refissa Products;
10. at the option of Spear, and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Refissa Products; and
11. all of the Respondent's books, records, and files directly related to the foregoing;

*provided, however,* that "Refissa Product Assets" shall not include: (1) documents relating to the Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products, where such documents do not discuss with particularity the Refissa Products; (2) administrative, financial, and accounting records;

*provided further, however,* that in cases in which documents or other materials included in the assets to be divested contain information: (1) that relates both to the Refissa Products and to Retained Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Refissa Products; or (2) for which the 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 Spear, the Respondent shall provide Spear 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 Respondent provides Spear with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

HH. "Refissa Product Co-Marketing Termination Agreement" means the "Termination and Release Agreement" between Valeant Pharmaceuticals North America LLC, Spear Pharmaceuticals, Inc. and Spear Dermatology Products, Inc., dated as of November 22, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Refissa Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Refissa Product Co-Marketing Termination Agreement is attached to this Order and contained in non-public Appendix I.

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

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

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

KK. "Spear" means Spear 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 located at 11924 Fairway Lakes Drive, Ft. Myers, Florida 33913.

LL. "Third Party(ies)" means any non-governmental Person other than the following: the Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

MM. "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 the 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 the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

## 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 Refissa Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Spear), to Spear and terminate the Refissa Product Co-Marketing Agreement, absolutely and in good faith, pursuant to the Refissa Product Co-Marketing Termination Agreement (which agreement shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Spear or to reduce any obligations of Respondent under such agreements);

*provided however*, that if Respondent has divested the Refissa Product Assets to Spear prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Refissa Product Assets to Spear (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 Refissa Product Assets to Spear, and to permit Spear to continue the research, Development, manufacture, sale, marketing or distribution of the Refissa Products;

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

- C. Respondent shall:

1. submit to Spear, at Respondent's expense, all Confidential Business Information related to the Refissa Products;
2. deliver all Confidential Business Information to Spear:
  - 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 Confidential Business Information to Spear, provide Spear and the Interim Monitor (if any has been appointed) with access to all 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 Refissa Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
  4. not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Refissa Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondent's obligations to Spear under the terms of any related Remedial Agreement; or
    - c. applicable Law;
  5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except Spear or other Persons specifically authorized by Spear to receive such information; and
  6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Refissa Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Refissa Products and that are approved for the same indication as the Refissa Products.
- D. Respondent shall not enforce any agreement against a Third Party or Spear to the extent that such agreement may limit or otherwise impair the ability of Spear to acquire the Confidential Business Information related to the Refissa Products from the Third Party.
- E. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.D. that allows the Third Party to provide the Confidential Business Information to Spear. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Spear.
- F. Until all of Respondent Spear's rights to enforce restrictions on the use, disclosure, conveyance or provision of Confidential Business Information are fully assigned or conveyed to Spear, Respondent shall enforce any agreement against a Third Party to the extent that such agreement prevents or limits the ability of the Third Party to provide any Confidential Business Information to any person or entity other than: (1) Spear or (2) any Person authorized by Spear to receive such information.

- G. 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 Refissa Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities to those Retained Products that contain the same active pharmaceutical ingredient and that are approved for the same indication as the Refissa Products 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 Refissa 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).
- H. 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 Refissa Products by Respondent's personnel to all of Respondent's employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Refissa Products;
  2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient and that are approved for the same indication as the Refissa Products; and/or
  3. may have Confidential Business Information related to the Refissa Products.

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 Spear. 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 Spear with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- I. Until Respondent completes the divestiture of the Refissa Product Assets to Spear,
1. Respondent shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with the Refissa Products;
    - 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 Refissa Products;
  - d. ensure the Refissa Product Assets are provided to Spear in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Refissa Products; 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 Refissa Products.

J. Respondent shall not, in the United States of America:

1. use the Product Trademarks related to the Refissa Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
2. attempt to register such Product Trademarks;
3. attempt to register any mark confusingly similar to or resulting in dilution of such Product Trademarks;
4. challenge or interfere with Spear's use and registration of such Product Trademarks; or
5. challenge or interfere with Spear's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

*provided however*, this Paragraph shall only apply to those Product Trademarks conceived, registered, or developed prior to the Acquisition Date.

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

1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Refissa Product(s), or that claims a device relating to the use thereof;
2. any Patent owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Refissa Products;

if such suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa Products anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Refissa Product. Respondent shall also covenant to Spear that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue Spear or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a Refissa Product.

- L. The purpose of the divestiture of the Refissa Product Assets, the termination of the Refissa Product Co-Marketing Agreement and the related obligations imposed on the Respondent by this Order is to ensure the continued research, Development, manufacture, distribution, sale and marketing of the Refissa Products independently of Respondent and for the purposes of the business associated with each Refissa Product within the Geographic Territory and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

### **III.**

**IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreement(s).
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Refissa Product Assets and the transfer and delivery of the related Confidential Business Information in a manner that fully satisfies the requirements of this Order; *provided, however*, that, with respect to each Refissa Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date; *provided, further*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.
  4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.
  5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
  6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.



7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.
  8. The Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
  - F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
  - G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
  - H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

#### 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 Refissa Product Assets or to terminate the Refissa Product Co-Marketing Agreement 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(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey 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 the 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 divest 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 Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from 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 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*, 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.

**V.**

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that Respondent's counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to Spear or access original documents provided to Spear, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- 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 Refissa Products or the assets and businesses associated with the Refissa 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 shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with Spear (but shall not be deemed to have violated this requirement if Spear

withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

## VI.

**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligations to Spear pursuant to this Order.
- D. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Refissa Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

## VII.

**IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A, and II.C.1.-3., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts related to the termination of the Refissa Co-Marketing Agreement and the identity of all Persons contacted, including 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 Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

### **VIII.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

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

- A. access, during business office hours of the 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 that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the Order Date.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: \_\_\_\_\_

**NON-PUBLIC APPENDIX I  
REFISSA CO-MARKETING AGREEMENT  
AND  
REFISSA PRODUCT CO-MARKETING TERMINATION AGREEMENT**

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