

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION**

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

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**In the Matter of** )  
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                                 )  
**ENDO HEALTH SOLUTIONS INC.,** )  
                                 **a corporation;** )  
                                 )  
**BOCA LIFE SCIENCE HOLDINGS, LLC,** )      **Docket C-4430**  
                                 **a limited liability company;** )  
                                 )  
**and** )  
                                 )  
**BOCA PHARMACAL, LLC,** )  
                                 **a limited liability company.** )

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The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, 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 Endo is 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 1400 Atwater Drive, Malvern, Pennsylvania 19355.
2. Respondent Boca Life is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126<sup>th</sup> Avenue, Coral Springs, Florida 33065.
3. Respondent Boca Pharma is a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Florida with its headquarters address located at 3550 NW 126<sup>th</sup> Avenue, Coral Springs, Florida 33065.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

## **ORDER**

### **I.**

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

- A. “Endo” means Endo Health Solutions Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Endo Health Solutions Inc. (including, without limitation, Generics International (US) Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Endo shall include Boca Pharma.
- B. “Boca Life” means: Boca Life Science Holdings, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Life Science Holdings, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Boca Pharma” means: Boca Pharmacal, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Boca Pharmacal, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. “Respondents” means Endo, Boca Life and Boca Pharma, individually and collectively. After the Acquisition, “Respondents” means Endo and Boca Pharma, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Acetic Acid Products” means the generic 2% acetic acid, glacial, hydrocortisone otic solution drop Product in Development by Respondent Boca Pharma.
- G. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent(s) 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 a Respondent(s) is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- H. “Acquisition” means Respondent Endo’s acquisition of the limited liability company membership interest, a.k.a. membership interests, of Boca Pharma. The acquisition is contemplated pursuant to a *Membership Interest Purchase and Sale Agreement* by and among Generics International (US) Inc., Boca Life Science Holdings, LLC, Boca Pharmacal, LLC and certain members of Boca Life Science Holdings, LLC, dated as of August 27, 2013, 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. “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 et seq., 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. 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.

- L. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement and sale of a Product.
- M. “Brompheniramine Products” means the following: the Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Endo pursuant to ANDA No. 202955, and any supplements, amendments, or revisions thereto.
- N. “Categorized Assets” means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), as such assets and rights are in existence as of the date the Respondent signs the Agreement Containing Consent Orders in this matter and as are maintained by the Respondent in accordance with the Asset Maintenance Order until the Closing Date:
  - 1. all rights to all of the Applications related to the specified Divestiture Product;
  - 2. all Product Intellectual Property related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
  - 3. all Product Approvals related to the specified Divestiture Product;
  - 4. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Licensed Intellectual Property;
  - 5. all Product Marketing Materials related to the specified Divestiture Product;
  - 6. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
  - 7. all Website(s) related exclusively to the specified Divestiture Product;
  - 8. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
  - 9. a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
    - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture 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 such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
  - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture 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 the Respondent prior to such notification(s) being disseminated to the customer(s);
10. all Product Development Reports related to the specified Divestiture Product;
11. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);

- b. anticipated reorder dates for each customer as of the Closing Date;
- 15. at the option of the Acquirer of the specified Divestiture Product 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 specified Divestiture Product;
- 16. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
- 17. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
- 18. all of the Respondent's books, records, and files directly related to the foregoing;  
*provided, however,* that "Categorized Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to the conduct of

- O. “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.
- P. “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.
- Q. “Closing Date” means, as to each Divestiture Product, the date on which a 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 an Acquirer pursuant to this Order.
- R. “Confidential Business Information” means all information owned by, or in the possession or control of, any Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to any Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
  2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
  3. information that is contained in documents, records or books of any Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
  4. 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.
- S. “Contract Manufacture” means, the following:
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;
  3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

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

1. the Brompheniramine Products; and
2. any ingredient, material, or component used in the manufacture of the foregoing Product including the active pharmaceutical ingredient, excipients or packaging materials;

*provided however*, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a therapeutic equivalent (as that term is defined by the FDA) form of such Product in performance of that Respondent’s agreement to Contract Manufacture.



- Y. “Divestiture Product Core Employees” means:
1. with respect to the Brompheniramine Products and the Hydrocodone/Acetaminophen Products, the Product Research and Development Employees and the Product Manufacturing Employees related to each Generic Divestiture Product; and
  2. with respect to the Vitamin Products,

trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.

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

EE. “Generic Divestiture Product(s)” means the following:

1. Acetic Acid Products;
2. Brompheniramine Products; and
3. Hydrocodone/Acetaminophen Products.

FF. “Generic Divestiture Product Agreements” means, the following:

1. The Asset Purchase Agreement between Generics International (US) Inc. and Rhodes Pharmaceuticals, L.P., dated January 9, 2014;
2. The Assignment and Assumption Agreement between Generics International (US) Inc. and Rhodes Pharmaceuticals, L.P., dated January 9, 2014;
3. The Supply Agreement between Vintage Pharmaceuticals, a wholly-owned

Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) the end of the last quarter following the Acquisition or the Closing Date.

- KK. “Hydrocodone/Acetaminophen Products” means the generic Products that are both: (i) oral solutions comprised of 10 mg hydrocodone bitartrate/15ml and 325 mg acetaminophen/15 ml, and (ii) in Development, manufactured, marketed, sold, owned or controlled, by Respondent Endo pursuant to ANDA No. 203744, and any supplements, amendments, or revisions thereto.
- LL. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order

- WW. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application related to that Product.
- XX. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to th

12. pursuant to which a Third Party provides any specialized services necessary to the

3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. 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 specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and

20. executed validation and qualification protocols and reports

*provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Endo” or “Boca” 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 Endo, Boca Life or Boca Pharma can be identified or defined.

CCC. “Product Licensed Intellectual Property” means the following:

1. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition;
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition; and
3. all Right(s) of Reference or Use that is either owned or controlled by, or has been granted or licensed to the Respondent that is related to the Drug Master File of an NDA of a Product that is the therapeutic equivalent (as that term is defined by the FDA) of the specified Divestiture Product.

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

EEE. “Product Manufacturing Technology” means all of the following related to a Divestiture Product:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;



2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients or packaging materials; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture that Product.

FFF. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product 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 specified Divestiture Product.

GGG. "Product Research and Development Employees" means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) w.16i008 {ackag)oe.y of teri

LLL. “Remedial Agreement(s)” means the following:

1. any agreement between a Respondent(s) 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 a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) related to a Divestiture 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 connection with the Commission’s determination to make this Order final and effective;
3. any agreement between a Respondent(s) and an Acquirer (or between a Divestiture Trustee and 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, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by that Respondent(s) 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 a Respondent(s) and a Third Party to effect the assignment of assets or rights of that Respondent(s) 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.

MMM. “Retained Product” means any Product(s) other than a Divestiture Product.

NNN. “Rhodes” means Rhodes Pharmaceuticals, L.P., a limited partnership organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its headquarters address located at 498 Washington Street, Coventry, Rhode Island 02816.

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

PPP. “Sonar” means Sonar Products, Inc. a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey with its headquarters address located at 609-613 Industrial Road, Carlstadt, New Jersey 07072.

QQQ. “Supply Cost” means a cost not to exceed the Respondent’s (as that Respondent is identified in the definition of the respective Divestiture Product) average direct per unit cost in United States dollars of manufacturing the specified Divestiture 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 that Divestiture Product.

RRR. “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, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,

1. designating employees of the Respondent(s) knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
  - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the specified Respondent (as that Respondent is identified in the definition of the specified Divestiture Product), or the manufacturer and/or developer of such Divestiture Product;
  - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and

- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

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

TTT. “Transition Period for the Vitamin Products” means for each Vitamin Product, the period beginning on the date the Order to Maintain Assets in this matter is issued by the Commission and ending, with respect to each Vitamin Product, on the earlier of the following dates: (i) the date thirty (30) days from a termination notice by Sonar and the New Marketing Partner as provided for in the Vitamin Product Divestiture Agreements; or (ii) the date six (6) months from the Order Date.

UUU. “Vitamin Product(s)” means all of the following Products sold or distributed by Boca Pharma:

1. Multi-Vitamin with Fluoride (0.25 MG) & Iron Drops (50 mL bottles sold under NDC Number 64376-0821-50);
2. Multi-Vitamin with Fluoride (0.25 MG) Drops (50 mL bottles sold under NDC Number 64376-0820-50);
3. Multi-Vitamin with Fluoride (0.50 MG) Drops (50 mL bottles sold under NDC Number 64376-0822-50);
4. Triple Vitamin with Fluoride (0.25 MG) Drops (50 mL bottles sold under NDC Number 64376-0823-50);

including, without limitation, any other package form or size of the foregoing strengths.

VVV. “Vitamin Product Divestiture Assets” means the following assets and rights of Respondent Boca Pharma:

1. for each Vitamin Product, all of Respondent Boca Pharma’s rights to import, Develop, manufacture, process, commercialize, distribute, sell, advertise, market, promote, out-license, or offer for sale, any of the Vitamin Products. Such rights include, without limitation, all of the foregoing rights acquired or held by Respondent Boca Pharma as a result of any agreement with Sonar and all rights to any and all improvements to the Vitamin Products;
2. all rights to all Product Marketing Materials related to each Vitamin Product;
3. all rights to all Website(s) related exclusively to each Vitamin Product;
4. all content related exclusively to each Vitamin Product that is displayed on any Website that is not dedicated exclusively to the specified Vitamin Product;

5. rights, to the extent permitted by Law:
  - a. to require any Respondent to discontinue the use of the NDC Numbers related to each Vitamin Product in the sale or marketing of the specified Vitamin Product

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

*provided, however,* that "Vitamin Product Divestiture Assets" shall not include: (i) documents relating to any Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Vitamin Product(s); (ii) administrative, financial, and accounting records; (iii) quality control records that are determined by the Interim Monitor or Sonar not to be material to the marketing, distribution or sale of the specified Vitamin Product; (iv) competitively sensitive pricing information to the extent that it is related to the Retained Products; (v) rights to the corporate names or corporate trade dress of "Endo" or "Boca", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by any Respondent or the related corporate logos thereof, or general registered images or symbols by which Endo, Boca Life or Boca Pharma can be identified or defined; and (vi) information that is contained in documents, records, or books of any Respondent provided to Sonar by such Respondent that is unrelated to the Vitamin Products or that is exclusively related to Retained Product(s);

*provided further, however,* the Respondents shall provide Sonar access to original documents under circumstances where copies of documents are insufficient for

owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a 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 Endo shall divest the Generic Divestiture Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Rhodes pursuant to, and in accordance with, the Generic Divestiture Product Agreement(s) (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Rhodes or to reduce any obligations of Respondent Endo under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Divestiture Product Assets is incorporated by reference into this Order and made a part hereof;

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

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

- B. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Vitamin Product Divestiture

not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Sonar or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Vitamin Product Divestiture Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the Vitamin Product Divestiture Assets to Sonar prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Vitamin Product Divestiture Assets to Sonar (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.

- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

*provided, however,* Respondents 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.

- D. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
  - 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



4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondents' obligations to each respective Acquirer 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 (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer to receive such information, (iii) the Commission, or (iv) the Interim 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 Divestiture Products 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 Divestiture Products.

E. For each Acquirer of a Generic Divestiture Product, Respondents shall provide, or cause to be provided to that 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 Divestiture Product(s) being acquired by that Acquirer; and
2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to any Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent Endo shall obtain any consents from Third Parties required to comply with this provision. No Respondent shall 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 Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- F. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondent Endo shall:
1. upon reasonable written notice and request from that Acquirer to Respondent Endo, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Supply Cost, for a period of time

aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
4. make representations and warranties to each Acquirer that Respondents 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 Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

*provided, however,* that in each instance where: (i)

Respondent (as that Respondent is identified in the definition of the respective Divestiture Product) and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent Endo and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products;

The foregoing provisions, II.F.1. - 9., shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer of that Contract Manufacture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Contract Manufacture Product in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Endo; (ii) the date the Acquirer of a particular Contract Manufacture Product notifies the Commission and Respondent Endo of its intention to abandon its efforts to manufacture such Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Contract Manufacture Product has abandoned its efforts to manufacture such Contract Manufacture Product, or (iv) the date five (5) years from the Closing Date.

- G. Respondent Endo 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 Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities related to the marketing or sales of those 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 Endo (other than as necessary to comply with the requirements of this Order).

H.

program has been implemented and is being complied with. Respondent Endo shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent Endo's personnel.

- I. For each Acquirer of a Divestiture Product, Respondent Endo shall:
1. for a period of six (6) months from the Closing Date or until the hiring of two (2) Divestiture Product Core Employees by that Acquirer or its Manufacturing Designee or its New Marketing Partner, whichever occurs earlier, provide that Acquirer, its Manufacturing Designee, or its New Marketing Partner with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"
  2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to Respondent Endo to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent Endo to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use, and (iv) destroy or return the information without retaining copies at such time as the specified and permitted use ends;
  3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer, its Manufacturing Designee, or its New Marketing Partner of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of Respondent Endo that may deter these employees from accepting employment with that Acquirer, its Manufacturing Designee or its New Marketing Partner, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents Endo or Boca Pharma that would affect the ability or incentive of those individuals to be employed by that Acquirer, its Manufacturing Designee or its New Marketing Partner. In addition, Respondents Endo or Boca Pharma shall not make any counteroffer to such a

Divestiture Product Core Employee who has received a written offer of employment from that Acquirer, its Manufacturing Designee, or its New Marketing Partner;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer, its Manufacturing Designee or its New Marketing Partner to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

*provided, however,* that this Paragraph does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not, directly or indirectly1.1tnicit or otherwise estituoym(DivestSuch inc,)i estSueiture P25 -1.67 ase es, Tf.75 0 TD(rr(rr-.0004 c-.is



interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- L. Upon reasonable written notice and request from an Acquirer to Respondent Endo, Respondent Endo shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent Endo to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.
- M. For any patent infringement suit filed prior to the Closing Date in which any Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that any Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the World of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale or offer for sale within the United States of America of such Divestiture Products; or (ii) the use within, import into, export from, or the supply, distribution, or sale or offer for sale within, the United States of America of such Divestiture Product(s), that Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
  2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
  3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of that Respondent's outside counsel related to that Divestiture Product.



- N. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory; and
  2. to create a viable and effective competitor, that is independent of Respondent Endo in the Business of each Divestiture Product within the Geographic Territory; and,
  3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

### **III.**

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

- A. At any time after the Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondent Endo 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 Endo of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent Endo shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor 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 Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the

related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and,

- a. with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of

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.

- H. Respondents 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 Respondents, and any reports submitted by each Acquirer with respect to the performance of Respondents' 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 Respondents of their obligations under the Order. *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.B., and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by each 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 Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. 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.
- K. 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.
- L. 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.
- M. 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 Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture 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(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey 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

information, as the Divestiture Trustee may request. Respondent shall develop

the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.

8.

*provided, however,* that a 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, the 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 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 a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of the Respondents, all as soon as reasonably practicable.
- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.





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 the Respondent related to compliance with this Order, which copying services shall be provided by the 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 on March 19, 2024.

By the Commission.

Donald S. Clark  
Secretary

SEAL  
ISSUED: March 19, 2014

**NON-PUBLIC APPENDIX I  
AGREEMENTS RELATED TO THE DIVESTITURES**

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