

FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS
JANUARY 1, 2022, TO JUNE 30, 2022

IN THE MATTER OF

**ANI PHARMACEUTICALS, INC.,
NOVITIUM PHARMA LLC,
AND
ESJAY LLC**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4754; File No. 211 0101
Complaint, November 9, 2021 – Decision, January 11, 2022*

This consent order addresses the \$210 million acquisition by ANI Pharmaceuticals, Inc. of certain assets of Novitium Pharma LLC and Esjay LLC. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening future competition in the markets for (1) generic SMX-TMP oral suspension; and (2) generic dexamethasone tablets in the United States. The consent order requires Respondents to divest all of ANI's rights and assets related to (1) generic sulfamethoxazole-trimethoprim oral suspension; and (2) generic dexamethasone tablets to Prasco LLC.

Participants

For the *Commission*: Kari A. Wallace.

For the *Respondents*: Patrick C. English and Amanda P. Reeves, Latham & Watkins LLP;
Elena Kamenir and Amy Ray, Orrick Herrington & Sutcliffe LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act ("FTC Act"), and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent ANI Pharmaceuticals, Inc. ("ANI"), a corporation subject to the jurisdiction of the Commission, has agreed to acquire non-corporate interests of Respondent Novitium Pharma LLC, whose ultimate parent entity is Respondent Esjay LLC (collectively, "Novitium"), companies subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

Complaint

I. RESPONDENTS

1. Respondent ANI Pharmaceuticals, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 210 Main Street West, Baudette, Minnesota 56623.

2. Respondent Novitium Pharma LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 70 Lake Drive, East Windsor, New Jersey 08520.

3. Respondent Esjay LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 16732 Strasbourg Lane, Delray Beach, Florida 33446.

4. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED ACQUISITION

5. Pursuant to an agreement and plan of merger dated March 8, 2021, Respondent ANI proposes to acquire the non-corporate equity interests of Respondent Novitium in transaction valued at approximately \$210 million (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

6. The relevant lines of commerce in which to analyze the effects of the Acquisition are the development, license, manufacture, marketing, distribution, and sale of the following generic pharmaceutical products:

- a. sulfamethoxazole-trimethoprim (“SMX-TMP”) oral suspension; and
- b. dexamethasone tablets.

7. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in the relevant lines of commerce.

IV. THE STRUCTURE OF THE MARKETS

8. Generic SMX-TMP oral suspension is an antibiotic product used to treat a variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX-TMP oral suspension in the near future.

Complaint

9. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Recently, dexamethasone tablets have been used to reduce mortality in hospitalized COVID-19 patients who require supplemental oxygen. Dexamethasone tablets are available in a variety of strengths, although the most widely-used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies entering the market in the near future.

V. ENTRY CONDITIONS

10. Entry into the relevant markets described in Paragraphs 6-7 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. *De novo* entry would not take place in a timely manner because the combination of drug development times and FDA approval requirements would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. THE EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating future competition between ANI and Novitium in the markets for (1) generic SMX-TMP oral suspension and (2) generic dexamethasone tablets, thereby (a) increasing the likelihood that the combined entity would forego or delay the launch of each product, and (b) increasing the likelihood that the combined entity would delay, eliminate, or otherwise reduce the substantial additional price competition that would have resulted from an additional supplier of each product.

VII. VIOLATIONS CHARGED

12. The Acquisition described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this ninth day of November 2021 issues its Complaint against said Respondents.

By the Commission.

Order to Maintain Assets

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission initiated an investigation of Respondent ANI Pharmaceuticals, Inc.'s proposal to acquire the non-corporate interests of Respondent Novitium Pharma LLC, whose ultimate parent entity is Respondent Esjay LLC (collectively "Respondents"). The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45 (collectively "Acts").

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and 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. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Order to Maintain Assets:

1. Respondent ANI Pharmaceuticals, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 210 Main Street West, Baudette, Minnesota 56623.
2. Respondent Novitium Pharma LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 70 Lake Drive, East Windsor, New Jersey 08520.
3. Respondent Esjay LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 16732 Strasbourg Lane, Delray Beach, Florida 33446.

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4. Prasco LLC is a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER TO MAINTAIN ASSETS**I. Definitions**

IT IS HEREBY ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the Decision and Order, which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Decision and Order” means the proposed Decision and Order contained in the Consent Agreement or the Decision and Order issued in this matter.
- B. “Orders” means this Order to Maintain Assets and the Decision and Order.

II. Divestiture Related Obligations

IT IS FURTHER ORDERED that:

- A. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

Provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.
- B. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.
- C. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the 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 a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the

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manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

Provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.

- D. Respondents shall transfer the Product Manufacturing Technology related to the Divestiture Products to the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondents shall bear all costs related to these transfers.
- E. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- F. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
 - 1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (a) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (b) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (c) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;
 - 2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;

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3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
 4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
 5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
 6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.
- G. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.
- H. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) 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 for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.
- I. For any patent infringement suit that is filed or to be filed within the United States that is (x) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (y) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:
1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;

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2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Dexamethasone Divestiture Assets and the Sulfamethoxazole/Trimethoprim Divestiture Assets to the Acquirer pursuant to Section II of the Decision and Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.
- B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.
- C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.
- D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.
- E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.

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- F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:
 - 1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and
 - 2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.
- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.
- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, however, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

IV. Transition Services and Manufacturing by Respondents**IT IS FURTHER ORDERED** that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from the Acquirer, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and

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supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Divestiture Products and any of the active pharmaceutical ingredients used in the Divestiture Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." The requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.

- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications and, with the consent of the Acquirer, shall amend any agreement between the Respondents and the Acquirer that is related to the quality controls of a Divestiture Product to address any necessary changes to the agreement in order to comply with relevant Agency regulations or recommendations.
- D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

Provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by this Order;

Provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (1) 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, and (2) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.
- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or

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created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.

- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (x) a breach by the Acquirer of a Divestiture Agreement, or (y) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

Provided, however, that this Paragraph IV.J shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.

- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (x) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (y) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.
- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and

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sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.

- N. For any Supplied Product that is made in a facility owned by Respondents, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by the Acquirer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Divestiture Product, at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

V. Employees

IT IS FURTHER ORDERED that:

- A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.
- B. Respondents shall:
 - 1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;
 - 2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;
 - 3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee;

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Provided, however, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.
- C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.
 - D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.
 - E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (1) were involved with any of the Divestiture Products, or (2) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Section V shall apply to such employees as of that notification date.
 - F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate the employee's employment with the Acquirer or its Manufacturing Designee;

Provided, however, Respondents may:

1. Hire an employee whose employment has been terminated by the Acquirer;
2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and

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3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of Section V.

VI. Business Information and Confidentiality**IT IS FURTHER ORDERED** that:

- A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:
 1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that ensures the completeness and accuracy of all information and ensures its usefulness;
 2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;
 3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:
 - a. The requirements of the Orders;
 - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or
 - c. Applicable law;
 4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (a) that Acquirer, (b) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing Technology), (c) the Commission, or (d) a Monitor, and *except* to the extent necessary to comply with applicable law;
 5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the

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business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;

6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:
 - a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
 - b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
 7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
 - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
 - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
 - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.
- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and

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the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).

- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (1) may be in possession of such Confidential Business Information or (2) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:
 - 1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, 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
 - 2. 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 an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

Provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph VI.D pursuant to an appropriate confidentiality order, agreement, or arrangement;

Provided further, however, that pursuant to this Paragraph VI.D, a Respondent needing such access to original documents shall: (1) require those who view such

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unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication

VII. Monitor**IT IS FURTHER ORDERED** that:

- A. The Commission appoints Denise Smart of Smart Consulting Group, LLC as Monitor to observe and report on Respondents' compliance with the terms of the Orders.
- B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement shall:
 - 1. Be subject to the approval of the Commission;
 - 2. Not limit, and the signatories shall not construe it to limit, the terms of Section VIII of the Decision and Order or Section VII of this Order to Maintain Assets ("Monitor Sections") and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and
 - 3. Include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.
- C. The Monitor shall:
 - 1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
 - 2. Act in consultation with the Commission or its staff;
 - 3. Serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
 - 4. Shall serve without bond or other security;

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5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into a non-disclosure or other confidentiality agreement with the Commission;
7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;
8. Report in writing to the Commission concerning Respondents' compliance with the Orders 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission; and
9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents obligations to provide manufacturing and supply of Divestiture Products pursuant to this Order have expired or been terminated and files a final report.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing the Monitor's duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
2. Not interfere with the ability of the Monitor to perform the Monitor's duties pursuant to the Orders;
3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing the Monitor's duties under the Orders, including expenses of any consultants, accountants, attorneys, and other representatives and

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assistants that are reasonably necessary to assist the Monitor in carrying out the Monitor's duties and responsibilities;

4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and
 5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.
- E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement provided that such agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.
- F. Respondents shall not require nor compel the Monitor to disclose to Respondents the substance of communications with the Commission, including the Monitor's written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.
- G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:
1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;
 2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and
 3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same

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terms as the Commission-approved agreement referenced in Paragraph VII.B of the Monitor Sections; or (b) receives Commission approval.

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

VIII. Divestiture Trustee**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by the Decision and 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 the Decision and 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 Section VIII 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 a Respondent to comply with the Orders.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.

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

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
2. The Divestiture Trustee shall have one 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- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) 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 2 times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestiture caused by a Respondent shall extend the time for divestiture under Section VIII in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission 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 Respondents from among those approved by the Commission;

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Provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct 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.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

Provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to enter into a non-disclosure or other confidentiality

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agreement with the Commission related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

- F. 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 Section VIII.
- G. 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(s) required by this Order.

IX. Prior Approval

IT IS FURTHER ORDERED that each Respondent shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Dexamethasone Products, the Sulfamethoxazole/Trimethoprim Products, and the Erythromycin/Ethylsuccinate Products, or the Therapeutic Equivalent or Biosimilar of any of these Products without the prior approval of the Commission.

X. Compliance Reports

IT IS FURTHER ORDERED that Respondents shall file verified written reports ("compliance reports") in accordance with the following:

- A. Respondents shall submit compliance reports 30 days after the Commission issues this Order to Maintain Assets and every 30 days thereafter until the Commission issues a Decision and Order in this matter.
- B. Each compliance report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondents are complying with their obligations under the Orders. Conclusory statements that Respondents have complied with its obligations are insufficient. Respondents shall include in their reports, among other information or documentation that may be necessary to demonstrate compliance:
 - 1. A full description of the measures Respondents have implemented or plan to implement to ensure that they have complied or will comply with each paragraph of in the Orders;
 - 2. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Divestiture Products to that Acquirer;

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3. A detailed description of the transfer of the Product Manufacturing Technology related to the Acquirer or the Acquirer's Manufacturing Designee and progress toward the manufacturing of these products at a facility that is not owned or controlled by Respondents; and
 4. A detailed description of the timing for the completion of such obligations.
- C. For a period of 5 years after filing a Compliance Report, each Respondent shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent's obligations under the Orders and provide copies of these documents to Commission staff upon request.
- D. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondent shall file its compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter

XI. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

- A. The dissolution of: ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC;
- B. Any proposed acquisition, merger, or consolidation of ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XII. Access

IT IS FURTHER ORDERED that that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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- A. Access, during business office hours of that 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 the Orders, 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 that Respondent; and
- B. To interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

XIII. Purpose

IT IS FURTHER ORDERED that the purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through its full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Divestiture Product Businesses; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

XIV. Term

IT IS FURTHER ORDERED that this Order shall terminate the day after the Decision and Order in this matter becomes final or the Commission withdraws acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34.

By the Commission.

DECISION

The Federal Trade Commission initiated an investigation of Respondent ANI Pharmaceuticals, Inc.'s proposal to acquire the non-corporate interests of Respondent Novitium Pharma LLC, whose ultimate parent entity is Respondent Esjay LLC (collectively "Respondents"). The Commission's Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45 (collectively "Acts").

Respondents and the Bureau of Competition executed an Agreement Containing Consent Orders ("Consent Agreement") containing (1) an admission by Respondents of all the

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jurisdictional facts set forth in the Draft Complaint; (2) a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in the Draft Complaint, or that the facts as alleged in the Draft Complaint, other than jurisdictional facts, are true; (3) waivers and other provisions as required by the Commission's Rules; and (4) a proposed Decision and Order and Order to Maintain Assets.

The Commission considered the matter and 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. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order ("Order"):

1. Respondent ANI Pharmaceuticals, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 210 Main Street West, Baudette, Minnesota 56623.
2. Respondent Novitium Pharma LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 70 Lake Drive, East Windsor, New Jersey 08520.
3. Respondent Esjay LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 16732 Strasbourg Lane, Delray Beach, Florida 33446.
4. Prasco LLC is a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040.
5. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

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ORDER**I. Definitions**

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

- A. “ANI” means ANI Pharmaceuticals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by ANI Pharmaceuticals, Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Novitium” means Novitium Pharma LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Novitium Pharma LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Esjay” means Esjay LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, including Novitium Pharma LLC, partnerships, divisions, groups, and affiliates controlled by Esjay LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- D. “Commission” means the Federal Trade Commission.
- E. “Respondents” means ANI, Novitium, and Esjay.
- F. “Acquirer(s)” means:
 - 1. Prasco; or
 - 2. Any other Person that the Commission approves to acquire Divestiture Assets pursuant to this Order.
- G. “Acquisition” means the proposed acquisition described in agreement titled the *Agreement and Plan of Merger* by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties LLC, Chad Gassert, Muthusamy Shanmugam, Thorappadi Vijayaraj, and Shareholder Representative Services LLC, dated as of March 8, 2021.
- H. “Acquisition Date” means the date of the closing on the above-referenced *Agreement and Plan of Merger*.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s),

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license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes the FDA.

- J. “Biosimilar” means any biologic drug product that is highly similar to, and has no clinically meaningful difference from, an existing FDA-approved biologic drug product or that otherwise meets the FDA’s criteria for classification as a biosimilar.
- K. “Business Information” means all written information, wherever located or stored, relating to or used in a Divestiture Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the Divestiture Product Business. For clarity, Business Information includes any Respondent’s rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.
- L. “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.
- M. “Confidential Business Information” means all Business Information that is not in the public domain.
- N. “Customer” means any Person that is either a direct purchaser or who negotiates price on behalf of a direct purchaser (*e.g.*, group purchasing organization) of any Divestiture Product from a Respondent or the Acquirer.
- O. “Development” means all research related to a Product, and all studies of the safety or efficacy of a Product, including: discovery or identification of a new chemical entity, test method development; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; stability testing; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product in animals or humans 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, labeling, and sale of a Product(including any government price or reimbursement approvals). “Develop” means to engage in Development.
- P. “Dexamethasone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to ANDA No. 080399, and any

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supplements, amendments, or revisions to this ANDA, and any other Products that are or were in Development or Developed by ANI as of March 8, 2021 (the date the Respondents signed the *Agreement and Plan of Merger*) that are orally administered tablets and contain, as the active pharmaceutical ingredient, dexamethasone at a 0.75mg strength.

- Q. “Dexamethasone Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Dexamethasone Products, including all of the Divestiture Assets related to the Dexamethasone Products.
- R. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees shall not exceed then-current average hourly wage rate for such employee.
- S. “Divestiture Agreements” mean:
1. Asset Purchase Agreement by and between Prasco and ANI Pharmaceuticals, Inc. dated as of October 21, 2021; and all amendments, exhibits, attachments, agreements to the above-referenced agreement; and
 2. Any other agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer, or between Respondents for the benefit of the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.
- T. “Divestiture Assets” mean Respondents’ equitable and legal right, title, and interests in and to all tangible and intangible assets that are not Excluded Assets, wherever located, relating to a Divestiture Product Business, including the following:
1. All Product Approvals;
 2. All FDA Authorizations;
 3. All Product Development Reports;
 4. All Product Intellectual Property;
 5. At the option of the Acquirer, Product Manufacturing Equipment;
 6. All technological, scientific, chemical, biological, pharmacological, toxicological, regulatory materials and information, including studies of the safety, efficacy, stability, bioequivalency, bioavailability, and toxicology of a Product;

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7. All website(s), Domain Names, and social media sites related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;
 8. At the option of the Acquirer, Product Contracts;
 9. All Business Information;
 10. At the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the specified Divestiture Product in existence as of the Divestiture Date including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to that Divestiture Product; and
 11. At the option of the Acquirer, the right to fill any or all unfilled Customer purchase orders for the specified Divestiture Product as of the Divestiture Date.
- U. “Divestiture Date” means the date on which a Respondent (or a Divestiture Trustee) closes on a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey rights or assets related to a Divestiture Product to the Acquirer as required by Section II of this Order.
- V. “Divestiture Products” means the:
1. Dexamethasone Products; and
 2. Sulfamethoxazole/Trimethoprim Products.
- W. “Divestiture Product Business” means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale related to a Divestiture Product.
- X. “Divestiture Trustee” means any Person appointed by the Commission to serve as a divestiture trustee pursuant to the Orders.
- Y. “Domain Name” means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- Z. “Employee Information” means the following, for each Relevant Employee, as and to the extent permitted by law:

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1. With respect to each such employee, the following information:
 - a. Name, job title or position, date of hire, and effective service date;
 - b. Specific description of the employee's responsibilities;
 - c. Base salary or current wages;
 - d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 - e. Employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - f. All other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
 2. At the option of the Acquirer, copies of all employee benefit plans and summary.
- AA. "Erythromycin/Ethylsuccinate Products" mean the Products in Development or authorized for marketing or sale in the United States pursuant to ANDA No. 211991, and any supplements, amendments, or revisions to this ANDA, and any other Products in Development or Developed, marketed or sold by any Person other than a Respondent that are orally administered granules (for suspension) and contain, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate at the EQ 200mg, BASE 5ml strengths.
- BB. "Excluded Assets" mean:
1. Any real estate and the buildings and other permanent structures located on such real estate;
 2. Corporate names or corporate trade dress of a Respondent or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which a Respondent can be identified or defined;
 3. The portion of any Business Information that contains information about any of a Respondent's business other than a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;

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4. Any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however*, that Respondents shall provide copies of the document to the Acquirer and shall provide that Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes;
5. Any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets;
6. All accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date;
7. All cash, cash equivalents, credit cards and bank accounts of any Respondent; and
8. Any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.

CC. “FDA” means the United States Food and Drug Administration.

DD. “FDA Authorization(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 holder and the FDA related thereto. “FDA Authorization” 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 holder and the FDA related thereto. “FDA Authorization” also includes any Biologic License Application (“BLA”) filed or to be filed with the FDA pursuant to 21 C.F.R. 601.2, et seq., and Section 351 of the Public Health Service Act, and any NDA deemed to be a BLA by the FDA, and all supplements, amendments, revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondents and the FDA or other government regulatory authority relative thereto.

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- EE. “Licensed Intellectual Property” means; (a) all Product Manufacturing Technology that is used (but not exclusively, predominantly, or primarily used) in the manufacture of a Divestiture Product, and (b) copyrights used (but not exclusively, predominantly, or primarily used), to commercialize, distribute, market, advertise, or sell any Divestiture Product as of the applicable Divestiture Date.
- FF. “Manufacturing Designee” means any Person other than a Respondent that has been designated by the Acquirer to perform any part of the manufacturing process, including the finish or packaging of a Divestiture Product on behalf of that Acquirer.
- GG. “Monitor” means any Person appointed by the Commission to serve as a monitor pursuant to the Orders.
- HH. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code and package size code for a specific Product.
- II. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- JJ. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- KK. “Orders” means this Decision and Order and the Order to Maintain Assets.
- LL. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Divestiture Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- MM. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or government entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- NN. “Prasco” means Prasco, LLC, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Prasco, LLC, and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.

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- OO. “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, or that is the subject of an FDA Authorization.
- PP. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory 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, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.
- QQ. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:
1. Pursuant to which any third party, including a Customer, purchases, or has the option to purchase, a Product from a Respondent or negotiates the purchase price on behalf of another Customer;
 2. Pursuant to which a Respondent had, or has as of the Divestiture Date, the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), from any third party for use in connection with the manufacture of a Product;
 3. Relating to any study of the safety or efficacy of a Product;
 4. With universities or other research institutions for the use of a Product in scientific research;
 5. For the marketing of a Product or educational matters relating solely to the Products;
 6. Pursuant to which a third party manufactures or plans to manufacture a Product as a finished dosage form on behalf of a Respondent;
 7. Pursuant to which a third party provides or plans to provide any part of the manufacturing process, including, without limitation, the finish or packaging of a Product on behalf of a Respondent;
 8. Pursuant to which a third party licenses any Product Intellectual Property or Product Manufacturing Technology related to a Product to a Respondent;

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9. Pursuant to which a third party is licensed by a Respondent to use any of the Product Intellectual Property or Product Manufacturing Technology;
 10. Constituting confidentiality agreements involving a Product;
 11. Involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Product;
 12. Pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Product to a Respondent including, consultation arrangements; and
 13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.
- RR. “Product Development Reports” means information related to the Development of a Product, including:
1. Pharmacokinetic study reports;
 2. Bioavailability study reports;
 3. Bioequivalence study reports;
 4. All correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s);
 5. Annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;
 6. FDA approved labeling or other Agency-approved labeling;
 7. Currently used or planned product package inserts (including historical change of controls summaries);
 8. FDA approved patient circulars;
 9. Adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;
 10. Summaries of complaints from physicians or other health care providers;
 11. Summaries of complaints from ultimate users of the Product;
 12. Summaries of complaints from Customers;

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13. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;
 14. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;
 15. Reports from any Person (e.g., 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 or defects;
 16. Reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of any Product;
 17. Analytical methods development records;
 18. Manufacturing batch or lot records;
 19. Stability testing records;
 20. Change in control history; and
 21. Executed validation and qualification protocols and reports.
- SS. “Product Intellectual Property” means intellectual property of any kind (other than Licensed Intellectual Property), that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including Patents, patent applications, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.
- TT. “Product Manufacturing Equipment” means equipment that is being used, or has been used to manufacture the specified Divestiture Product.
- UU. “Product Manufacturing Technology” means all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including the following: all product specifications, processes, analytical methods, product designs, plans, 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 conformance of any Product Approvals, conformance with any

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Agency requirements, and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.

VV. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States as of the Divestiture Date that are owned or controlled by a Respondent, 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 dollars and units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

WW. “Product Releasee(s)” means any of the following Persons:

1. The Acquirer;
2. Any Person controlled by or under common control with that Acquirer;
3. Any Manufacturing Designee(s); and
4. Any licensees, sublicensees, manufacturers, suppliers, marketers, distributors, and Customers of that Acquirer, or of such Acquirer-affiliated entities, in each such case, as related to each Divestiture Product acquired by that Acquirer.

XX. “Relevant Employees” includes:

1. Manufacturing Employees means all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition Date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: (a) Developing and validating the commercial manufacturing process, (b) formulating the manufacturing process performance qualification protocol, (c) controlling the manufacturing process to assure performance Product quality, (d) assuring that during routine manufacturing the process remains in a state of control, (e) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (f) managing the operation of the

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manufacturing process, or (g) managing the transfer of the Product Manufacturing Technology to a different facility; and

2. Marketing Employees means all management-level employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: sales management, brand management, sales training, market research, or marketing and contracting with any of the following: drug wholesalers or distributors, group purchasing organizations, pharmacy benefit organizations, managed care organizations, or hospitals, *excluding* administrative assistants.
- YY. “Retained Product(s)” means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.
- ZZ. “Sulfamethoxazole/Trimethoprim Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorizations: ANDA No. 077612, and any supplements, amendments, or revisions to this ANDAs.
- AAA. “Sulfamethoxazole/Trimethoprim Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Sulfamethoxazole/Trimethoprim Products, including all of the Divestiture Assets related to the Sulfamethoxazole/Trimethoprim.
- BBB. “Supply Cost” means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation in cases in which those costs are incurred by a Respondent.
- CCC. “Technology Transfer Standards” mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered 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, as related to the specified Divestiture Product(s), *inter alia*:
1. Designating employees or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology who will be responsible for communicating directly with the receiving Person, and a Monitor, for the purpose of effecting such delivery;

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2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Product that are acceptable to the receiving Person;
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 to the receiving Person;
4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the receiving Person to visit the Respondent's facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of the Respondent involved in that process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and methods to ensure batch or lot consistency); and
5. Providing, in a timely manner, assistance and advice to enable the receiving Person to:
 - a. Manufacture the Product in the quality and quantities achieved by a Respondent prior to the Acquisition Date;
 - b. Obtain any Product Approvals necessary for the receiving Person to manufacture the Product for the Acquirer in a manner that allows that Acquirer to distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and
 - c. Receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

DDD. "Therapeutic Equivalent" means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA's criteria for such classification.

EEE. "United States" means the United States of America, and its territories, districts, commonwealths, and possessions.

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II. Divestitures**IT IS FURTHER ORDERED** that:

- A. No later than 10 days after the Acquisition Date, Respondents shall, absolutely and in good faith, divest the Dexamethasone Divestiture Assets and the Sulfamethoxazole/Trimethoprim Divestiture Assets and grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to use the related Licensed Intellectual Property in the related Divestiture Product Business to Prasco.

Provided, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and a Monitor, the Acquirer needs one or more Excluded Assets to operate any of the Divestiture Product Businesses in a manner that achieves the purposes of this Order, Respondents shall divest or license (as applicable) absolutely and in good faith, the needed Excluded Assets to that Acquirer.

- B. If Respondents have divested any of the Divestiture Assets or granted or assigned rights to the Divestiture Products to Prasco prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:

1. The named Acquirer is not an acceptable purchaser of any of the Divestiture Assets or rights related to the Divestiture Products, then Respondents shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the respective Divestiture Assets or grant or assign the rights related to the Divestiture Products, as applicable, within 180 days after the Order Date, absolutely and in good faith, at no minimum price, to a different Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission; or
2. The manner in which the divestiture was accomplished is not acceptable, then Respondents shall make such modifications to the manner of divestiture of the Divestiture Assets or the grant or assignment of rights to the Divestiture Products, as applicable, to the Acquirer named in this Order (including, entering into additional agreements or arrangements) as the Commission determines are necessary to satisfy the requirements of this Order.

- C. Prior to the Divestiture Date, Respondents shall provide the Acquirer with the opportunity to review Product Contracts related to each of the Divestiture Products so that the Acquirer can determine whether to assume each Product Contract;

Provided, however, that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or

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otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

- D. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.
- E. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the 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 a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product. Such agreements include agreements that might limit the ability of a third party to disclose Confidential Business Information related to such Product Manufacturing Technology to the Acquirer. No later than 10 days after the Divestiture Date, Respondents shall grant a release to each third party that is subject to any such agreement that allows the third party to provide the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture Product to the Acquirer. Within 5 days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer;

Provided, however, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant third parties.
- F. Respondents shall transfer the Product Manufacturing Technology related to the Divestiture Products to the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondents shall bear all costs related to these transfers.
- G. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- H. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
 - 1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency

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- determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (a) a detailed description of the known deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (b) the corrective actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (c) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;
2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;
 3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
 4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
 5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
 6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.
- I. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.
 - J. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) 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 for the Divestiture Products

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acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.

- K. For any patent infringement suit that is filed or to be filed within the United States that is (x) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (y) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:
1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
 2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
 3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

III. Divestiture Agreements

IT IS FURTHER ORDERED that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Divestiture Agreements shall constitute a violation of this Order;
- Provided, however,* that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.
- B. Respondents shall include in the Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.
- C. Respondents shall not modify or amend any of the terms of any Divestiture 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).

IV. Transition Services and Manufacturing by Respondents**IT IS FURTHER ORDERED** that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from the Acquirer, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Divestiture Products and any of the active pharmaceutical ingredients used in the Divestiture Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." The requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.
- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications and, with the consent of the Acquirer, shall amend any agreement between the Respondents and the Acquirer that is related to the quality controls of a Divestiture Product to address any necessary changes to the agreement in order to comply with relevant Agency regulations or recommendations.
- D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

Provided, however, that the Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the Respondents' responsibilities to supply the Supplied Products in the manner required by this Order;

Provided further, however, that this obligation shall not require the Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondents to the Acquirer in a Divestiture Agreement.

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- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (1) 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, and (2) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.
- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.
- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied Products due to (x) a breach by the Acquirer of a Divestiture Agreement, or (y) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

Provided, however, that this Paragraph IV.J shall not prohibit a Respondent from seeking compensatory damages from the Acquirer for that Acquirer's breach of its payment obligations to the Respondent under the agreement.
- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (x) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (y) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied

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Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.

- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.
- N. For any Supplied Product that is made in a facility owned by Respondents, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by the Acquirer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Divestiture Product, at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

V. Asset Maintenance

IT IS FURTHER ORDERED that, until the Respondents have physically transferred the Dexamethasone Divestiture Assets and the Sulfamethoxazole/Trimethoprim Divestiture Assets to the Acquirer pursuant to Section II of this Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

- A. Take all actions necessary to maintain the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses, to minimize the risk of loss of competitive potential of such Divestiture Product Businesses, to operate such Divestiture Product Businesses in a manner consistent with applicable laws and regulations, and to prevent the destruction, removal, wasting, or deterioration of any of the Divestiture Assets, except for ordinary wear and tear.

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- B. Not sell, transfer, encumber, or otherwise impair such Divestiture Assets, or terminate any of the operations of such Divestiture Product Businesses, other than in the ordinary course of business consistent with past practice or as prescribed in the Orders.
- C. Make all payments required to be paid under any contract or lease when due, and pay all liabilities and satisfy all obligations associated with such Divestiture Product Businesses.
- D. Provide such Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls, to perform routine or necessary maintenance, to repair or replace facilities and equipment, and to carry on, at least at their scheduled pace, all capital projects, business plans, promotional plans, capital expenditure plans, research and development plans, and commercial activities for such Divestiture Product Businesses.
- E. Use best efforts to preserve the existing relationships and goodwill with suppliers, customers, employees, vendors, distributors, landlords, licensors, licensees, government entities, brokers, contractors, and others having business relations with such Divestiture Product Businesses.
- F. Maintain the working conditions, staffing levels, and a work force of equivalent size, training, and expertise associated with such Divestiture Product Businesses, including by:
 - 1. Filling vacancies that occur in the regular and ordinary course of business consistent with past practice; and
 - 2. Not transferring any employees from such Divestiture Product Businesses to another of Respondents' businesses.
- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.

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- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

Provided, however, Respondents may take actions that the Acquirer has requested or agreed to in writing and that has been approved in advance by a Monitor (in consultation with Commission staff), in all cases to facilitate that Acquirer's acquisition of the Divestiture Assets and rights in the Divestiture Products and consistent with the purposes of the Orders.

VI. Employees**IT IS FURTHER ORDERED** that:

- A. Until 2 years after the Divestiture Date, Respondents shall cooperate with and assist the Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.
- B. Respondents shall:
1. No later than 10 days after a request from the Acquirer, provide to that Acquirer a list of all Relevant Employees and provide Employee Information for each Relevant Employee;
 2. No later than 10 days after a request from the Acquirer, provide that Acquirer or its Manufacturing Designee an opportunity to meet individually and outside the presence or hearing of any employee or agent of Respondents with any of the Relevant Employees, and to make offers of employment to any of the Relevant Employees;
 3. Remove any impediments within the control of Respondents that may deter Relevant Employees from accepting employment with the Acquirer or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondents that may affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee, and shall not make any counteroffer to a Relevant Employee who receives an offer of employment from that Acquirer or its Manufacturing Designee;

Provided, however, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and
 4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that

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Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.

- C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.
- D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.
- E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (1) were involved with any of the Divestiture Products, or (2) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Section VI of this Order shall apply to such employees as of that notification date.
- F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate the employee's employment with the Acquirer or its Manufacturing Designee;

Provided, however, Respondents may:

- 1. Hire an employee whose employment has been terminated by the Acquirer;
- 2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and
- 3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of Section VI.

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VII. Business Information**IT IS FURTHER ORDERED** that:

- A. Respondents shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer pursuant to the following:
1. Respondents shall deliver the Business Information to that Acquirer, at Respondents' expense, in good faith, in a timely manner (*i.e.* as soon as practicable, avoiding any delays in transmission), and in a manner that ensures the completeness and accuracy of all information and ensures its usefulness;
 2. Pending complete delivery of all Confidential Business Information, Respondents shall provide that Acquirer with access to all Business Information and to employees who possess or are able to locate this information for the purposes of identifying the Business Information that contains Confidential Business Information and facilitating the delivery in a manner consistent with the Orders;
 3. Not use, directly or indirectly, any such Confidential Business Information other than as necessary to comply with the following:
 - a. The requirements of the Orders;
 - b. Respondents' obligations to that Acquirer under the terms of the related Divestiture Agreements; or
 - c. Applicable law;
 4. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person *except* (a) that Acquirer, (b) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent providing transition services, manufacturing Divestiture Products, or who are engaged in the transfer and delivery of the Product Manufacturing Technology), (c) the Commission, or (d) a Monitor, and *except* to the extent necessary to comply with applicable law;
 5. Not provide, disclose, or otherwise make available, directly or indirectly, any Confidential Business Information to the employees associated with the business that is being retained, owned, or controlled by a Respondent, other than those employees specifically authorized as described above;

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6. Institute procedures and requirements to ensure that those employees of a Respondent that are authorized by that Acquirer to have access to such Confidential Business information:
 - a. Do not provide, disclose, or otherwise make available, directly or indirectly, any such Confidential Business Information in contravention of the Orders; and
 - b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
 7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
 - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
 - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
 - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.
- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as 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 such Confidential Business Information as strictly confidential, including the nondisclosure of that

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information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).

- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (1) may be in possession of such Confidential Business Information or (2) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondents shall provide that Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:
1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, 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
 2. 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 an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

Provided, however, that a Respondent may disclose such information as necessary for the purposes set forth in this Paragraph VII.D pursuant to an appropriate confidentiality order, agreement, or arrangement;

Provided further, however, that pursuant to this Paragraph VII.D, a Respondent needing such access to original documents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain

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a protective order to protect the confidentiality of such information during any adjudication.

VIII. Monitor**IT IS FURTHER ORDERED** that:

- A. The Commission appoints Denise Smart of Smart Consulting Group, LLC as Monitor to observe and report on Respondents' compliance with the terms of the Orders.
- B. The Respondents and the Monitor may enter into an agreement relating to the Monitor's services. Any such agreement shall:
 - 1. Be subject to the approval of the Commission;
 - 2. Not limit, and the signatories shall not construe it to limit, the terms of this Section VIII or Section VII of the Order to Maintain Assets ("Monitor Sections") and to the extent any provision in the agreement varies from or conflicts with any provision in the Monitor Sections, Respondents and the Monitor shall comply with the Monitor Sections; and
 - 3. Include a provision stating that the agreement does not limit, and the signatories shall not construe it to limit, the terms of the Orders in this matter, and to the extent any provision in the agreement varies from or conflicts with any provision in the Orders, Respondents and the Monitor shall comply with the Orders.
- C. The Monitor shall:
 - 1. Have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
 - 2. Act in consultation with the Commission or its staff;
 - 3. Serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
 - 4. Shall serve without bond or other security;
 - 5. At the Monitor's option, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
 - 6. Enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that

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each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into a non-disclosure or other confidentiality agreement with the Commission;

7. Notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict;
8. Report in writing to the Commission concerning Respondents' compliance with the Orders 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission; and
9. Unless the Commission or its staff determine otherwise, the Monitor shall serve until Commission staff determines that Respondents obligations to provide manufacturing and supply of Divestiture Products pursuant to this Order have expired or been terminated and files a final report.

D. Respondents shall:

1. Cooperate with and assist the Monitor in performing the Monitor's duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
2. Not interfere with the ability of the Monitor to perform the Monitor's duties pursuant to the Orders;
3. Pay the Monitor's fees and expenses as set forth in an agreement approved by the Commission, or if such agreement has not been approved, pay the Monitor's customary fees, as well as expenses the Monitor incurs performing the Monitor's duties under the Orders, including expenses of any consultants, accountants, attorneys, and other representatives and assistants that are reasonably necessary to assist the Monitor in carrying out the Monitor's duties and responsibilities;
4. Not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders; and

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5. Indemnify and hold the Monitor harmless against any loss, claim, damage, liability, and expense (including attorneys' fees and out of pocket costs) that arises out of, or is connected with, a claim concerning the performance of the Monitor's duties under the Orders, unless the loss, claim, damage, liability, or expense results from gross negligence or willful misconduct by the Monitor.
- E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement provided that such agreement does not restrict the Monitor's ability to access personnel, information, and facilities or provide information to the Commission, or otherwise observe and report on the Respondents' compliance with the Orders.
 - F. Respondents shall not require nor compel the Monitor to disclose to Respondents the substance of communications with the Commission, including the Monitor's written reports submitted to the Commission, or any other Person with whom the Monitor communicates in the performance of their duties.
 - G. If the Monitor resigns or the Commission determines that the Monitor has ceased to act, has failed to act diligently, or is otherwise unable to continue serving as a Monitor due to the existence of a conflict or other reasons, the Commission may appoint a substitute Monitor. The substitute Monitor shall be afforded all rights, powers, and authorities and shall be subject to all obligations of the Monitor Sections of the Orders. The Commission shall select the substitute Monitor, subject to the consent of the Respondents. Respondents:
 1. Shall not unreasonably withhold consent to the appointment of the selected substitute Monitor;
 2. Shall be deemed to have consented to the selection of the proposed substitute Monitor if, within 10 days of notice by staff of the Commission of the identity of the proposed substitute Monitor, Respondents have not opposed in writing, including the reasons for opposing, the selection of the proposed substitute Monitor; and
 3. May enter into an agreement with the substitute Monitor relating to the substitute Monitor's services that either (a) contains substantially the same terms as the Commission-approved agreement referenced in Paragraph B of the Monitor Sections; or (b) receives Commission approval.
 - H. The Commission may on its own initiative or at the request of a Monitor issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

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IX. Divestiture Trustee**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products 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 Section IX 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 a Respondent to comply with the Orders.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to Section IX, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.

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2. The Divestiture Trustee shall have one 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- year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) 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 2 times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestitures. Any delays in divestiture caused by a Respondent shall extend the time for divestiture under Section IX in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to the Acquirer that receives the prior approval of the Commission 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 Respondents from among those approved by the Commission;

Provided further, however, that Respondents shall select such Person within 5 days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are

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necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct 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.
8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every 30 days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement;

Provided, however, that such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. 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 Section IX.
- G. 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

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additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

X. Prior Approval

IT IS FURTHER ORDERED that each Respondent shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Dexamethasone Products, the Sulfamethoxazole/Trimethoprim Products, and the Erythromycin/Ethylsuccinate Products, or the Therapeutic Equivalent or Biosimilar of any of these Products without the prior approval of the Commission.

XI. Prior Approval for Acquirer

IT IS FURTHER ORDERED that:

- A. For a period of 3 years after the Divestiture Date, Prasco or any other Acquirer shall not sell or license, through subsidiaries or otherwise, without the prior approval of the Commission, any of the FDA Authorizations that were divested pursuant to Section II, to any Person; and
- B. For a period of 7 years after the term of Paragraph XI.A ends, Prasco or any other Acquirer shall not sell or license, through subsidiaries or otherwise, without the prior approval of the Commission, any FDA Authorizations that were divested pursuant to Section II, to any Person who owns, directly or indirectly, an FDA Authorization, or is seeking approval from the FDA for an FDA Authorization, to manufacture and sell a Therapeutic Equivalent of a Divestiture Product.

Provided, however, Prasco is not required to obtain prior approval of the Commission under this Section XI for a change of control, merger, reorganization, or sale of all or substantially all of its business, or for a non-exclusive license to a contract manufacturer for the purpose of manufacturing a Divestiture Product.

XII. Compliance Reports

IT IS FURTHER ORDERED that:

- A. Respondents shall:
 - 1. Notify Commission staff via email at bccompliance@ftc.gov of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and
 - 2. Submit the complete copies of each of the Divestiture Agreements to the Commission at ElectronicFilings@ftc.gov and bccompliance@ftc.gov no later than 30 days after the Divestiture Date.

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- B. Respondents shall file verified written reports (“Compliance Reports”) in accordance with the following:
1. Respondents shall submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (a) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (b) the transfer and delivery of all of the Product Manufacturing Technology related to the Divestiture Products to the Acquirer or the Acquirer’s Manufacturing Designee, (c) the transfer and delivery of all Business Information to the Acquirer, and (d) the Acquirer or the Acquirer’s Manufacturing Designee is FDA approved to manufacture each of the Divestiture Products at a facility that is not owned or controlled by Respondents; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 4 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;
 2. Each Respondent’s Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:
 - a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Divestiture Products to that Acquirer;
 - b. A detailed description of the transfer of the Product Manufacturing Technology related to the Acquirer or the Acquirer’s Manufacturing Designee and progress toward the manufacturing of these products at a facility that is not owned or controlled by Respondents; and
 - c. A detailed description of the timing for the completion of such obligations.
 3. Each annual Compliance Report shall include the previous year’s market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the

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extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;

4. For a period of 5 years after filing a Compliance Report, each Respondent shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent's obligations under the Orders and provide copies of these documents to Commission staff upon request.
- C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or another officer or employee specifically authorized to perform this function. Respondent shall file its compliance reports with the Secretary of the Commission at ElectronicFilings@ftc.gov and the Compliance Division at bccompliance@ftc.gov, as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a). In addition, Respondent shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

XIII. Change in Respondents

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least 30 days prior to:

- A. The dissolution of: ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC;
- B. Any proposed acquisition, merger, or consolidation of ANI Pharmaceuticals, Inc., Novitium Pharma LLC, and Esjay LLC; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XIV. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with the Orders, subject to any legally recognized privilege, upon written request, and upon 5 days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during business office hours of that 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

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or under the control of that Respondent related to compliance with the Orders, 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 that Respondent; and

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

XV. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy in a timely and sufficient manner the lessening of competition as alleged in the Commission's Complaint by:

- A. Ensuring that the Acquirer can continue to use the Divestiture Assets and rights in the Divestiture Products granted or assigned pursuant to this Order for the purposes of each of the respective Divestiture Product Businesses within the United States; and
- B. Creating a viable and effective competitor in the respective Divestiture Product Businesses within the United States.

XVI. Term

IT IS FURTHER ORDERED that this Order shall terminate 10 years from the date it is issued.

By the Commission.

NONPUBLIC APPENDIX I**AGREEMENTS RELATED TO THE DIVESTITURES**

[Redacted from the Public Record but Incorporated by Reference]

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NONPUBLIC APPENDIX II

MONITOR COMPENSATION

[Redacted from the Public Record but Incorporated by Reference]

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PUBLIC APPENDIX

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MONITOR AGREEMENT

This Monitor Agreement (Monitor Agreement) entered into as of this 6th day of October, 2021 by and among Denise Smart of SMART CONSULTING GROUP, LLC, 420 W. Miner St., West Chester, PA 19382 (Monitor) and ANI PHARMACEUTICALS, INC., 210 Main Street West Baudette, MN 56623 (Respondent) provides as follows:

WHEREAS, the United States Federal Trade Commission (the Commission) has or shortly will approve a Decision and Order and Order to Maintain Assets (Orders) with Respondent which, among other things, requires Respondent to license or transfer certain defined assets and maintain those assets pending such license or transfer, and provided for the appointment of a Monitor to ensure that Respondent complies with its obligations under the Orders;

WHEREAS, the Commission may appoint Denise Smart as such Monitor (the Monitor) pursuant to the Orders to monitor Respondent's compliance with the terms of the Consent Agreement and Orders and with the Divestiture Agreements referenced in the Orders, and to monitor the efforts of the Acquirer (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and the Monitor has consented to such appointment;

WHEREAS, the Orders further provides or will provide that Respondent shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement conforms with the requirements of the Orders and does not contradict the Orders;

WHEREAS, this Monitor Agreement, although subject to Commission approval, is effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents or the Monitor under the Orders, upon execution by the parties; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound; NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders.
2. The Monitor shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders including all of the powers, responsibilities and protections conferred upon the Monitor by the Orders. This authority shall include, but is not limited to:
 - a. supervising the divestiture of the Assets; and
 - b. supervising the performance of any transition services required by the Orders
 - c. acting in consultation with the Commission or its staff

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The Orders are hereby attached as Exhibit A to this Monitor Agreement, the terms of which are incorporated herein by reference.

3. Respondent hereby agrees that, upon execution by both parties of the Monitor Agreement, Respondent will fully comply with all terms of the Orders requiring them to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon themselves any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.
4. Respondent further agrees that:
 - a. it will cooperate with and assist the Monitor in performing the Monitor's duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
 - b. it will not interfere with the ability of the Monitor to perform the Monitor's duties pursuant to the Orders;
 - c. it shall not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders;
 - d. it will use their best efforts to ensure that the Acquirer which is acquiring or licensing assets pursuant to the Orders (or as otherwise specified by the Commission) enters into an appropriate agreement with the Monitor as soon as practicable after the execution of this Monitor Agreement;
 - e. no later than **ten (10) Business Days** after the Commission approves this Monitor Agreement, it will provide the Monitor with:
 - (1) a copy of the Divestiture Agreements (or drafts thereof) relating to the Assets, including any exhibits, schedules and appendices;
 - (2) offering or information memoranda, or similar documents and information, provided to the Acquirer(s) relating to the sale of the Assets;
 - (3) copies of correspondence with, and written reports or minutes of meetings of all substantive contacts and discussions with, any Acquirer(s) relating to the Assets or Divestiture Agreements; and
 - (4) a complete description of the Assets being divested, identifying, in particular, those Assets which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;

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- (5) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Assets identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
 - (6) a complete inventory of all activities or operations that relate to the manufacture of the Products relating to the Assets, and which relate to Respondent's compliance with the Orders, including, to the extent applicable, processes and process validations which are under development, key equipment, test methods, special facilities, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture; and
 - (7) a complete inventory of all Patents included in the Assets, if any, related to the manufacture or sale of the Assets in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions;
- f. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals involved in the licensing of the Divestiture Assets to the Acquirer, together with their location, telephone numbers, electronic mail address (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
- g. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Assets, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
- h. it will provide the Monitor the minutes of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- i. it will provide the Monitor with all correspondence, meeting minutes, reports, sent to or received from the FDA relating to the Divestiture Assets; and will provide prompt notice of any and all meetings or communications with the FDA relating to or affecting the Divestiture Assets;
- j. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- k. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as requested by the Monitor, full and detailed

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electronic or hard copy reports to the Monitor as to all of Respondent's activities and obligations under the Orders concerning the Divestiture Assets including, without limitation to the extent applicable:

- (1) all activities involving the research and development, preclinical and clinical studies where appropriate and pursuit and maintenance of FDA clearance or approvals relating to the Divestiture Assets;
- (2) all activities concerned with the licensing, manufacture, supply and technology transfer of the Product that is identified in the Divestiture Assets, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
- (3) all minutes and records of meetings, action plans, and follow-ups to actions plans and meetings, with the Acquirers related to the licensing, manufacture, supply, and technology transfer of the Products identified in the Divestiture Assets;
- (4) all activities concerning the assistance, advice and consultation provided to any Acquirer generally as provided in the Decision and Orders; and
- (5) on request, Respondent will provide the Monitor with any and all records that relate to the licensing and manufacture of the Products identified in the Divestiture Assets with the right to use them to achieve the purpose of the Orders;

provided, however, that at the time the Orders become final, the reports described in this paragraph together with all other information and documents referred to herein shall be due to the Monitor either as requested by the Monitor or within five (5) Business Days of the date that Respondent files the Respondent's reports with the Commission as required pursuant to the relevant provisions of the Orders;

- l. it will comply with the Monitor's requests for on-site visits and audits of Respondent's facility used to manufacture the Products identified in the Divestiture Assets;
- m. it will comply with the Monitor's requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Agreement or in connection with any matters the Monitor deems reasonably necessary to perform its responsibilities under the Orders, including, without limitation, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale, licensing, and/or divestiture of the Divestiture Assets or any Product comprised therein and, further including, actions necessary to maintain all necessary FDA or other foreign regulatory agency equivalent approvals to manufacture and sell any of the Divestiture Assets, to maintain the viability and marketability of the Divestiture Assets, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Assets, and to prevent the destruction,

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- removal, wasting, deterioration or impairment of the Divestiture Assets, and will provide the Monitor with access to and hard and electronic copies of all other data, records or other information that the Monitor believes are necessary to the proper discharge of its responsibilities under the Orders;
- n. it will provide prompt notice of any meetings, activities or events affecting or likely to affect the maintenance of the Divestiture Assets including, but not limited to, any and all meetings or communications with the FDA; and
 - o. it will provide the Monitor with such other information, documents and the like requested by the Monitor in order to carry out its responsibilities under this Monitoring Agreement.
5. Respondent shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondent related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.
6. Respondent agrees that, to the extent authorized by the Orders, the Monitor shall have the option and authority to employ, at the expense of the Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information, and Intellectual Property, as defined in the Orders, related to the Divestiture Assets.
7. Respondent and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Respondent's compliance with the Respondent's obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Respondent's compliance with the Respondent's obligations to maintain or divest assets pursuant to the Orders.
- Specifically, but not to limit the foregoing, the Monitor shall issue a written report to the Commission concerning Respondents' compliance with the Orders 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission.
8. The Monitor shall maintain the confidentiality of all non-public information provided to the Monitor by Respondent. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitor to any third party other than:
- a. persons engaged or employed by, or working with, the Monitor under this Monitor Agreement who agree to be bound by the confidentiality stipulations contained herein;

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- b. the Acquirer to the extent that the information is of a non-privileged nature and relates to the Divestiture Assets; or
- c. persons employed at or by the Commission and working on this matter.
- d. A recipient who can demonstrate that such information was already known to the recipient at the time of receipt from a source other than the Monitor, Respondent, or any director, officer, employee, agent, consultant or affiliate of the Monitor or Respondent, when such source is entitled to make such disclosure to such recipient.

Notwithstanding anything herein to the contrary, Respondent shall use its best efforts to identify and/or label such information in writing they desire to treat as confidential and not to be disclosed to the Acquirer.

However, it is understood that to the extent that Respondent fails to so identify such confidential to the Monitor (a "Failure to Identify"), the Monitor shall not have liability for disclosure of same to the Acquirer, unless, notwithstanding a Failure to Identify by Respondent, the Monitor knew or should have known that information was privileged or not to be disclosed, and nonetheless discloses such information to the Acquirer.

- 9. The Monitor shall maintain a record and inform the Commission of all persons (other than representatives of the Commission) to whom confidential information related to this Agreement has been disclosed.
- 10. The Monitor shall enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into a non-disclosure or other confidentiality agreement with the Commission;
- 11. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor shall, at the Respondent's request and expense, promptly return to Respondent all material provided to the Monitor by Respondent that is confidential to Respondent and shall destroy any material prepared by the Monitor that contains or reflects any confidential information of Respondents provided that the Monitor provides notice to the Commission staff and the Commission staff does not require the Monitor to maintain the materials; provided, however, notwithstanding the foregoing, the Monitor shall be entitled to retain for its records, on a confidential basis, any materials or documents developed by it in furtherance of its responsibilities and obligations under this Monitor Agreement, regardless of whether such materials contain confidential information. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of five (5) years after the termination of this Monitor Agreement. The Monitor shall provide Respondent with a copy of the list of parties to whom the Monitor has divulged Respondent's confidential and privileged information.
- 12. In addition and except as otherwise permitted in Section 10 above, the Monitor shall keep confidential for a period of five (5) years all other aspects of the performance of its duties under this Monitor Agreement and shall not disclose any confidential or proprietary

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information relating thereto. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that such persons execute an appropriate confidentiality agreement.

For the purpose of this Section, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known or became known to the recipient at the time of receipt from a source other than the Monitor, the Respondent or any director, officer, employee, agent, consultant or affiliate of Respondent when such source is entitled to make such disclosure to such recipient.

13. Nothing in this Monitor Agreement shall require Respondent to disclose any materials or information that is subject to a legally recognized privilege or that Respondent is prohibited from disclosing by reason of law or an agreement with a third party.
14. The Monitor shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission.
15. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to Respondent.
16. Respondent will pay the Monitor in accordance with the fee schedule attached hereto as Confidential Appendix A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of the Acquirer of the Divestiture Assets (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with Respondent.
 - a. In addition, Respondent will pay (i) all reasonable out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, which conform to the Respondent's expense policies in effect from time to time including any auto, train or air travel in the performance of the Monitor's duties, international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
 - b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

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- c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
17. Respondent hereby confirms its obligation and agrees to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Assets).
- Without in any way limiting the generality of the foregoing, Respondent shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principles, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities, expenses (including attorneys' fees and out of pocket costs) incurred in connection with the preparations for, or defense of any claim, whether or not resulting in any liability, that may arise out of or is connected with, a claim concerning the performance of the Monitor's duties and obligations under the Orders, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the gross negligence or willful misconduct of the Monitor. This section shall survive the termination or expiration of this Agreement.
18. The Monitor's maximum liability to the Respondent relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort or otherwise) shall be limited to the total sum of the fees paid to the Monitor by Respondent, not to exceed one hundred fifty thousand dollars (\$150,000). IN NO CIRCUMSTANCES WHATSOEVER SHALL MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES. The Monitor is not responsible for evaluating the legal or technical sufficiency of any documents, materials or actions of Respondent or the Acquirer under the Orders. The Monitor shall not incur any liability of any nature for the failure of Respondents, any Acquirer, or the Commission to perform any acts, or not perform any acts. This section shall survive the termination or expiration of this Agreement.
19. Respondent agrees that the Monitor and any subcontractor, consultants, agents, partners, principles, directors, officers, members, managers and employees will serve without bond or other security.
20. Respondent agrees that the Respondents' obligations to indemnify the Monitor and the Indemnified Parties extend to any agreement that is entered between the Monitor and any Acquirer and that relates to the Monitor's responsibilities under the Monitor Agreement or the Orders. This section shall survive the termination or expiration of this Agreement.
21. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondent shall be required, to notify the Acquirer with respect to this appointment as Monitor.

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22. In the event that a disagreement or dispute between Respondent and the Monitor cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules, but only if the individual in charge of the Commission's Compliance division determines within the Commission's reasonable discretion that such a matter is appropriate for submission to the American Arbitration Association. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Orders.
23. This agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdictions choice of law principles).
24. This Monitor Agreement shall terminate when the Monitor and Respondent have been notified by the Commission in writing that the Commission staff has determined that Respondents obligations to provide manufacturing and supply of Divestiture Products pursuant to this Order have expired or been terminated and files a final report or (2) at any other such time as determined by the Commission or its staff.. or (2) In all cases, the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality and indemnity obligations of this Monitor Agreement shall survive its termination.
25. The Monitor shall notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict; The Monitor represents that it is aware of no such conflicts as of the Effective Date of this Agreement.
26. This Agreement is for the sole benefit of the Parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
27. This Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings.
28. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by certified mail or electronic mail (with acknowledgement of receipt by the recipient of such electronic mail having been received), to the applicable party at its address below (orto such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Address: Denise Smart, Esq.
President
Smart Consulting Group, LLC

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P.O. Box 884
West Chester, PA 19382

Telephone: 610-344-9218
Mobile Phone: 484-467-0707
Email: dsmart@smartconsultinggroup.com

If to Respondents, to:

Address: Nikhil Lalwani
Chief Executive Officer and President
ANI Pharmaceuticals, Inc.
210 Main Street
West Baudette, MN 56623

Telephone: 218-634-3500
Email: nikhil.lalwani@anipharmaceuticals.com

If to the Commission, to:

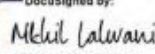
Address: Danielle Sims, Esq.
Compliance Division
Federal Trade Commission
601 New Jersey Avenue, N.W.
Washington, DC 20580

Telephone: 202-326-3241
Email: dsims1@ftc.gov

This Monitor Agreement shall become binding upon execution, although it will be subject to approval by the Commission.

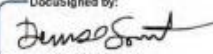
IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

ANI PHARMACEUTICALS, INC.

DocuSigned by:

E0357CB4804D41D...

Nikhil Lalwani
Chief Executive Officer and President

SMART CONSULTING GROUP
MONITOR

DocuSigned by:

EFE07271C9FA43B...

Denise Smart
President

ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from ANI Pharmaceuticals, Inc. (“ANI”) and Novitium Pharma LLC and Esjay LLC (collectively, “Novitium”) that is designed to remedy the anticompetitive effects resulting from ANI’s acquisition of the non-corporate interests of Novitium. Pursuant to an agreement dated March 8, 2021, ANI proposes to acquire Novitium in a transaction valued at approximately \$210 million. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate 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, by lessening future competition in the following two U.S. markets: (1) generic SMX-TMP oral suspension; and (2) generic dexamethasone tablets. The Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

Under the terms of the proposed Decision and Order (“Order”), Respondents are required to divest all of ANI’s rights and assets related to the following two products to Prasco LLC (“Prasco”): (1) generic sulfamethoxazole-trimethoprim (“SMX-TMP”) oral suspension; and (2) generic dexamethasone tablets. The Commission and Respondents have agreed to an Order to Maintain Assets that requires Respondents to operate and maintain each divestiture product in the normal course of business until the products are ultimately divested to Prasco. The Commission also issued the Order to Maintain Assets.

The Consent Agreement has been placed on the public record for thirty days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the Consent Agreement, modify it, or make final the proposed Order.

I. The Respondents

Respondent ANI is a public specialty pharmaceutical company headquartered in Baudette, Minnesota selling both branded and generic pharmaceutical products.

Respondent Novitium is a privately-held company based in East Windsor, New Jersey. The company develops, manufactures, and commercializes generic pharmaceutical products.

II. The Products and Structure of the Markets

In human pharmaceutical markets, price(s) generally decreases as the number of generic competitors increase. Prices continue to decrease incrementally with the entry of the second, third, fourth, and further pharmaceutical competitors. Accordingly, a reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

The Proposed Acquisition would reduce future competition in the SMX-TMP oral suspension market, where ANI is a current competitor and Novitium is likely to enter the market.

Analysis to Aid Public Comment

Generic SMX-TMP oral suspension is an antibiotic product used to treat a variety of infections. Five companies, including ANI, currently market the product in the United States, but at least one has had difficulty manufacturing the product. Novitium is one of a limited number of suppliers capable of entering the market for SMX-TMP oral suspension in the near future.

Similarly, the Proposed Acquisition would reduce future competition in the 4 mg strength of generic dexamethasone tablets market, where both ANI and Novitium are likely to enter the market in the near future. Generic dexamethasone tablets are an oral steroid product used to treat inflammation associated with a variety of conditions. Dexamethasone tablets are available in a variety of strengths, although the most widely-used strength is the 4 mg strength. Only two companies sell the 4 mg strength of dexamethasone tablets in the United States today, and ANI and Novitium are two of a limited number of companies likely to enter the market in the near future.

III. Entry

Entry into the two markets at issue would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including approval by the FDA, is costly and lengthy.

IV. Competitive Effects

The Proposed Acquisition likely would delay or reduce the introduction of beneficial competition, and subsequent price decreases, by eliminating future competition in the two markets at issue. While five companies, including ANI, currently market the generic SMX-TMP product in the United States, at least one has had difficulty manufacturing the product, and Novitium is one of a limited number of suppliers capable of entering the market in the near future. In the generic dexamethasone tablets market, only two companies sell the 4 mg strength in the United States today and ANI and Novitium are two of a limited number of companies entering the market in the near future. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

V. The Proposed Order and the Order To Maintain Assets

The proposed Order and the Order to Maintain Assets effectively remedy the competitive concerns raised by the Proposed Combination for the two generic pharmaceutical product areas at issue. Pursuant to the proposed Order, the parties are required to divest ANI's rights and assets related to the two products to Prasco. The parties must accomplish these divestitures no later than ten days after the Proposed Combination is consummated. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products.

While ANI and Novitium do not compete against each other in the market for generic erythromycin and ethylsuccinate granules for oral suspension, Novitium has an unexecuted option to acquire a product from another company and ANI sells a product today. The proposed Order requires prior Commission approval before ANI or Novitium may acquire any rights or interests

Analysis to Aid Public Comment

in certain products containing, as the active pharmaceutical ingredients, erythromycin and ethylsuccinate. This provision allows the Commission to evaluate whether a future acquisition of the erythromycin and ethylsuccinate product would reduce competition at the time the acquisition is proposed. The proposed Order also requires ANI and Novitium to seek Commission approval before acquiring any other SMX-TMP or dexamethasone tablet product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Combination. Prasco is a capable purchaser with management and employees who have experience marketing and distributing generic pharmaceutical products. It will be able to replicate the competition otherwise lost from the Proposed Combination.

The proposed Order contains several provisions to help ensure that the divestitures are successful. ANI will supply Prasco with SMX-TMP oral suspension and dexamethasone tablets for up to three years while the company transfers the manufacturing technology to Prasco's contract manufacturing designee. The proposed Order also requires ANI to provide transitional services to Prasco to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to have the products manufactured in substantially the same manner and quality employed or achieved by ANI. It also includes advice and training from knowledgeable employees of the parties. Further, the proposed Order requires prior Commission approval before Prasco may sell, license, or otherwise convey any of the assets divested pursuant to the proposed Order.

Under the proposed Order, the Commission also will appoint a Monitor to ensure that ANI and Novitium comply with their obligations under the proposed Order and Order to Maintain Assets. The Commission has appointed Denise Smart of Smart Consulting Group, LLC as the Monitor. Ms. Smart is an expert in areas such as pharmaceutical R&D, regulatory approval, manufacturing and supply, and marketing, and she has over thirty years of experience in the pharmaceutical area and has provided consulting services in healthcare business development to major pharmaceutical companies, biotechnology companies, universities, and other government agencies, including the FDA, Department of Defense, and Health and Human Services.

The proposed Order also contains a prior approval provision relating to Prasco, which prohibits Prasco from selling the acquired products for a combined period of ten years after the Order is issued, except to an acquirer that receives the prior approval of the Commission.

* * *

The purpose of this analysis is to facilitate public comment on the Consent Agreement and proposed Order to aid the Commission in determining whether it should make the proposed Order final. This analysis is not an official interpretation of the proposed Order and does not modify its terms in any way.

Complaint

IN THE MATTER OF

**DAVITA INC.,
AND
TOTAL RENAL CARE, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT*Docket No. C-4752; File No. 211 0013**Complaint, October 21, 2021 – Decision, January 12, 2022*

This consent order addresses the \$80.9 million acquisition by DaVita, Inc. of certain assets of University of Utah. The complaint alleges that the Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by reducing competition and increasing concentration in outpatient dialysis services provided in the Provo, Utah market. The consent order requires DaVita to divest three dialysis clinics to Sanderling Renal Services, Inc., (“SRS”) and provide SRS with transition services for one year.

Participants

For the *Commission*: *Stuart Hirschfeld, Ben Lorigo, Danica Noble, and David Von Nirschl.*

For the *Respondents*: *Michael Perry, Steve Pet, and Stephen Weissman, Gibson Dunn; David Simon, Foley & Lardner.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent DaVita Inc., through its wholly-owned subsidiary, Total Renal Care, Inc. (“DaVita”), subject to the jurisdiction of the Commission, entered into an agreement to acquire substantially all the dialysis assets of the dialysis business of the University of Utah (“the University”), in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent DaVita is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its executive offices and principal place of business located at 2000 16th Street, Denver, Colorado 80202. DaVita is the largest provider of dialysis services in the United States. DaVita owns and manages outpatient dialysis facilities throughout the United States and provides acute inpatient dialysis services within hospitals.