

Complaint

IN THE MATTER OF

**AMNEAL HOLDINGS, LLC,
AMNEAL PHARMACEUTICALS LLC,
IMPAX LABORATORIES, INC.,
AND
IMPAX LABORATORIES, 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-4650; File No. 181 0017
Complaint, April 27, 2018 – Decision, June 29, 2018*

This consent order addresses the \$1.45 billion acquisition by Amneal Holdings, LLC and Amneal Pharmaceuticals LLC of certain assets of Impax Laboratories, Inc. and Impax Laboratories, 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 current competition in the markets for: (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets in the United States. The complaint also alleges that the acquisition would violate the aforementioned statutes by lessening future competition in the markets for: (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray in the United States. The consent order requires the parties to divest all of Impax's rights and assets related to 1) generic desipramine hydrochloride tablets; 2) generic felbamate tablets; 3) generic aspirin and dipyridamole extended release ("ER") capsules; 4) generic diclofenac sodium and misoprostol delayed release ("DR") tablets; 5) generic ezetimibe and simvastatin immediate release ("IR") tablets; 6) generic erythromycin tablets; and 7) generic methylphenidate hydrochloride ER tablets to ANI Pharmaceuticals, Inc. Under the consent order, the parties also are required to divest all of Impax's rights and assets related to generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray to Perrigo Company plc, and to divest all of Impax's rights and assets related to generic fluocinonide-E cream to G&W Laboratories.

Participants

For the Commission: *Kenneth A. Libby, Vanessa Schlueter,
David von Nirschl and Kari A. Wallace.*

Complaint

For the *Respondents: Patrick C. English and Amanda P. Reeves, Latham & Watkins LLP; William Diaz, McDermott Will & Emery 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 Amneal Holdings, LLC, and Respondent Amneal Pharmaceuticals LLC (collectively, “Amneal”), corporations subject to the jurisdiction of the Commission, have agreed to acquire the equity interests of Respondent Impax Laboratories, Inc., and Respondent Impax Laboratories, LLC (collectively, “Impax”), corporations 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:

I. RESPONDENTS

1. Respondent Amneal Holdings, 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Respondent Amneal Pharmaceuticals 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

2. Respondent Impax Laboratories, 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 30831 Huntwood Avenue, Hayward, California 94544. Respondent Impax Laboratories,

Complaint

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 30831 Huntwood Avenue, Hayward, California 94544.

3. 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.

THE PROPOSED ACQUISITION

4. Pursuant to a business combination agreement dated October 17, 2017, Respondent Amneal proposes to acquire the equity interests of Respondent Impax in a series of transactions valued at approximately \$1.45 billion (the “Acquisition”). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

THE RELEVANT MARKETS

5. 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. desipramine hydrochloride tablets;
- b. ezetimibe and simvastatin immediate release (“IR”) tablets;
- c. felbamate tablets;
- d. aspirin and dipyridamole extended release (“ER”) capsules;
- e. azelastine nasal spray;
- f. diclofenac sodium and misoprostol delayed release (“DR”) tablets;

Complaint

- g. erythromycin tablets;
- h. fluocinonide-E cream;
- i. methylphenidate hydrochloride ER tablets; and
- j. olopatadine hydrochloride nasal spray.

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

THE STRUCTURE OF THE MARKETS

7. Desipramine hydrochloride is a tricyclic antidepressant. Only five companies currently sell generic desipramine hydrochloride tablets in the United States: Amneal, Impax, Heritage Pharmaceuticals, Inc. (“Heritage”), Sandoz, and Teva Pharmaceutical Industries Ltd. (“Teva”). Sales by Teva, Sandoz, and Amneal account for more than 95 percent of the market. Heritage accounts for the remaining 5 percent while Impax only launched its product in late 2017. The Acquisition would reduce the number of suppliers of generic desipramine hydrochloride tablets from five to four and eliminate the most recent entrant into the market.

8. Ezetimibe and simvastatin is used to improve cholesterol and lower triglycerides. Only four companies currently sell generic ezetimibe and simvastatin IR tablets in the United States: Amneal, Impax, Dr. Reddy’s Laboratories (“Dr. Reddy’s”), and Teva. Sales by Impax account for more than half the market, while Dr. Reddy’s and Teva share the remainder. Amneal entered the generic ezetimibe and simvastatin IR tablets market at the end of 2017. The Acquisition would reduce the number of suppliers from four to three and eliminate the most recent entrant.

9. Felbamate is an anticonvulsant used in the treatment of epilepsy. Only four companies currently sell generic felbamate tablets in the United States: Amneal, Impax, Alvogen, and Wallace Pharmaceuticals, Inc. (“Wallace”). The Acquisition

Complaint

would reduce the number of suppliers of generic felbamate from four to three.

10. Aspirin and dipyridamole is an antiplatelet therapy used to reduce the risk of stroke. Only Amneal currently sells generic aspirin and dipyridamole ER capsules in the United States. Impax is one of only a limited number of suppliers capable of entering the market for generic aspirin and dipyridamole ER capsules in the near future.

11. Azelastine nasal spray is used to treat seasonal allergies. Three companies currently sell generic azelastine nasal spray: Impax, partnered with Perrigo Company plc (“Perrigo”); Wallace; and Apotex Inc. (“Apotex”). Amneal is one of a limited number of suppliers capable of entering the market in the near future.

12. Diclofenac sodium and misoprostol is used to provide pain relief while minimizing gastrointestinal side effects. Four companies—Amneal, Teva, Sandoz, and Exela Pharma Sciences LLC (“Exela”)—have approved ANDAs to sell generic diclofenac sodium and misoprostol DR tablets in the United States. In addition, Greenstone LLC, a Pfizer subsidiary, sells an authorized generic version. Sandoz does not sell its product directly to customers and supplies only to a private labeler. The Exela product, marketed by both Eagle Pharmaceuticals, Inc. and Dash Pharmaceuticals LLC, has limited sales. Impax, partnered with Micro Labs Limited, is one of only a few suppliers capable of entering the market for generic diclofenac sodium and misoprostol DR tablets in the near future.

13. Erythromycin is an antibiotic which until recently had only one supplier, Arbor Pharmaceuticals, LLC, in the United States. Amneal’s ANDA to sell generic erythromycin tablets was approved in March of 2018, and it has launched the product. Impax is one of a limited number of suppliers capable of entering the market for generic erythromycin in the near future.

14. Fluocinonide-E cream is a corticosteroid used on the skin to reduce swelling, redness, itching, and allergic reactions. Only four companies currently sell generic fluocinonide-E cream in the United States: Impax, Alvogen, Sun Pharmaceutical Industries

Complaint

Ltd. (“Sun”), and Teva. Sun and Teva are the market leaders, while Impax and Alvogen are recent entrants into the market. Amneal is one of only a few suppliers capable of entering the market for generic fluocinonide-E cream in the near future.

15. Methylphenidate hydrochloride is a central nervous system stimulant used to treat attention-deficit disorder and attention-deficit/hyperactivity disorder. Only four companies currently sell generic methylphenidate hydrochloride ER tablets in the United States: Teva is the leading supplier with more than 80 percent share, while Mylan N.V. and Trigen each have less than 10 percent share. Amneal’s ANDA was approved in February of 2018, and it has since launched the product. Impax is one of a limited number of suppliers capable of entering the market for generic methylphenidate hydrochloride ER tablets in the near future.

16. Olopatadine hydrochloride nasal spray is used to treat seasonal allergies. Three companies currently sell generic olopatadine hydrochloride nasal spray in the United States: Impax, partnered with Perrigo; Sandoz; and Apotex. Amneal is one of only a few suppliers capable of entering the market for generic olopatadine hydrochloride nasal spray in the near future.

ENTRY CONDITIONS

17. Entry into the relevant markets described in Paragraphs 7-16 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.

EFFECTS OF THE ACQUISITION

18. 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

Complaint

FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Amneal and Impax and reducing the number of independent significant competitors in the markets for (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets, thereby increasing the likelihood that: (a) Amneal would be able to unilaterally exercise market power in these markets; (b) the remaining competitors would engage in coordinated interaction between or among each other; and (c) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Amneal and Impax in the markets for (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray, 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.

VIOLATIONS CHARGED

19. The Acquisition described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

20. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the

Order to Maintain Assets

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 twenty-seventh day of April, 2018, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent Amneal Holdings, LLC and Respondent Amneal Pharmaceuticals LLC (collectively “Amneal”) of the equity interests of Respondent Impax Laboratories, Inc. and Respondent Impax Laboratories, LLC (collectively “Impax”). The resulting combined entity is to be named Amneal Pharmaceuticals, Inc. Amneal, Impax, and Amneal Pharmaceuticals, Inc. are hereinafter collectively referred to as “Respondents.” The Commission’s Bureau of Competition prepared and furnished to Respondents 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.

Respondents and the Bureau of Competition executed an agreement (“Agreement Containing Consent Orders” or “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 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

Order to Maintain Assets

provisions as required by the Commission's Rules, and (4) a proposed Decision and Order and this Order to Maintain Assets; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Amneal Holdings, 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Respondent Amneal Pharmaceuticals 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.
2. Respondent Amneal 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.
3. Respondent Impax Laboratories, 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 30831 Huntwood Avenue, Hayward, California 94544. Respondent Impax Laboratories, LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of

Order to Maintain Assets

the State of Delaware with its executive offices and principal place of business located at 30831 Huntwood Avenue, Hayward, California 94544.

4. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

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

- A. “Amneal” means: Amneal Holdings, LLC; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Holdings, LLC (including, without limitation, Amneal Pharmaceuticals LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Amneal also means: Amneal Pharmaceuticals, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Amneal will include Impax.
- B. “Impax” means: Impax Laboratories, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Impax Laboratories, Inc. (including, without limitation, Impax Laboratories, LLC), and the

Order to Maintain Assets

respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Respondent(s)” means Amneal and Impax, individually and collectively.
- E. “Decision and Order” means the:
 - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 - 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- F. “Divestiture Product Business(es)” means the Business of Respondent (as that Respondent is specified in the definition of each Divestiture Product) related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- G. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondent(s) to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date

Order to Maintain Assets

four (4) months after the Closing Date for such Divestiture Product(s).

- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High

Order to Maintain Assets

Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:

1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by the Respondents, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;

Order to Maintain Assets

5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and
 6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Not later than one (1) day after the date this Order to Maintain Assets is issued by the Commission, for each Divestiture Product that has been marketed or sold prior to the Closing Date, Respondents shall provide to the Proposed Acquirer of that Divestiture Product, for each High Volume Account, a list by either SKU or NDC Number containing the current net price per SKU or NDC Number, *i.e.*, the final price per SKU or NDC Number, charged by the relevant Respondent (as that Respondent is identified in the definition of each Divestiture Product) net of all customer-level discounts, rebates, or promotions, for that Divestiture Product, as of five (5) business days or less prior to the date this Order to Maintain Assets is issued.
- E. Respondents shall:
1. for a period of twelve (12) months from the Closing Date, provide that Acquirer or its

Order to Maintain Assets

Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s);”

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and

Order to Maintain Assets

Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

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

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

Order to Maintain Assets

scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and

5. for a period of one (1) year from the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

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

- F. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States by the Respondents before the Closing Date for that Divestiture Product, Respondents, in

Order to Maintain Assets

consultation with the Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:

1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Divestiture Products by the Acquirer is not delayed or impaired by the Respondents;
2. designate employees of Respondents knowledgeable about the marketing, distribution, and sale related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer to the Acquirer of the Business related to the Divestiture Products;
3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
4. continue to market, distribute, and sell the Divestiture Products;
5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
6. to the extent known or available to the specified Respondent, provide the Acquirer with a list of the inventory levels (weeks of supply) in the

Order to Maintain Assets

possession of each customer (*i.e.*, healthcare provider, hospital, group purchasing organization, wholesaler, or distributor) by stock keeping unit or NDA Number on a regular basis and in a timely manner;

7. to the extent known by the specified Respondent, provide the Acquirer with anticipated reorder dates for each customer by stock keeping unit or NDC Number on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.

G. Pending divestiture of the Divestiture Product Assets, Respondents shall:

1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of the Respondents responsible for the Contract Manufacture or continued Development

Order to Maintain Assets

of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;

3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing, sales or Development of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products;
 4. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products *unless* authorized by the Acquirer of the particular Divestiture Product to do so; and
 5. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- H. Not later than ten (10) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, each Respondent shall provide written notification of the restrictions on

Order to Maintain Assets

the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.

- I. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Each Respondent shall provide a copy of the notification to the Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgment program. Each Respondent shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.
- J. Each Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through their 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 Product Assets except for ordinary wear and tear.

Order to Maintain Assets

III.**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor each Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out

Order to Maintain Assets

the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;

2. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission; and
3. The Monitor shall serve until the divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is a Contract Manufacture Product or an Aspirin/Dipyridamole Product, until the earliest of:
 - a. the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Divestiture Product and able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
 - b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product;

Order to Maintain Assets

provided, however, that, with respect to each Divestiture Product, the Monitor's service shall not extend more than five (5) years after the Order Date unless the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or

Order to Maintain Assets

expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

- H. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by each Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

Order to Maintain Assets

- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as the Monitor pursuant to the Decision and Order.
- N. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders.

- A. Respondents shall include in their reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including: a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the relevant Respondent to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and a detailed description of the timing for the completion of such obligations.

Order to Maintain Assets

- B. Respondents shall verify each compliance report with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports of compliance required to be submitted by Respondents pursuant to the Decision and Order.

V.

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

- A. any proposed dissolution of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, Inc., or Impax Laboratories, LLC;
- B. any proposed acquisition, merger, or consolidation of Amneal Holdings, LLC, Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals, Inc., Impax Laboratories, Inc., or Impax Laboratories, LLC; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution

Order to Maintain Assets

of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters address, the notified 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 business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or

Decision and Order

- B. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Product Manufacturing Technology related to each Divestiture Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION

The Federal Trade Commission (“Commission”) initiated an investigation of the proposed acquisition by Respondent Amneal Holdings, LLC and Respondent Amneal Pharmaceuticals LLC (“collectively Amneal”) of the equity interests of Respondent Impax Laboratories, Inc. and Respondent Impax Laboratories, LLC (collectively “Impax”). The resulting combined entity is to be named Amneal Pharmaceuticals, Inc. Amneal, Impax, and Amneal Pharmaceuticals, Inc. hereinafter are collectively referred to as “Respondents.” The Commission’s Bureau of Competition prepared and furnished to Respondents 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

Decision and Order

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.

Respondents and the Bureau of Competition executed an agreement (“Agreement Containing Consent Orders” or “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 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. Now, in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Amneal Holdings, 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Respondent Amneal Pharmaceuticals 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

Decision and Order

2. Respondent Amneal 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 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.
3. Respondent Impax Laboratories, 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 30831 Huntwood Avenue, Hayward, California 94544. Respondent Impax Laboratories, 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 30831 Huntwood Avenue, Hayward, California 94544.
4. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER**I.**

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

- A. “Amneal” means: Amneal Holdings, LLC; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Holdings, LLC (including, without limitation, Amneal Pharmaceuticals LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Amneal also means: Amneal Pharmaceuticals, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures,

Decision and Order

subsidiaries, divisions, groups, and affiliates, in each case controlled by Amneal Pharmaceuticals, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Amneal will include Impax.

- B. “Impax” means: Impax Laboratories, Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Impax Laboratories, Inc. (including, without limitation, Impax Laboratories, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Respondent(s)” means Amneal and Impax, individually and collectively.
- E. “Acquirer(s)” means the following:
 - 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
 - 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Amneal’s acquisition of Impax pursuant to the Acquisition Agreement.

Decision and Order

- G. “Acquisition Agreement” means the *Business Combination Agreement* by and among Impax Laboratories, Inc., Atlas Holdings, Inc., a wholly owned subsidiary of Impax Laboratories, Inc., K2 Merger Sub Corporation, a wholly owned subsidiary of Impax Laboratories, Inc., and Amneal Pharmaceuticals LLC, that was submitted by the Respondents to the Commission in this matter. The Acquisition Agreement is contained in Non-Public Appendix I.
- H. “Acquisition Date” means the earlier of the following dates: (i) the date on which Respondent Amneal acquires fifty percent (50%) or more of the voting securities of Impax; or (ii) the date on which Respondent Amneal acquires any ownership interest in the assets of Impax pursuant to the Acquisition Agreement.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- J. “Amneal Aspirin/Dipyridamole ER Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Amneal pursuant to the following Application: ANDA No. 206392, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as the active pharmaceutical ingredients, aspirin and dipyridamole, at the following strength: 25mg aspirin/200mg dipyridamole.
- K. “ANI Pharmaceuticals” means ANI Pharmaceuticals, Inc., a corporation organized, existing, and doing

Decision and Order

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. ANI includes any subsidiaries of ANI Pharmaceuticals, Inc.

- L. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), 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. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- M. “Aspirin/Dipyridamole ER Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 206964, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release capsules containing, as the active pharmaceutical ingredients, aspirin and dipyridamole, at the following strength: 25mg aspirin/200mg dipyridamole.
- N. “Aspirin/Dipyridamole ER Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Aspirin/Dipyridamole ER Products, to the extent legally transferable, including, without limitation, the

Decision and Order

Categorized Assets related to the Aspirin/Dipyridamole ER Products.

- O. “Azela**stine** Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax or its co-development partner, Perrigo, pursuant to the following Application: ANDA No. 202743, and any supplements, amendments, or revisions to this ANDA. These Products are nasally administered metered sprays containing, as the active pharmaceutical ingredient, azela**stine**, at the following strength: eq 0.1876mg/spray.
- P. “Azela**stine** Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Azela**stine** Products to the extent that such rights are owned, controlled, or held by Impax under and by virtue of the *Development, Manufacturing, and Commercialization Agreement* between Impax Laboratories, Inc., and Perrigo Israel Pharmaceuticals Ltd., dated July 27, 2010, as amended November 4, 2013, and June 19, 2014. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.
- Q. “Azela**stine**/Olopatadine Product Divestiture Agreements” means the following:
1. *Transfer Agreement* by and between Impax Laboratories, Inc. and Perrigo Pharma International Designated Activity Company, dated March 23, 2018; and
 2. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement(s).

Decision and Order

The Azelastine/Olopatadine Product Divestiture Agreements are contained in Non-Public Appendix II.B. The Azelastine/Olopatadine Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- R. "Business" means (i) the research, Development, and manufacture of a Product wherever located throughout the world, and (ii) the commercialization, distribution, marketing, importation, advertisement, and sale of a Product in the United States.
- S. "Categorized Assets" means the following assets and rights of the specified Respondent (as that Respondent is identified in the definition of the Divestiture Product), as such assets and rights are in existence as of the date the specified Respondent signs the Consent Agreement in this matter and to be maintained by the Respondents in accordance with the Order to Maintain Assets until the Closing Date for each Divestiture Product:
1. all rights to all of the Applications related to the specified Divestiture Product;
 2. all rights to all of the Clinical Trials related to the specified Divestiture Product;
 3. all Product Intellectual Property related to the specified Divestiture Product that is not Product Shared Intellectual Property;
 4. all Product Approvals related to the specified Divestiture Product;
 5. all Product Manufacturing Technology related to the specified Divestiture Product that is not Product Shared Intellectual Property;

Decision and Order

6. all Product Marketing Materials related to the specified Divestiture Product;
7. all Product Scientific and Regulatory Material related to the specified Divestiture Product;
8. all Website(s) related exclusively to the specified Divestiture Product;
9. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
10. for each specified Divestiture Product that has been marketed or sold by the specified Respondent prior to the Closing Date, a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
 - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement;
 - b. to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Closing Date and *except* as may be required by applicable Law;
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a

Decision and Order

Retained Product (including the right to receive notification from the Respondents of any such cross-referencing that is discovered by a Respondent);

- d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
 - e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Closing Date and *except* as may be required by applicable Law and *except* as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement; and
 - f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondents prior to such notification(s) being disseminated to the customer(s);
- 11. all Product Development Reports related to the specified Divestiture Product;
 - 12. at the option of the Acquirer of the specified Divestiture Product, all Product Contracts related to the specified Divestiture Product;
 - 13. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the

Decision and Order

investigation of adverse effects related to the specified Divestiture Product (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);

14. for each specified Divestiture Product that has been marketed or sold by a Respondent prior to the Closing Date:
 - a. a list of all customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers during the one (1) year period immediately prior to the Closing Date, stated on either an annual, quarterly, or monthly basis, including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
 - b. for each High Volume Account, a list by either SKU or NDC Number containing the following: (i) the net price per SKU or NDC Number as of the Closing Date, *i.e.*, the final price per SKU or NDC Number, charged by the specified Respondent net of all customer-level discounts, rebates, or promotions; (ii) the net price per SKU or NDC Number charged by the specified Respondent at the end of each quarter during the one (1) year immediately prior to the Closing Date; (iii) any supply outages by SKU or NDC Number during the one (1) year period immediately prior to the Closing Date the result of which caused the specified Respondent to make a financial payment to the customer or to incur a penalty

Decision and Order

for a failure to supply; and (iv) to the extent known by the specified Respondent, the status of the Divestiture Product on the customer's respective formulary (*i.e.*, primary, secondary, or backup);

- c. for each month for the one (1) year period immediately prior to the Closing Date, a list containing the following historical information for the specified Divestiture Product: wholesale acquisition cost; and
 - d. backorders by SKU or NDC Number as of the Closing Date;
15. for each specified Divestiture Product, a list of all suppliers that are listed as a qualified source of the active pharmaceutical ingredient on any Application of a Retained Product that is the Therapeutic Equivalent of that Divestiture Product, but only in those instances wherein a Respondent is (i) the holder of the Application for that Retained Product and (ii) the Application is not subject to an exclusive license to a Third Party;
16. a list of each specified Divestiture Product that has had any finished product batch or lot determined to be out-of-specification during the three (3) year period immediately preceding the Closing Date, and, for each such Divestiture Product: (i) a detailed description of the deficiencies or defects (*e.g.*, impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure) with respect to any out-of-specification batch or lot; (ii) the corrective actions taken to remediate the cGMP deficiencies in the Divestiture Product; and (iii) to the extent known by the specified Respondent, the employees (whether current or former) responsible for taking such corrective actions;

Decision and Order

17. for each specified Divestiture Product:

- a. to the extent known or available to the specified Respondent, a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, healthcare provider, hospital, group purchasing organization, wholesaler, or distributor) as of the date prior to and closest to the Closing Date as is available; and
- b. to the extent known by the specified Respondent, any pending reorder dates for a customer as of the Closing Date;

18. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the specified Divestiture Product;

19. the quantity and delivery terms in all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;

20. at the option of the Acquirer of the specified Divestiture Product, the right to fill any or all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date; and

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

provided, however, that "Categorized Assets" shall not include: (i) documents relating to a Respondent's

Decision and Order

general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Monitor or the Acquirer of the specified Divestiture Product; (iv) information that is exclusively related to the Retained Products; (v) any real estate and the buildings and other permanent structures located on such real estate; and (vi) all Product Shared Intellectual Property;

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

- T. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

Decision and Order

- U. “Clinical Trial(s)” means a controlled study in humans of the safety, efficacy, or bioequivalence of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- V. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- W. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the conduct of the Business related to a Divestiture Product(s). The term “Confidential Business Information” *excludes*, and Respondents are not required to submit the following information to an Acquirer:
1. information relating to a Respondent’s general business strategies or practices that does not discuss with particularity the Divestiture Products;
 2. information specifically excluded from the Divestiture Product Assets conveyed to the Acquirer of the related Divestiture Product(s);
 3. information that is contained in documents, records, or books of a Respondent that is provided to an Acquirer by a Respondent that is unrelated to the Divestiture Products acquired by that Acquirer or that is exclusively related to Retained Product(s); and
 4. information that is protected by the attorney work product, attorney-client, joint defense, or other

Decision and Order

privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

X. “Contract Manufacture” means the following:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer (including, without limitation, for the purposes of Clinical Trials and/or commercial sales);
2. to manufacture, or to cause to be manufactured, a Product that is the Therapeutic Equivalent of, and in the identical dosage strength, formulation, and presentation as, a Contract Manufacture Product on behalf of an Acquirer; or
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

Y. “Contract Manufacture Product(s)” means, individually and collectively:

1. Ezetimibe/Simvastatin Products;
2. Erythromycin Products; and
3. any ingredient, material, or component used in the manufacture of the foregoing Products including the active pharmaceutical ingredient(s), excipient(s), or packaging materials;

provided, however, that with the consent of the Acquirer of the specified Product, a Respondent may substitute a Therapeutic Equivalent form of such Product in performance of that Respondent’s agreement to Contract Manufacture.

Decision and Order

- Z. “Desipramine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 205153, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as the active pharmaceutical ingredient, desipramine, at the following strengths: 10mg; 25mg; 50mg; 75mg; 100mg; and 150mg.
- AA. “Desipramine Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Desipramine Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Desipramine Products.
- BB. “Development” means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- CC. “Diclofenac/Misoprostol Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax or its co-development partner, Micro Labs, pursuant to the following Application: ANDA No. 204355, and any supplements, amendments, or revisions to this ANDA. These Products are orally

Decision and Order

administered delayed-release tablets containing, as active pharmaceutical ingredients, diclofenac and misoprostol, at the following strengths: 50mg diclofenac/0.2mg misoprostol; and 75mg diclofenac/0.2mg misoprostol.

DD. “Diclofenac/Misoprostol Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Diclofenac/Misoprostol Products to the extent that such rights are owned, controlled, or held by Impax under and by virtue of the *License, Supply and Distribution Agreement*, by and between Micro Labs Limited and Corepharma LLC, dated June 22, 2012. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.A.

EE. “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’ labor shall not exceed the average hourly wage rate for such employee;

provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.

FF. “Divestiture Product(s)” means the following, individually and collectively:

1. Aspirin/Dipyridamole ER Products;
2. Azelastine Products;
3. Desipramine Products;

Decision and Order

4. Diclofenac/Misoprostol Products;
5. Erythromycin Products;
6. Ezetimibe/Simvastatin Products;
7. Felbamate Products;
8. Fluocinonide Products;
9. Methylphenidate Products; and
10. Olopatadine Products.

GG. “Divestiture Product Assets” means the following, individually and collectively:

1. Aspirin/Dipyridamole ER Product Assets;
2. Azelastine Product Assets;
3. Desipramine Product Assets;
4. Diclofenac/Misoprostol Product Assets;
5. Erythromycin Product Assets;
6. Ezetimibe/Simvastatin Product Assets;
7. Felbamate Product Assets;
8. Fluocinonide Product Assets;
9. Methylphenidate Product Assets; and
10. Olopatadine Product Assets.

HH. “Divestiture Product Core Employee(s)” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.

Decision and Order

II. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) under a Remedial Agreement with rights to sublicense to all Product Shared Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, held, or controlled by a Respondent:

1. to research and Develop the specified Divestiture Product(s) for marketing, distribution, or sale within the United States;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the specified Divestiture Product(s) within the United States;
3. to import or export the specified Divestiture Product(s) to or from the United States to the extent related to the marketing, distribution, or sale of the specified Divestiture Products in the United States; and
4. to have the specified Divestiture Product(s) made anywhere in the world for distribution or sale within, or import into the United States;

provided, however, that for any Product Shared Intellectual Property or Product Manufacturing Technology that is the subject of a license from a Third Party entered into by a Respondent prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to that Respondent.

JJ. “Divestiture Product Releasee(s)” means the following Persons:

1. the Acquirer for the assets related to a particular Divestiture Product;

Decision and Order

2. any Person controlled by or under common control with that Acquirer; and
 3. any Manufacturing Designee(s), licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- KK. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- LL. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- MM. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- NN. “Erythromycin Product(s)” means the Products manufactured or in Development owned or controlled by Impax (ANDA not filed as of the date of the Consent Agreement) that are being developed as oral tablets that contain, as the active pharmaceutical ingredient, erythromycin at the following strengths: 250mg and 500mg.
- OO. “Erythromycin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Erythromycin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Erythromycin Products.

Decision and Order

- PP. “Ezetimibe/Simvastatin Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 201890, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as the active pharmaceutical ingredients, ezetimibe and simvastatin, at the following strengths: 10mg ezetimibe/10mg simvastatin; 10mg ezetimibe/20mg simvastatin; 10mg ezetimibe/40mg simvastatin; and 10mg ezetimibe/80mg simvastatin.
- QQ. “Ezetimibe/Simvastatin Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Ezetimibe/Simvastatin Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Ezetimibe/Simvastatin Products.
- RR. “Felbamate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 202284, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as the active pharmaceutical ingredient, felbamate, at the following strengths: 400mg; and 600mg.
- SS. “Felbamate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Felbamate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Felbamate Products.
- TT. “Fluocinonide Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the

Decision and Order

following Application: ANDA No. 074204, and any supplements, amendments, or revisions to this ANDA. These Products are topically administered emulsified creams containing, as the active pharmaceutical ingredient, fluocinonide, at the following strength: 0.05%.

- UU. “Fluocinonide Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Fluocinonide Products to the extent that such rights are owned, controlled, or held by Impax under and by virtue of the *Assignment and Assumption Agreement* between Actavis Pharma, Inc., Actavis Mid Atlantic LLC, and Impax Laboratories, Inc. dated August 3, 2016. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.
- VV. “Fluocinonide Product Divestiture Agreement(s)” means the following:
1. *Termination Agreement* by and between Impax Laboratories, Inc. and G&W Laboratories, Inc., dated [insert], 2018; and
 2. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreement(s), including without limitation, Appendix I, *Seller NDC Number Transition Services*.

The Fluocinonide Product Divestiture Agreements are contained in Non-Public Appendix II.C. The Fluocinonide Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective are Remedial Agreements.

Decision and Order

- WW. “G&W” means G&W Laboratories, a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey with its principal executive offices located at 111 Coolidge Street, South Plainfield, New Jersey 07080-3895. G&W includes any subsidiaries of G&W Laboratories.
- XX. “Government Entity” means any Federal, state, local, or non-U.S. government; any court, legislature, government agency, or government commission; or any judicial or regulatory authority of any government.
- YY. “Group A Product(s)” means the following Divestiture Products, individually and collectively:
1. Aspirin/Dipyridamole ER Products;
 2. Desipramine Products;
 3. Diclofenac/Misoprostol Products;
 4. Erythromycin Products;
 5. Ezetimibe/Simvastatin Products;
 6. Felbamate Products; and
 7. Methylphenidate Products.
- ZZ. “Group A Product Assets” means the following Divestiture Product Assets, individually and collectively:
1. Aspirin/Dipyridamole ER Product Assets;
 2. Desipramine Product Assets;
 3. Diclofenac/Misoprostol Product Assets;
 4. Erythromycin Product Assets;

Decision and Order

5. Ezetimibe/Simvastatin Product Assets;
6. Felbamate Product Assets; and
7. Methylphenidate Product Assets.

AAA. “Group A Product Divestiture Agreement(s)” means the following:

1. the *Asset Purchase Agreement* by and between ANI Pharmaceuticals, Inc. and Impax Laboratories, Inc. dated as of April 23, 2018;
2. the letter agreement from Amneal Pharmaceuticals LLC to ANI Pharmaceuticals, Inc. to provide consulting services through certain named employees of Respondents to ANI Pharmaceuticals, Inc. with respect to the Aspirin/Dipyridamole Products, to be executed on or before the Closing Date for the Group A Product Assets;
3. the *Supply Agreement* by and between ANI Pharmaceuticals, Inc. and Impax Laboratories, Inc. to be executed on or before the Closing Date for the Group A Product Assets (for the supply of the Contract Manufacture Products);
4. the letter agreement from Impax Laboratories, Inc. to ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets (regarding the labeling of certain products);
5. the *Agreement for the Exchange of Drug Safety Information* between Amneal Pharmaceuticals LLC & ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets;
6. the *Supply Agreement* by and between ANI Pharmaceuticals, Inc. and Amneal Pharmaceuticals

Decision and Order

LLC to be executed on or before the Closing Date for the Group A Product Assets (for supply of Amneal Aspirin/Dipyridamole ER Products);

7. the *Quality Agreement* by and between Amneal Pharmaceuticals LLC & ANI Pharmaceuticals, Inc. to be executed on or before the Closing Date for the Group A Product Assets; and
8. all amendments, exhibits, attachments, agreements, and schedules attached to and submitted to the Commission with the foregoing listed agreements.

The Group A Product Divestiture Agreements are contained in Non-Public Appendix II.A. The Group A Product Divestiture Agreements that have been approved by the Commission to accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective are Remedial Agreements.

- BBB. "High Volume Account(s)" means any retailer, wholesaler, or distributor whose annual or projected annual purchase amounts, in units or in dollars, of a Divestiture Product in the United States from a Respondent, was or was forecasted (prior to the public announcement of the Acquisition and subsequent divestiture) to be among the top twenty (20) highest such purchase amounts of that Respondent's total sales of that Divestiture Product to U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; (iii) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (iv) for forecasts of purchases of the Divestiture Product, the quarter immediately following the Closing Date.

Decision and Order

- CCC. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- DDD. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- EEE. “Methylphenidate Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax pursuant to the following Application: ANDA No. 208607, and any supplements, amendments, or revisions to this ANDA. These Products are orally administered extended release tablets containing, as active pharmaceutical ingredients, methylphenidate, at the following strengths: 18mg; 27mg; 36mg; and 54mg.
- FFF. “Methylphenidate Product Assets” means all rights, title, and interest in and to all assets related to the Business of Impax related to each of the Methylphenidate Products, to the extent legally transferable, including, without limitation, the Categorized Assets related to the Methylphenidate Products.
- GGG. “Micro Labs” means Micro Labs Limited a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its executive offices and principal place of business located at 27, Race Course Road, Bangalore-560001, India. Micro Labs includes any subsidiaries of Micro Labs Limited.
- HHH. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- III. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by

Decision and Order

the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.

- JJJ. “Olopatadine Product(s)” means the following: the Products manufactured, in Development, marketed, sold, owned, or controlled by Impax or its co-development partner, Perrigo, pursuant to the following Application: ANDA No. 202853, and any supplements, amendments, or revisions to this ANDA. These Products are nasally administered metered sprays containing, as the active pharmaceutical ingredient, olopatadine, at the following strength: 0.665mg/spray.
- KKK. “Olopatadine Product Assets” means all rights, title, and interest in and to all assets related to the Business related to the Olopatadine Products to the extent that such rights are owned, controlled, or held by Impax under and by virtue of the *Development, Manufacturing, and Commercialization Agreement* between Impax Laboratories, Inc., and Perrigo Israel Pharmaceuticals Ltd., dated July 27, 2010, as amended November 4, 2013, and June 19, 2014. This agreement was submitted to the Commission by Respondents and is contained in Non-Public Appendix II.B.
- LLL. “Orders” means this Decision and Order and the related Order to Maintain Assets.
- MMM. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- NNN. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- OOO. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications

Decision and Order

for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.

- PPP. “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.
- QQQ. “Perrigo” means Perrigo Company plc, a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of Ireland with its executive offices and principal place of business located at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland. Perrigo includes Perrigo Israel Pharmaceuticals Ltd., a company incorporated under the laws of Israel, and any subsidiaries of Perrigo Company plc.
- RRR. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- SSS. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States, and includes, without limitation, all approvals, registrations, licenses, or

Decision and Order

authorizations granted in connection with any Application related to that Product.

TTT. “Product Contracts” means all contracts or agreements:

1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent *unless* such contract applies generally to a Respondent’s sales of Products to that Third Party;
2. pursuant to which a Respondent had or has as of the Closing 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 the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the specific marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished dosage form Product on behalf of a Respondent;

Decision and Order

7. pursuant to which a Third Party provides or plans to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of a Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
9. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology related to the specified Divestiture Product;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture, or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of the specified Divestiture Product or the Business related to such Divestiture Product;

provided, however, that where any such contract or agreement also relates to a Retained Product(s), a Respondent shall, at the Acquirer's option, assign or otherwise make available to the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently

Decision and Order

may retain similar rights for the purposes of the Retained Product(s).

UUU. “Product Copyrights” means rights to all original works of authorship of any kind directly related to a Divestiture Product and any registrations and applications for registrations thereof within the United States, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and all educational materials for the sales force; copyrights in all preclinical, clinical, and process development data and reports relating to the research and Development of that Product or of any materials used in the research, Development, manufacture, marketing, or sale of that Product, including all copyrights in raw data relating to Clinical Trials of that Product, all case report forms relating thereto, and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports, and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, that Product’s sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees of a Respondent who accept employment with an Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to that Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data

Decision and Order

contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

VVV. “Product Development Reports” means:

1. pharmacokinetic study reports related to the specified Divestiture Product;
2. bioavailability study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
3. bioequivalence study reports (including Reference Listed Drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from, or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;
8. FDA approved patient circulars and information related to the specified Divestiture Product;

Decision and Order

9. adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians or clinicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies, and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities or defects found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including, without limitation, identification and sources of impurities or defects;
15. reports of vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

Decision and Order

17. manufacturing batch or lot records related to the specified Divestiture Product;
18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

WWW. “Product Employee Information” means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by a Respondent within ninety (90) days of the execution date of any Remedial Agreement); and
2. with respect to each such employee, the following information:
 - a. direct contact information for the employee, including telephone number;
 - b. the date of hire and effective service date;
 - c. job title or position held;
 - d. a specific description of the employee’s responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, a Respondent may provide the employee’s most recent performance appraisal;
 - e. the base salary or current wages;

Decision and Order

- f. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 - g. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
 - h. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.

XXX. "Product Intellectual Property" means all of the following intellectual property related to a Divestiture Product (other than Product Shared Intellectual Property) that is owned, licensed, held, or controlled by a Respondent as of the Closing Date:

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

Decision and Order

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Amneal”, “Impax”, 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 Amneal or Impax can be identified or defined.

YYY. “Product Manufacturing Employees” means all salaried employees of a Respondent who have directly participated in any of the following: (i) defining the commercial manufacturing process, (ii) confirming that the manufacturing process is capable of reproducible commercial manufacturing, (iii) formulating the manufacturing process performance qualification protocol, (iv) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the technological transfer of the manufacturing process to a different facility, of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved, *unless* such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

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

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not

Decision and Order

limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists;

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

AAAA. "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 Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, Website content,

Decision and Order

artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

BBBB. “Product Research and Development Employees” means all salaried employees of a Respondent who have directly participated in the research, Development, regulatory approval process, or Clinical Trials of the specified Divestiture Product (irrespective of the portion of working time involved, *unless* such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

CCCC. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.

DDDD. “Product Shared Intellectual Property” means the following:

1. all of the following intellectual property related to a Divestiture Product that is owned, licensed, held, or controlled by a Respondent as of the Closing Date, as follows:
 - a. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn) NDA or ANDA as of the Acquisition Date; and
 - b. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the United States to limit the use or disclosure thereof, that are related to a

Decision and Order

Divestiture Product and that a Respondent can demonstrate have been used, prior to the Acquisition Date, for any Retained Product that is the subject of an active (not discontinued or withdrawn) NDA or ANDA as of the Acquisition Date; and

2. in those instances in which (i) a Respondent is the holder of an ANDA or NDA for a Product that is the Therapeutic Equivalent of any Divestiture Product, (ii) the ANDA or NDA is not subject to an exclusive license to a Third Party, and (iii) the Product subject to such ANDA or NDA is a Retained Product, a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the ANDA or NDA for this Retained Product to reference or use in any Application related to that Divestiture Product.

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

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

GGGG. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed pursuant to this Order.

Decision and Order

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

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

Decision and Order

the Commission to accomplish the requirements of this Order; and/or

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

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

JJJ. “Right of Reference or Use” means the authority to rely upon, and otherwise use all of the following:

1. an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials);
2. Product Development Reports; or
3. Product Scientific and Regulatory Material;

for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.

KKKK. “SKU” means stock keeping unit.

LLLL. “Supply Cost” means a cost not to exceed any of the following: (i) a Respondent’s average direct cost per SKU or NDC Number in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) a Respondent’s lowest net

Decision and Order

price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit and any allocation or absorption of costs for excess or idle capacity; *provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Divestiture Product, but only if the "Supply Cost" specified in such Remedial Agreement during the first twelve (12) month period of a Respondent supplying the Contract Manufacture Product does not exceed a Respondent's lowest net price (*i.e.*, the final price per SKU or NDC Number charged by a Respondent net of all discounts, rebates, or promotions) of the relevant Divestiture Product to any of a Respondent's top 5 High Volume Accounts (as measured in units of the Divestiture Product purchased by those customers) for the relevant Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date.

MMMM. "Technology Transfer Standards" means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*:

Decision and Order

1. designating employees of a Respondent knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Monitor (if one has been appointed), for the purpose of effecting such delivery;
2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;
4. permitting employees of the Acquirer to visit the Respondent's facility from which the Divestiture Product will be transferred for the purposes of evaluating and learning the manufacturing process of such Divestiture Product and/or discussing the process with employees of Respondent involved in the manufacturing process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, methods to ensure batch or lot consistency), pharmaceutical development, and validation of the manufacturing of the Divestiture Product at the Respondent's facility; and
5. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:

Decision and Order

- a. manufacture the specified Divestiture Product in the quality and quantities achieved by a Respondent, or the manufacturer and/or developer of such Divestiture Product;
- b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
- c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

NNNN. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product.

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

PPPP. “United States” means the United States of America, and its territories, districts, commonwealths and possessions.

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

Decision and Order

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

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Group A Product Assets and grant the Divestiture Product License related to the Group A Products, absolutely and in good faith, to ANI Pharmaceuticals pursuant to, and in accordance with, the Group A Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of ANI Pharmaceuticals or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Group A Product Assets is incorporated by reference into this Order and made a part hereof;

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

provided further, that if Respondents have divested the Group A Product Assets to ANI Pharmaceuticals prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in

Decision and Order

which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Group A Product Assets to ANI Pharmaceuticals (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Azelastine Product Assets and the Olopatadine Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Perrigo), absolutely and in good faith, to Perrigo pursuant to, and in accordance with, the Azelastine /Olopatadine Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Perrigo or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Azelastine Product Assets or the Olopatadine Product Assets is incorporated by reference into this Order and made a part hereof;

provided however, that if Respondents have divested the Azelastine Product Assets or the Olopatadine Product Assets to Perrigo prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Azelastine Product Assets or the Olopatadine Product Assets (whichever is relevant) to Perrigo (including, but not limited to, entering into additional agreements or arrangements) as the

Decision and Order

Commission may determine are necessary to satisfy the requirements of this Order.

- C. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Fluocinonide Product Assets (to the extent that such assets are not already owned, controlled or in the possession of G&W), absolutely and in good faith, to G&W pursuant to, and in accordance with, the Fluocinonide Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of G&W or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the G&W Product Assets is incorporated by reference into this Order and made a part hereof;

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

- D. Prior to the Closing Date for each respective Divestiture Product, Respondent shall provide the Acquirer with the opportunity to review all contracts or agreements that are Product Contracts related to the Divestiture Products being acquired by that Acquirer for the purposes of the Acquirer's determination whether to assume such contracts or agreements.

Decision and Order

- E. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Product Assets to an Acquirer, and to permit the Acquirer to continue the Business of the Divestiture Product(s) being acquired by that Acquirer;

provided, however, Respondents may satisfy this requirement by certifying that the Acquirer for the Divestiture Product Assets has executed all such agreements directly with each of the relevant Third Parties.

- F. Respondents shall:
1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
 2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
 - a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
 3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide that Acquirer and the Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products

Decision and Order

acquired by that Acquirer that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;

4. not use, directly or indirectly, any such Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Products, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission to receive such information (*e.g.*, employees of a Respondent responsible for the Contract Manufacture or continued Development of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Divestiture Products to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products; and
7. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and

Decision and Order

Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products or in Development to become the Therapeutic Equivalent of a Divestiture Product *unless* authorized by the Acquirer of the particular Divestiture Product to do so.

- G. Respondents shall provide, or cause to be provided, to the Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
 2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed to a Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to such agreements that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of

Decision and Order

the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

- H. Respondents shall employ a staff of sufficient size, training, and expertise as is necessary to complete all of the transfers of the Product Manufacturing Technology to each of the Acquirers in a timely manner and to ensure that the Acquirer has sufficient assistance from Respondents to validate the manufacture of the Contract Manufacture Products being acquired by that Acquirer in commercial quantities, and in a manner consistent with cGMP at a facility chosen by the Acquirer.
- I. Respondents shall:
 - 1. upon reasonable written notice and request from the Acquirer to Respondents, Contract Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished dosage form drug product independently of Respondents, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of a Respondent from Persons other than Respondents;
 - 2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied by Respondents pursuant to a Remedial Agreement meet the relevant Agency-approved specifications;

Decision and Order

3. for the Contract Manufacture Product(s) to be marketed or sold in the United States, 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 Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the supplying Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further, however*, that this obligation shall not require such Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the supplying Respondent to the Acquirer in an agreement to Contract Manufacture;

4. give priority to supplying a Contract Manufacture Product to the Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
5. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by

Decision and Order

Respondents, and (ii) Respondents are able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure;

6. during the term of any agreement to Contract Manufacture, upon written request of that Acquirer or the Monitor (if any has been appointed), make available to the Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
7. for each Contract Manufacturer Product for which Respondents purchase the active pharmaceutical ingredient(s), components(s), or excipient(s) from a Third Party, provide that Acquirer with the actual price paid by Respondents for each active pharmaceutical ingredient(s), component(s), and excipient(s), respectively, used to manufacture that Contract Manufacture Product;
8. for each Contract Manufacturer Product for which Respondents are the source of the active pharmaceutical ingredient(s), component(s), or excipient(s), not charge the Acquirer any intracompany transfer profit for such active pharmaceutical ingredient(s), component(s) or excipient(s) in calculating the total price for the final finished Contract Manufacture Product to the Acquirer, but such charges shall only reflect Respondents' actual cost;
9. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
10. in the event Respondents become (i) unable to supply or produce a Contract Manufacture Product

Decision and Order

from the facility or facilities originally contemplated under a Remedial Agreement with an Acquirer and (ii) that Product is the subject of an ANDA: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondents use or have used to source their own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;

11. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture;
12. not be entitled to terminate any agreement to Contract Manufacture due to an 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;
13. shall notify the Commission at least ninety (90) days prior to terminating any agreement with an Acquirer to Contract Manufacture for any reason, and shall submit at the same time a copy of such notice to the Monitor; and
14. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondents and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the

Decision and Order

Contract Manufacture Products acquired by that Acquirer in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products.

The foregoing requirements to Contract Manufacture shall remain in effect with respect to each Contract Manufacture Product until the earliest of: (i) the date the Acquirer (or the Manufacturing Designee(s) of that Acquirer) is approved by the FDA to manufacture such Contract Manufacture Product for sale in the United States and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (ii) the date the Acquirer notifies the Commission and Respondents of their intention to abandon their efforts to manufacture the relevant Contract Manufacture Product; (iii) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the relevant Contract Manufacture Product; or (iv) five (5) years after the Closing Date.

- J. Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale (including administrative logistics of sales to the respective High Volume Accounts) related to each of the Divestiture Products to assist the Acquirer, in the transfer and integration of the Business related to the Divestiture Products into the Acquirer's business.
- K. Respondents shall require, as a condition of continued employment post-divestiture of the Divestiture Product

Decision and Order

Assets, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date, and each employee that has responsibilities related to the marketing or sales of those Retained Products that are the Therapeutic Equivalent of the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of the Respondents (other than as necessary to comply with the requirements of this Order).

- L. Not later than ten (10) days after the Closing Date, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Each Respondent shall provide a copy of the notification to the Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Each Respondent shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

Decision and Order

M. Respondents shall:

1. for a period of twelve (12) months after the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”;
2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however*, that the provision of such information may be conditioned upon the Acquirer’s or Proposed Acquirer’s written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in connection with considering whether to provide, or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer’s or Proposed Acquirer’s employees who need such access in connection with the specified and permitted use;

Decision and Order

3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer, and remove any impediments within the control of a Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to any Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

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

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall include a continuation of all

Decision and Order

employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the Divestiture Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

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

5. for a period of one (1) year after the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

Decision and Order

- N. If the Acquirer of the Aspirin/Dipyridamole ER Product Assets has not obtained all of the relevant Product Approvals necessary to manufacture (in a manner consistent with cGMP), market, and sell the Aspirin/Dipyridamole ER Products in commercial quantities by July 1, 2019, then, at the request of that Acquirer, Respondents shall:
1. grant an immediate license to that Acquirer to enable that Acquirer to market and sell the Amneal Aspirin/Dipyridamole ER Products;
 2. supply the Amneal Aspirin/Dipyridamole ER Products to that Acquirer in commercial quantities in time to enable the Acquirer to commence the delivery of the Amneal Aspirin/Dipyridamole ER Products to customers by October 1, 2019;
 3. make representations and warranties to the Acquirer that the Amneal/Dipyridamole ER Products supplied by Respondents pursuant to a Remedial Agreement meet the relevant Agency-approved specifications;
 4. agree to hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure of the Amneal Aspirin/Dipyridamole ER Products to be delivered in a timely manner *unless* (i) 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 (ii) Respondents are able to cure the supply failure not later than thirty (30) days after the receipt of notice from the Acquirer of a supply failure;
 5. give the firm purchase orders of the Acquirer for the Amneal Aspirin/Dipyridamole ER Products equal footing with the manufacture and supply of the Amneal Aspirin/Dipyridamole ER Products for Respondents' own use or sale; and

Decision and Order

6. not be entitled to terminate any agreement to supply the Amneal Aspirin/Dipyridamole ER Products to the Acquirer due to that Acquirer's 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;

The above-described requirements for the Respondents to license and supply the Amneal Aspirin/Dipyridamole ER Products shall continue until the earliest of the following dates: (i) the date that Acquirer terminates the license and supply; (ii) the date one (1) month after that Acquirer receives all relevant Product Approvals necessary to manufacture (in a manner consistent with cGMP), market, and sell the Aspirin/Dipyridamole ER Products in commercial quantities; or (iii) March 1, 2021.

- O. Until Respondents complete the divestitures required by this Order and fully provide, or cause to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the Acquirer:
 1. Respondents shall take actions as are necessary to:
 - a. maintain the full economic viability and marketability of the Businesses associated with that Divestiture Product;
 - b. minimize any risk of loss of competitive potential for that Business;
 - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;

Decision and Order

- d. ensure the assets related to each Divestiture Product are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the Business associated with each Divestiture Product;
 - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.
- P. Respondents shall not, in the United States:
1. use any of the Product Trademarks related to Divestiture Products or any mark confusingly similar to the Product Trademarks as a trademark, tradename, or service mark *except* as may be necessary to sell inventory of Divestiture Products in existence as of the Acquisition Date;
 2. attempt to register the Product Trademarks;
 3. attempt to register any mark confusingly similar to the Product Trademarks;
 4. challenge or interfere with an Acquirer's use and registration of the Product Trademarks acquired by that Acquirer; or
 5. challenge or interfere with an Acquirer's efforts to enforce its trademark registrations for and trademark rights in the relevant Product Trademarks against Third Parties.

Decision and Order

- Q. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer:
1. under any Patent owned by or licensed to a Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
 2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to a Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States. Respondents shall also covenant to that Acquirer that as a condition of any assignment or license from Respondents to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or

Decision and Order

offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from a Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- R. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States.
- S. For any patent infringement suit filed prior to the Closing Date in which a Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that a Respondent has prepared or is preparing to defend against as of the Closing Date, and where such a suit would have the potential directly to limit or interfere with the Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of

Decision and Order

marketing, sale, or offer for sale within the United States of such Divestiture Product(s); or (ii) the import, export, use, supply, distribution, sale, or offer for sale of the Divestiture Product(s) acquired by that Acquirer, into, from, or within the United States, that Respondent shall:

1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;
2. waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to that Divestiture Product.

T. The purpose of the divestiture of the Divestiture Product Assets and the provision of the related Product Manufacturing Technology (for the Contract Manufacture Products) and the related obligations imposed on the Respondents by this Order is:

1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the United States;
2. to create a viable and effective competitor that is independent of Respondents in the Business of each Divestiture Product within the United States; and
3. to remedy the lessening of competition resulting from the Acquisition as alleged in the

Decision and Order

Commission's Complaint in a timely and sufficient manner.

III.**IT IS FURTHER ORDERED** that:

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

Decision and Order

1. The Monitor shall have the power and authority to monitor each Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;
2. The Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission; and
3. The Monitor shall serve until divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is Contract Manufacture Product or an Aspirin/Dipyridamole ER Product, until the earliest of:
 - a. the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture the finished dosage form Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
 - b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondents of its intention to abandon its efforts to manufacture that Divestiture Product; or

Decision and Order

- c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture that Divestiture Product;

provided, however, that the Monitor's service shall not extend more than five (5) years after the Order Date unless the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's

Decision and Order

duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.

- H. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by the Acquirer with respect to the performance of a Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by a Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph VII.C., and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by the Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.
- I. Each Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and

Decision and Order

assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

IV.**IT IS FURTHER ORDERED** that:

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney

Decision and Order

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 this Order.

- 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 Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
 - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.

Decision and Order

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(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 two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by a Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer as required by

Decision and Order

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 five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the

Decision and Order

performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
 8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) 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 sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.

Decision and Order

- 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 this Paragraph.
- 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.

V.

IT IS FURTHER ORDERED that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, 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 an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. to assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products;

Decision and Order

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

provided further, however, that pursuant to this Paragraph V, a Respondent needing such access to original documents shall: (i) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (ii) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

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

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of each Respondent's obligation to the Acquirer pursuant to this Order.
- D. For each Divestiture Product that is a Contract Manufacture Product, Respondents shall include in the Remedial Agreement(s) related to that Divestiture Product a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product,

Decision and Order

as applicable, and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.

- E. No Respondent shall seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. No Respondent shall modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission, except as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5). Notwithstanding any term of the Remedial Agreement(s), any modification or amendment of any Remedial Agreement made without the prior approval of the Commission, or as otherwise provided in Rule 2.41(f)(5), shall constitute a failure to comply with this Order.

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

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition Date occurred, including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov.
- B. Within five (5) days of each Closing Date, Respondents shall submit to Commission staff a letter certifying the date on which that particular divestiture occurred, including a paper original submitted to the Secretary of the Commission and electronic copies to

Decision and Order

the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov.

- C. Within thirty (30) days after the Order Date, and every ninety (90) days thereafter until Respondents have (i) completed their obligations to Contract Manufacture the Contract Manufacture Products for an Acquirer, and (ii) fully provided the Product Manufacturing Technology related to the Divestiture Products to the Acquirer, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondents intend to comply, are complying, and have complied with these requirements of this Order. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Orders, including:
1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional and/or consulting services being provided by Respondents to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- D. One (1) year after the Order Date, annually for the next four (4) years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order. In addition to the foregoing, Respondents shall include in these reports a list containing (i) all of the Retained Products that are the Therapeutic Equivalent of a Divestiture Product and (ii) total sales in units and dollars in the United States

Decision and Order

of each of these Retained Products by Respondents for either the one-year period immediately preceding the report or the full calendar or fiscal year that immediately precedes the report.

- E. Respondents shall verify each compliance report with a notarized signature or sworn statement of the Chief Executive Officer or other officer or employee specifically authorized to perform this function, or self-verified in the manner set forth in 28 U.S.C. § 1746. Respondents shall submit an original and 2 copies of each compliance report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bccompliance@ftc.gov. In addition, Respondents shall provide a copy of each compliance report to the Monitor if the Commission has appointed one in this matter.

VIII.

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

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

Decision and Order

IX.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal place of business as identified in this Order, registered office of its United States subsidiary, or its headquarters address, the notified 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 business and other records and all documentary material and electronically stored information as defined in Commission Rules 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that this Order shall terminate on June 29, 2028.

By the Commission.

Decision and Order

**NON-PUBLIC APPENDIX I
ACQUISITION AGREEMENT****[Cover Page]****[Redacted From the Public Record Version, But Incorporated
By Reference]****NON-PUBLIC APPENDIX II.A
AGREEMENTS RELATED TO THE
GROUP A PRODUCTS REMEDY****[Cover Page]****[Redacted From the Public Record Version, But Incorporated
By Reference]****NON-PUBLIC APPENDIX II.B.
AGREEMENTS RELATED TO THE
AZELASTINE PRODUCT AND OLOPATADINE
PRODUCT REMEDY****[Cover Page]****[Redacted From the Public Record Version, But Incorporated
By Reference]**

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX II.C.
AGREEMENTS RELATED TO THE
FLUOCINONIDE PRODUCT REMEDY**

[Cover Page]

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

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Amneal Holdings, LLC, Amneal Pharmaceuticals LLC (collectively, “Amneal”), Impax Laboratories, Inc., and Impax Laboratories, LLC (collectively, “Impax”) that is designed to remedy the anticompetitive effects resulting from Amneal’s acquisition of equity interests of Impax. Under the terms of the proposed Consent Agreement, the parties are required to divest all of Impax’s rights and assets related to the following seven products to ANI Pharmaceuticals, Inc. (“ANI”): generic desipramine hydrochloride tablets; generic felbamate tablets; generic aspirin and dipyridamole extended release (“ER”) capsules; generic diclofenac sodium and misoprostol delayed release (“DR”) tablets; generic ezetimibe and simvastatin immediate release (“IR”) tablets; generic erythromycin tablets; and generic methylphenidate hydrochloride ER tablets. Pursuant to the Consent Agreement, the parties also are required to divest all of Impax’s rights and assets related to generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray to Perrigo Company plc (“Perrigo”), and to divest all of Impax’s rights and assets related to generic fluocinonide-E cream to G&W Laboratories (“G&W”).

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments from

Analysis to Aid Public Comment

interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again evaluate the proposed Consent Agreement, along with the comments received, to make a final decision as to whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to agreements dated October 17, 2017, Amneal proposes to acquire the equity interests of Impax in a series of transactions valued at approximately \$1.45 billion (the “Proposed Acquisition”). 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 current competition in the following three U.S. markets: (1) generic desipramine hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets. The Commission also alleges that the Proposed Acquisition would violate the aforementioned statutes by lessening future competition in the following seven U.S. markets: (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the Proposed Acquisition.

I. The Products and Structure of the Markets

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

The Proposed Acquisition would reduce current competition in the markets for three products: (1) generic desipramine

Analysis to Aid Public Comment

hydrochloride tablets; (2) generic ezetimibe and simvastatin IR tablets; and (3) generic felbamate tablets.

Desipramine hydrochloride, a tricyclic antidepressant, is sold by only three companies, other than Amneal and Impax, in the United States: Heritage Pharmaceuticals, Inc., Sandoz (a subsidiary of Novartis AG), and Teva Pharmaceutical Industries Ltd. (“Teva”).

Ezetimibe and simvastatin is used to improve cholesterol and lower triglycerides. Only four companies currently sell generic ezetimibe and simvastatin IR tablets in the United States: Amneal, Impax, Dr. Reddy’s Laboratories, and Teva.

Felbamate is an anticonvulsant used in the treatment of epilepsy. For generic felbamate tablets, Alvogen, and Wallace Pharmaceuticals, Inc. (“Wallace”) are the only two companies in addition to Amneal and Impax that sell the product in the United States.

The Proposed Acquisition also would reduce future competition in seven markets in which Amneal or Impax is a current competitor and the other is likely to enter the market: (1) generic aspirin and dipyridamole ER capsules; (2) generic azelastine nasal spray; (3) generic diclofenac sodium and misoprostol DR tablets; (4) generic erythromycin tablets; (5) generic fluocinonide-E cream; (6) generic methylphenidate hydrochloride ER tablets; and (7) generic olopatadine hydrochloride nasal spray.

Aspirin and dipyridamole is an antiplatelet therapy used to reduce the risk of stroke. Amneal is the only company currently selling generic aspirin and dipyridamole ER capsules in the United States, and Impax is one of only a limited number of suppliers capable of entering the market in the near future.

Azelastine nasal spray is used to treat seasonal allergies. Impax partners with Perrigo to sell generic azelastine nasal spray. In addition, Wallace and Apotex Inc. also sell the product. Amneal, one of a limited number of suppliers capable of entering the market for generic azelastine nasal spray in the near future,

Analysis to Aid Public Comment

already has tentative approval from the United States Food and Drug Administration (“FDA”).

Diclofenac sodium and misoprostol is used to provide pain relief while minimizing gastrointestinal side effects. Four companies—Amneal, Teva, Sandoz, and Exela Pharma Sciences LLC (“Exela”)—have approved ANDAs to sell generic diclofenac sodium and misoprostol DR tablets in the United States. In addition, Greenstone LLC, a Pfizer subsidiary, sells an authorized generic version. Sandoz does not sell its product directly to customers and supplies only to a private labeler. The Exela product, marketed by both Eagle Pharmaceuticals, Inc. and Dash Pharmaceuticals LLC, has limited sales. Impax, partnered with Micro Labs Limited, is one of only a few suppliers capable of entering the market for generic diclofenac sodium and misoprostol DR tablets in the near future.

Erythromycin is an antibiotic that had only one supplier, Arbor Pharmaceuticals, LLC, before the FDA approved Amneal’s ANDA for generic erythromycin tablets in March of 2018. Amneal is the only supplier of generic erythromycin tablets in the United States. Impax is one of only a few suppliers capable of entering the market for generic erythromycin in the near future.

Fluocinonide-E cream, a topical corticosteroid used to reduce swelling, redness, itching, and allergic reactions, is sold in generic form by Impax, Alvogen, Sun Pharmaceutical Industries Ltd., and Teva in the United States. Amneal is one of very few suppliers capable of entering the market for generic fluocinonide-E cream in the near future.

Methylphenidate hydrochloride is a central nervous system stimulant used to treat attention-deficit disorder and attention-deficit/hyperactivity disorder. Only four companies currently sell generic methylphenidate hydrochloride ER tablets in the United States: Amneal, Mylan N.V., Teva, and Trigen Labs. Impax is one of only a limited number of suppliers capable of entering the market for generic methylphenidate hydrochloride ER tablets in the near future.

Analysis to Aid Public Comment

Olopatadine hydrochloride nasal spray is used to treat seasonal allergies. Generic olopatadine hydrochloride nasal spray is sold in the United States by Sandoz, Apotex, and Impax partnered with Perrigo. Amneal is one of very few suppliers capable of entering the market in the near future.

II. Entry

Entry into the ten 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.

III. Competitive Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Amneal and Impax in the markets for generic desipramine hydrochloride tablets, generic ezetimibe and simvastatin IR tablets, and generic felbamate tablets. Generic desipramine hydrochloride tablets, generic ezetimibe and simvastatin IR tablets, and generic felbamate tablets are commodity products, and prices typically are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. Customers also raise concerns about their ability to source product at a competitive price if one supplier experiences manufacturing difficulties when there are fewer competitors in the market. The Proposed Acquisition would combine two of the only five companies selling generic desipramine hydrochloride tablets, and would combine two of the only four companies selling generic ezetimibe and simvastatin IR tablets and generic felbamate tablets, likely resulting in higher prices.

But for the proposed Consent Agreement, the Proposed Acquisition also is likely to delay the introduction of beneficial competition, and subsequent price decreases, by eliminating

Analysis to Aid Public Comment

future competition in seven markets in which either Amneal or Impax is a current competitor and the other is likely to enter. Multiple customers expressed concerns about the effect of the proposed merger on the market for generic aspirin and dipyridamole ER capsules, in which Amneal is the only current generic competitor and Impax is approved to enter. Impax is one of only three competitors providing generic azelastine nasal spray, and the imminent entry of Amneal likely would allow customers to negotiate more competitive prices and secure adequate supply. Impax is one of very few well-positioned entrants in the market for generic diclofenac sodium and misoprostol DR tablets, in which Amneal is one of four current competitors, and customers note that they would benefit from additional entry to negotiate pricing. Amneal is the only generic erythromycin tablet competitor, and Impax is one of a limited number of companies with products in development that upon entry would allow customers to negotiate lower prices. Amneal is the only foreseeable entrant in the market for generic fluocinonide-E cream, in which Impax is one of only three competitors. In the market for generic methylphenidate hydrochloride ER tablets, Amneal is one of four current competitors and Impax is one of few potential entrants. Finally, Amneal is one of only a few entrants poised to enter the market for generic olopatadine hydrochloride nasal spray, in which Impax is one of only three current competitors. Absent a remedy, the Proposed Acquisition likely would cause U.S. consumers to pay higher prices for the aforementioned generic products.

IV. The Consent Agreement

As the Commission explained in its remedy review, *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (hereafter "*The FTC Merger Remedies Study*")¹, products made at third-party manufacturing sites are easier to divest and involve less risk than the technology transfer from in-house manufacturing to a new facility, and thus

¹ See *The FTC's Merger Remedies 2006-2012: A Report of the Bureaus of Competition and Economics* (Jan. 2017) at 36-37, https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-com-petition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

Analysis to Aid Public Comment

help ensure the success of divestitures. As a result, in most cases, if one of the products is developed or manufactured by a third party, the Commission will require divestiture of that product.

Additionally, in mergers involving complex pharmaceutical products that are difficult to manufacture, the Commission generally will require the divestiture of an on-market product over a pipeline product to place the greater risk on the merging parties rather than the public, with exceptions for compelling and fact-specific reasons. When such compelling, fact-specific reasons exist, “The goal of a divestiture is to put the product development effort (including any pending regulatory filings) in the hands of a new firm with the same ability and incentive to bring the pipeline product to market.”²

The proposed Consent Agreement conforms to this approach and remedies the competitive concerns raised by the Proposed Acquisition in the generic azelastine nasal spray and generic olopatadine hydrochloride nasal spray markets by requiring Impax to return any rights and assets it has to its partner and ANDA-owner for these products, Perrigo. The proposed Consent Agreement remedies the competitive concerns raised by the Proposed Acquisition in the generic fluocinonide-E cream market by requiring Impax to return any rights and assets it has to its partner and ANDA-owner for this product, G&W. The parties must accomplish these divestitures no later than ten days after they consummate the Proposed Acquisition.

The proposed Consent Agreement remedies the competitive concerns raised by the Proposed Acquisition in seven of the markets at issue by requiring Impax to divest all of its rights and assets related to those products to ANI. ANI is a pharmaceutical corporation that develops, manufactures, sells, and distributes solid oral, liquid, and topical pharmaceutical products in the United States. ANI’s track record in developing and bringing to market pipeline products suggests that the divested products will be placed in the hands of a firm with the same ability and incentive to bring the products to market. As explained below, the Consent Agreement helps make that outcome more likely.

² See *The FTC’s Merger Remedies Study* at 31.

Analysis to Aid Public Comment

For two of the products that both Amneal and Impax currently market, generic desipramine hydrochloride tablets and felbamate tablets, Impax will assign its contract manufacturing agreements to ANI. For the third currently-marketed product, Amneal will supply ANI with generic ezetimibe and simvastatin IR tablets for two years with the option to extend for two additional years.

In four overlap markets in which Amneal has an on-market product and Impax has a product in development, Impax will divest its rights and assets to ANI rather than requiring Amneal to divest its on-market, in-house manufactured products. Each of these product markets has specific facts that warrant the divestiture of the Impax rights and assets rather than the Amneal product. Of note, three products—generic aspirin and dipyridamole ER capsules, generic methylphenidate hydrochloride ER tablets, and generic diclofenac sodium and misoprostol DR tablets—are more complicated to manufacture because they have extended or delayed release characteristics.

For generic aspirin and dipyridamole ER capsules, Amneal is the only manufacturer with a product on the market. Amneal manufactures this product in-house. Impax received FDA approval for its ANDA in 2017 and had expected to use a third-party manufacturer to launch its product. That manufacturer experienced some manufacturing difficulties and Impax had begun the process of developing the means to produce the product at its own facilities. With the divestiture, ANI will finalize the manufacturing process and expects to have the Impax drug on the market soon. Nevertheless, should ANI be unable to market its own version of this product by October 1, 2019, ANI has the option to source generic aspirin and dipyridamole ER capsules from Amneal until ANI obtains the necessary regulatory approvals or through March 1, 2021, whichever date is earlier. This ensures that ANI will be able to market a competing product near the time Impax likely would have had the product on market, and provides the incentive for ANI to manufacture and market its own product. An alternative divestiture of the Amneal product would involve more risk and could jeopardize the only generic product on the market.

Analysis to Aid Public Comment

The FDA approved Amneal's ANDA for generic methylphenidate hydrochloride ER tablets in February 2018. Impax also has an approved ANDA. Impax's product is contract manufactured, but the contract manufacturer needs to resolve manufacturing issues before it can resume manufacturing the product. It will be less risky for Impax to assign its manufacturing contract to ANI than to affect a technology transfer from Amneal for this complex product, and it will put the product in ANI's hands, which has the same ability and incentive as Impax to bring methylphenidate hydrochloride ER tablets to market. Thus, the proposed Order requires the divestiture of Impax's rights and assets to ANI.

For generic diclofenac sodium and misoprostol DR tablets, Amneal has an on-market in-house manufactured product, and Impax is partnered with Micro Labs to commercialize a competing product. Impax holds only marketing rights to the product; Micro Labs is responsible for development and manufacturing. Impax will transfer its marketing agreement with Micro Labs to ANI, and Micro Labs will manufacture the product for ANI for the current contract term.

For erythromycin tablets, Amneal launched its product in March 2018, and only one other competitor, Arbor Pharmaceuticals, is currently selling erythromycin tablets. Amneal manufactures the erythromycin tablets in-house. Impax is one of a few companies developing the product, and once approved, it plans to outsource the manufacturing. Here, the easier-to-divest product is the Impax drug in development. Thus, Commission staff considers it prudent to leave the in-house Amneal-manufactured product with the merged firm, an ongoing and viable competitor to Arbor. Further, Impax will transfer all of its assets related to its development of erythromycin tablets to ANI, which has the same ability and incentive to bring a competing third erythromycin tablet to market.

The proposed Order also requires Amneal to provide transitional services to ANI, Perrigo, and G&W to assist them in establishing their manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture the ten products at issue in

Analysis to Aid Public Comment

substantially the same manner and quality employed or achieved by Impax. It also includes advice and training from knowledgeable employees of the parties. Under the proposed Consent Agreement, the Commission also will appoint an Interim Monitor.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that ANI, Perrigo, and/or G&W are not acceptable acquirers, or that the manner of the divestitures is not acceptable, the proposed Order requires the parties to unwind the sale of rights to ANI, Perrigo, and/or G&W and then divest the affected products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

INTERLOCUTORY, MODIFYING,
VACATING, AND MISCELLANEOUS
ORDERS

IN THE MATTER OF

**LOUISIANA REAL ESTATE APPRAISERS
BOARD**

Docket No. 9374. Order, January 10, 2018

Order scheduling oral argument on Respondent's Motion to Dismiss Complaint and Complaint Counsel's Motion for Partial Summary Decision.

ORDER SCHEDULING CONSOLIDATED ORAL ARGUMENT AND
EXTENDING DEADLINES FOR COMMISSION RULINGS

On November 27, 2017, Respondent Louisiana Real Estate Appraisers Board filed a Motion to Dismiss Complaint in this proceeding. On that same date, Complaint Counsel submitted a Motion for Partial Summary Decision. Both motions raise issues regarding application of the state action doctrine. Respondent's Motion argues that re-promulgation of a regulation, establishment of new procedures, and various steps to address ongoing or prospective effects of prior regulation – all of which have occurred after issuance of the Commission's Complaint – bring Respondent's activities within the scope of the state action doctrine and render this proceeding moot. Complaint Counsel's Motion seeks summary determination that two of Respondent's defenses – asserting that "[t]he Complaint fails adequately to allege that the Board has a controlling number of active participants in the relevant **residential** appraisal market" (emphasis in original) and that "LREAB is immune from antitrust liability under *Parker v. Brown*, 317 U.S. 341 (1943)" – should be dismissed. Each party has since opposed the other's motion and has filed a timely Reply in support of its own motion.

Respondent has requested oral argument regarding its Motion to Dismiss, and we believe that entertaining oral argument on both motions would be beneficial. Although both parties should be prepared to address all issues raised by both motions, we