

Complaint

IN THE MATTER OF

**MYLAN LABORATORIES, INC.,
AND
E. MERCK oHG****CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT***Docket C-4200; File No. 071 0164**Complaint, September 26, 2007 – Decision, November 1, 2007*

The consent order addresses the \$6.6 billion proposed acquisition by Mylan of Merck's generic subsidiary ("Merck Generics") and all subsidiaries held directly by Merck Generics. The complaint alleged that the Merger Agreement violates of Section 5 of the FTC Act, and the acquisition, if consummated, would violate of Section 7 of the Clayton Act by substantially lessening competition and creating a monopoly in the U.S. markets for the manufacture and sale of (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets. The Consent Agreement requires Mylan and Merck are to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically the consent order requires that Merck divest its assets in the Products to Amneal.

Participants

For the *Commission*: Daniel P. Ducore, Leslie Farber, Mark Frankena, Roy Levy, Michael R. Moiseyev, David Von Nirschl, David P. Wales, Kari A. Wallace, and Alissa N. Wantman.

For the *Respondents*: Alexandra Carter and Katherine Forrest, Cravath, Swaine & Moore LLP; Andrea Haggerty and Mary Lou Steptoe, Skadden, Arps, Slate, Meagher & Flom LLP.

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COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Mylan Laboratories, Inc. (“Mylan”), a corporation subject to the jurisdiction of the Commission, has agreed to certain assets of E. Merck oHG and its controlled entity Merck KGaA (collectively “Merck”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act (“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. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Mylan and Merck, individually and collectively.

II. RESPONDENTS

4. Respondent Mylan is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

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5. Respondent Merck is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at 250 Frankfurter Street, Darmstadt, Germany. Merck markets and sells generic products in the United States through its U.S. subsidiary, Genpharm L.P., located at 150 Motor Parkway, Suite 309 in Hauppauge, New York 11788. Merck also has an agreement with Par Pharmaceutical Companies, Inc. (“Par”), whereby Merck manufactures a number of generic products and Par markets them in the United States. Merck receives a royalty payment on Par’s sales of these products. Merck is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

6. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. THE PROPOSED ACQUISITION

7. On May 12 and 13, 2007, Mylan and Merck entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Mylan proposes to acquire Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries for approximately \$6.6 billion.

IV. THE RELEVANT MARKETS

8. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of the following generic pharmaceutical products:

- a. acebutolol hydrochloride capsules;

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- b. flecainide acetate tablets;
- c. guanfacine hydrochloride tablets;
- d. nicardipine hydrochloride capsules; and
- e. sotalol hydrochloride AF tablets.

9. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant line of commerce.

V. THE STRUCTURE OF THE MARKETS

10. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Acebutolol is a beta blocker used to treat hypertension. The market for generic acebutolol capsules is already highly concentrated with a preacquisition HHI of 5,158 points. The proposed merger would raise the HHI concentration by 4,842 points and create a monopoly in the acebutolol market.

11. Generic flecainide tablets are produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (“Roxane”), Barr Pharmaceuticals Inc. (“Barr”), and Ranbaxy Pharmaceuticals Inc. (“Ranbaxy”). Flecainide is an anti-arrhythmia drug used to treat heart problems. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. Combined, Barr and Ranbaxy account for less than 5 percent market share. The proposed acquisition would increase the market concentration by 2,344 points, resulting in a post-merger HHI of 6,369 points.

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12. Guanfacine, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (“Watson”), Merck/Par, Actavis Group hf. (“Actavis”), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States. Mylan, Merck/Par, Watson and Actavis, however, are the only suppliers of the 2 mg formulation of guanfacine. The proposed acquisition would raise the current HHI concentration in the generic guanfacine tablet market from 3,824 points to 4,908 points.

13. Nicardipine is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (“Teva”) are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed acquisition would raise the HHI from its current level of 4,170 points to 7,631 points and leave Teva as the only competitor to the combined Mylan/Merck in the generic nicardipine market.

14. Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is led by Apotex Inc. (“Apotex”). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007.

VI. ENTRY CONDITIONS

15. Entry into the relevant product markets described in Paragraph 8 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant

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markets are relatively small and in decline, limiting sales opportunities for any potential new entrant.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

a. by eliminating actual, direct, and substantial competition between Mylan and Merck in the market for the manufacture and sale of generic acebutolol capsules, thereby: (1) increasing the likelihood that Mylan will be able to unilaterally exercise market power in this market, (2) increasing the likelihood that customers would be forced to pay higher prices; and

b. by eliminating this actual, direct, and substantial competition between Mylan and Merck in the markets for the manufacture and sale of generic flecainide tablets, generic guanfacine tablets, generic nicardipine capsules, and generic sotalol AF tablets, thereby: (1) increasing the likelihood that Mylan will be able to unilaterally exercise market power in these markets, (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors, and (3) increasing the likelihood that customers would be forced to pay higher prices.

VIII. VIOLATIONS CHARGED

17. The Merger Agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the Clayton Act, as

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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-sixth day of September, 2007, issues its Complaint against said Respondents.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan Laboratories Inc. (“Mylan”) of the Merck Generics Business of Respondent E. Merck oHG (“Merck”), and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, 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; and

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

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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 Mylan Laboratories Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Suite 400, Canonburg, Pennsylvania 15317.

2. Respondent E. Merck oHG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address at Frankfurter Strasse 250, D-64293, Germany and the address of the principal place of business of its United States subsidiary, EMD, Inc. at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

3. Merck Generic Business includes the following: Merck dura GmbH, Merck Generics Group B.V., EMD, Inc., Merck Generics Belgium B.V.B.A. and Merck Genericos S.L.

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

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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, the Decision and Order), which are attached hereto as Appendix A and incorporated herein by reference and made a part hereof, shall apply:

- A. “Mylan” means Mylan 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 Mylan and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include the Merck Generics Business of Respondent Merck.
- B. “Merck” means E. Merck oHG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck (including, but not limited to, the Merck Generics Business), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Merck Generics Business” means the generic pharmaceutical business operated by Merck KgaA including, the following: Merck dura GmbH (Alsfelder Str. 19, 64289, Darmstadt, Germany); Merck Generics Group B.V. (Rokin 55, Amsterdam, Netherlands 1012 KK); EMD, Inc. (2751 Napa Valley Corporate Drive, Napa, CA 94558); Merck Generics Belgium B.V.B.A. (3090 Overijse, Brusselsesteenweg 288); Merck Genericos S.L. (Poligono Merck, Mollet de Valles Spain 8100; and all other such

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entities as are listed item 6(a) of the *Notification and Report Form for Certain Mergers and Acquisitions* filed by Respondent Merck dated June 5, 2007, in connection with the Acquisition, and the directors, officers, employees, agents, representatives, predecessors, successors, and assigns of the foregoing entities; and the joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by the foregoing entities, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- D. “Respondents” means Mylan and Merck, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Divestiture Assets” means the Acebutolol Product Assets, Flecainide Product Assets, Guanfacine Product Assets, Nicardipine Product Assets, and the Sotalol Product Assets, as defined in the attached Decision and Order.
- G. “Divestiture Product Business(es)” means the relevant Respondent’s business within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing, and sale of each Divestiture Product and the assets related to such business, including, but not limited to, the Divestiture Assets.
- H. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

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- J. “Pre-Acquisition Marketing Plan” means any marketing or sales plan that was planned or implemented within the period immediately prior to the Acquisition and without consideration of the influence of the pending Acquisition for the Divestiture Product Businesses

II.

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

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses, 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 the Divestiture Product Businesses except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Divestiture 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 Divestiture Product Businesses.
- B. Respondents shall maintain the operations of the 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 businesses) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors, including, but not limited to, the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Divestiture Product Businesses. Respondents’

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responsibilities shall include, but are not limited to, the following:

1. providing the 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 businesses and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Divestiture Product Businesses;
2. continuing, at least at their scheduled pace, any additional expenditures for the Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing and sales expenditures;
3. provide such resources as may be necessary to respond to competition against the Divestiture Products and/or to prevent any diminution in sales of the Divestiture Products during and after the Acquisition process and prior to divestiture of the related Divestiture Assets;
4. provide such resources as may be necessary to maintain the competitive strength and positioning of the Divestiture Products at the High Volume Accounts;
5. making available for use by the 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 business, including the Divestiture Assets;
6. providing the Divestiture Product Businesses with such funds as are necessary to maintain the full economic

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viability, marketability and competitiveness of the Divestiture Product Businesses; and

7. providing such support services to the Divestiture Product Businesses as were being provided to these businesses by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Product's most recent Pre-Acquisition Marketing Plan.
- D. Until the Closing Date for each respective set of Divestiture Assets, Respondents shall provide all the related Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the relevant Divestiture Products consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture and to ensure successful execution of the Pre-Acquisition Marketing Plans related to the relevant Divestiture Products. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the respective Divestiture Assets has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and additional incentives as may be necessary to prevent any diminution of the relevant Divestiture Product's competitiveness.
- E. Respondents shall:
1. for a period of at least six (6) months from the relevant Closing Date, provide the relevant Acquirer with the opportunity to enter into employment contracts with the

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Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”; and

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondents 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;
3. during the Divestiture Product Core Employee Access Period, not interfere with the hiring or employing by the relevant Acquirer of Divestiture Product Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with such Acquirer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the relevant Acquirer; *provided, however*, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.E.3. shall not prohibit Respondents from

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continuing to employ any Divestiture Product Core Employee under the terms of such employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer to such employee.

F. Pending divestiture of the relevant Divestiture Assets, Respondents shall:

1. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following:
 - a. the requirements of the Orders;
 - b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the relevant Acquirer or other persons specifically authorized by the Acquirer to receive such information;
3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products; and

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4. 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 under this Order to Maintain Assets from receiving for any reason or purpose.
- G. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:
 1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition, and or that contain the same active pharmaceutical ingredient as the relevant Divestiture Products; and/or
 3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with

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return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondent Mylan's headquarters address and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

- H. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that the Orders shall not be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- I. 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 respective transfer to the Acquirer(s), to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

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

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim 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. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders, and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Mylan, which consent shall not be unreasonably withheld. If Respondent Mylan has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Mylan of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent Mylan shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Decision and Order in this matter, Respondents shall consent

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to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:

1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission;
3. The Interim Monitor shall serve until the date of completion by Respondents of the divestiture of all Divestiture Assets and the transfer of the Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
 - a. with respect to each Divestiture Product, the date the relevant Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
 - b. with respect to each Divestiture Product, the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - c. with respect to each Divestiture Product, the date of

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written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement to Contract Manufacture such Divestiture Product.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim 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 Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are

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reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order to Maintain Assets and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement;

provided, however, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.

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- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the relevant provisions of the Decision and Order in this matter.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets or the relevant provisions of the Decision and Order in this matter 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 becomes final, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A., II.B., and II.C. of the related Decision and Order in this matter, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to

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Maintain Assets and the related Decision and Order; *provided, however*, that, after the Decision and Order in this matter becomes final, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VI of the Decision and Order.

V.

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

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

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarter's address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of

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

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

VII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on the earlier 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
 - B. The latter of:
 - 1. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and each Interim 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 such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
 - 2. the day the related Decision and Order becomes final.
- By the Commission.

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APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS
AGREEMENT CONTAINING CONSENT ORDER
AND
PROPOSED DECISION AND ORDER

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan Laboratories Inc. (“Mylan”) of the Merck Generics Business of Respondent E. Merck oHG (“Merck”), and Respondents having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, 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; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint,

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other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Mylan Laboratories Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Suite 400, Canonburg, Pennsylvania 15317.

2. Respondent E. Merck oHG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address at Frankfurter Strasse 250, D-64293, Germany and the address of the principal place of business of its United States subsidiary, EMD, Inc. at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

3. Merck Generic Business includes the following: Merck dura GmbH, Merck Generics Group B.V., EMD, Inc., Merck Generics Belgium B.V.B.A. and Merck Genericos S.L.

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

Decision and Order

ORDER**I.**

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

- A. “Mylan” means Mylan 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 Mylan and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include the Merck Generics Business of Respondent Merck.
- B. “Merck” means E. Merck oHG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck (including, but not limited to, the Merck Generics Business), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Merck Generics Business” means the generic pharmaceutical business operated by Merck KgaA including the following: Merck dura GmbH (Alsfelder Str. 19, 64289, Darmstadt, Germany); Merck Generics Group B.V. (Rokin 55, Amsterdam, Netherlands 1012 KK); EMD, Inc. (2751 Napa Valley Corporate Drive, Napa, CA 94558); Merck Generics Belgium B.V.B.A. (3090 Overijse, Brusselsesteenweg 288); Merck Genericos S.L. (Poligono Merck, Mollet de Valles Spain 8100; and all other such entities as are listed item 6(a) of the *Notification and Report Form for Certain Mergers and Acquisitions* filed by Respondent Merck dated June 5, 2007, in connection with the Acquisition, and the directors, officers, employees,

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agents, representatives, predecessors, successors, and assigns of the foregoing entities; and the joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by the foregoing entities, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- D. “Respondents” means Mylan and Merck, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Acebutolol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:
 - 1. ANDA No. 75-047 (Acebutolol in the 200 mg and 400 mg dosage strengths); and
 - 2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Acebutolol Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient acebutolol in the dosage strengths identified above.

- G. “Acebutolol Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Acebutolol Products to the extent legally transferable, including the research, Development,

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manufacture, distribution, marketing, and sale of the Acebutolol Products, including, without limitation, the Categorized Assets related to the Acebutolol Products.

H. “Acquirer” means the following:

1. an entity specified by name in this Order to acquire particular assets or rights that Respondents are 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; or
2. an entity approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.

I. “Acquisition” means the Respondent Mylan’s acquisition of fifty percent (50%) or more of the voting securities of the Merck Generics Business pursuant to the executed Share Purchase Agreement by and between Merck Generics Holding GmbH, Merck S.A., Merck Internationale Beteiligungen GmbH (collectively, “Sellers”), Merck KGaA (“Seller’s Guarantor” and “Seller’s Representative”) and Mylan Laboratories Inc. (“Purchaser”) dated May 12/13, 2007.

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

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- K. “Amneal” means Amneal Pharmaceuticals, L.L.C., a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 209 McLean Boulevard, Paterson, New Jersey 07504.
- 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, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondents and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between Respondents and the FDA related thereto.
- M. “Categorized Assets” means the following assets related to the specified Divestiture Product(s):
1. all Product Intellectual Property related to such Divestiture Product(s)
 2. perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold,

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imported, or exported the Divestiture Product(s) within the specified Geographic Territory;

3. all Product Approvals related to such Divestiture Product(s);
4. all Product Manufacturing Technology related to such Divestiture Product(s);
5. all Product Marketing Materials related to such Divestiture Product(s);
6. all Website(s) related to such Divestiture Product(s);
7. a list of all of the NDC Numbers related to such Divestiture Product(s), 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 Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
 - b. to prohibit Respondents from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s);
 - c. to seek to change any cross-referencing by a customer of those NDC Numbers with the Retained Product(s) (including the right to receive notification from Respondents of any such cross-referencing that is discovered by Respondents);
 - d. to seek cross-referencing from a customer of those NDC Numbers with the relevant Acquirer's NDC Numbers related to the Divestiture Product(s);

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- e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
 - f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such numbers by Respondents prior to such notification(s) being disseminated to the customer(s);
- 8. all rights to all of Respondents' Applications related to such Divestiture Product(s);
 - 9. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);
 - 10. all Product Development Reports related to such Divestiture Product(s);
 - 11. at the relevant Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Acquirer on or before the Closing Date);
 - 12. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;
 - 13. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to

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be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);

14. a list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture Products to such customers 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 such Divestiture Products on behalf of the High Volume Account and his or her business contact information
15. at the relevant Acquirer's option 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 such Divestiture Product(s);
16. copies of all unfilled customer purchase orders for such Divestiture Product(s) as of the Closing Date, to be provided to the relevant Acquirer not later than two (2) days after the Closing Date;
17. at the relevant Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Divestiture Products; and
18. all of the Respondents' books, records, and files directly related to the foregoing or to such Divestiture Product(s);

provided, however, that "Categorized Assets" shall not include: (1) documents relating to Respondents' general business strategies or practices relating to research,

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Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products; (2) shall not include administrative, financial, and accounting records; (3) quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Divestiture Product(s); and (4) any real estate and the buildings and other permanent structures located on such real estate;

provided further, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such Divestiture Product(s) and to other Products or businesses of the Respondents and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Divestiture Product(s); or (2) for which the relevant party has a legal obligation to retain the original copies, the relevant party 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 relevant Acquirer, the relevant party shall provide such Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that Respondents provide the relevant Acquirer with the above-described information without requiring Respondents completely to divest themselves of information that, in content, also relates to Retained Product(s).

- N. “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.

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- O. "Closing Date" means, as to each Divestiture Product, the date on which Respondent(s) (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.
- P. "Confidential Business Information" means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Divestiture Product(s); *provided however*, that the restrictions contained in this Order regarding the use, conveyance, provision, or disclosure of "Confidential Business Information" shall not apply to the following:
1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by Respondents;
 2. information related to the Divestiture Products that Respondent Mylan can demonstrate it obtained without the assistance of Respondent Merck prior to the Acquisition;
 3. information that is required by Law to be publicly disclosed;
 4. information that does not directly relate to the Divestiture Product(s);
 5. information relating to Respondents' general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or

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6. information specifically excluded from the Categorized Assets.
- Q. “Contract Manufacture” means the manufacture of a Divestiture Product to be supplied by Respondents or a Designee to an Acquirer.
- R. “Designee” means any entity other than Respondents that will manufacture a Divestiture Product for an Acquirer.
- S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- T. “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 Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee; *provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is

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provided in such Remedial Agreement for that Divestiture Product.

- U. “Divestiture Product(s)” means the following Products: the Acebutolol Products, the Flecainide Products, Guanfacine Products, Nicardipine Products, and Sotalol Products, individually and collectively.
- V. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- W. “Divestiture Product Releasee(s)” means the Acquirer for the assets related to a particular Divestiture Product or any entity controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.
- X. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- Y. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- Z. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

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AA. “Effective Date” means the date on which the Acquisition occurs.

BB. “Flecainide Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 75-442 (Flecainide in 50 mg, 100 mg, and 150 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Flecainide Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient flecainide in the dosage strengths identified above.

CC. “Flecainide Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Flecainide Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Flecainide Products, including, without limitation, the Categorized Assets related to the Flecainide Products.

DD. “Guanfacine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

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1. ANDA No. 75-109 (Guanfacine in 1 mg and 2 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Guanfacine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient guanfacine in the dosage strengths identified above.

EE. “Guanfacine Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Guanfacine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Guanfacine Products, including, without limitation, the Categorized Assets related to the Guanfacine Products.

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

1. “Asset Purchase Agreement” by and between Genpharm, Inc., Genpharm LP, Alphapharm Pty. LTD. and Amneal Pharmaceuticals, LLC, dated August 30, 2007, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. “Transitional Supply Agreement” by and between Genpharm, Inc. and Amneal Pharmaceutical LLC (attached as “Exhibit A” to the “Asset Purchase Agreement”), and all amendments, exhibits, attachments, agreements, and schedules thereto; and

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3. “Transitional Supply Agreement” by and between Alphapharm PTY. LTD..and Amneal Pharmaceutical LLC (attached as “Exhibit B” to the “Asset Purchase Agreement”), and all amendments, exhibits, attachments, agreements, and schedules thereto;

related to the Acebutolol Product Assets, Flecainide Product Assets, Guanfacine Product Assets, Nicardipine Product Assets, and the Sotalol Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Divestiture Product Agreements are attached to this Order and contained in non-public Appendix II.A.

GG. “Geographic Territory” shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.

HH. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

II. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from either Respondent (whichever Respondent is relevant to such Divestiture Product) was, is, or is projected to be among the top twenty highest of such purchase amounts by that Respondent’s (whichever Respondent is relevant to such Divestiture Product) U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date

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for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

JJ. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

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

LL. “NDC Numbers” means the National Drug Code number(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

MM. “Nicardipine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 74-928 (Nicardipine in 20 mg and 30 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Nicardipine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient nicardipine in the dosage strengths identified above.

NN. “Nicardipine Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to

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Respondent Merck's business within the Geographic Territory related to the Nicardipine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Nicardipine Products, including, without limitation, the Categorized Assets related to the Nicardipine Products.

OO. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

PP. "Patents" means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by Respondents as of the Closing Date (*except* where this Order specifies a different time).

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

RR. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.

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SS. “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 the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.

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

1. that make specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product(s) from Respondent (whichever Respondent is relevant to such Divestiture Product) unless such contract applies generally to the divesting entity’s sales of Products to that Third Party;
2. pursuant to which Respondent (whichever Respondent is relevant to such Divestiture Product) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);
3. relating to any clinical trials involving the Divestiture Product(s);
4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;

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5. relating to the particularized marketing of the Divestiture Product(s) or educational matters relating solely to the Divestiture Product(s);
6. pursuant to which a Third Party manufactures or packages the Divestiture Product(s) on behalf of Respondent (whichever Respondent is relevant to such Divestiture Product);
7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the Divestiture Product(s) to Respondent (whichever Respondent is relevant to such Divestiture Product);
8. pursuant to which a Third Party is licensed by Respondent (whichever Respondent is relevant to such Divestiture Product) to use the Product Manufacturing Technology;
9. constituting confidentiality agreements involving the Divestiture Product(s);
10. involving any royalty, licensing, or similar arrangement involving the Divestiture Product(s);
11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Divestiture Products to Respondent (whichever Respondent is relevant to such Divestiture Product) including, but not limited to, consultation arrangements; and/or
12. pursuant to which any Third Party collaborates with Respondent (whichever Respondent is relevant to such Divestiture Product) in the performance of research, Development, marketing, distribution or selling of the

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Divestiture Product(s) or the Divestiture Product(s) business;

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

UU. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers; all promotional materials for patients; educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all copyrights in raw data relating to clinical trials of the Divestiture Product(s), all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the Divestiture Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all copyrights in records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call

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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 the Divestiture Product(s) or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

VV. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product(s);
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product(s);
4. all correspondence to the Respondent (whichever Respondent is relevant to such Divestiture Product) from the FDA and from the Respondent (whichever Respondent is relevant to such Divestiture Product) to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent (whichever Respondent is relevant to such Divestiture Product) related to the specified Divestiture Product;

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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(s);
7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
8. FDA approved patient circulars and information related to the specified Divestiture Product(s);
9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);
10. summary of Product complaints from physicians related to the specified Divestiture Product(s);
11. summary of Product complaints from customers related to the specified Divestiture Product(s); and
12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

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

1. a complete and accurate list containing the name of each relevant employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement);
2. with respect to each such employee, the following information:

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- a. the date of hire and effective service date;
 - b. job title or position held;
 - c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal;
 - d. the base salary or current wages;
 - e. the most recent bonus paid, aggregate annual compensation for Respondents' last fiscal year and current target or guaranteed bonus, if any;
 - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
 - g. any 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.

XX. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;

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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 and copyrights and registrations thereof;

provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Mylan” or “Merck”, or the corporate names or corporate trade dress of any other corporations or companies owned by Respondents or the related logos.

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

1. Patents that are related to a Divestiture Product that Respondents can demonstrate have been routinely used, prior to the Effective Date, by either Respondent (whichever Respondent is relevant to such Divestiture Product) for a Retained Product(s) that:
 - a. has been marketed or sold on an extensive basis by either Respondent (whichever Respondent is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or
 - b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by either Respondent; and

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2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that Respondents can demonstrate have been routinely used, prior to the Effective Date, by either Respondent (whichever Respondent is relevant to such Divestiture Product) for a Retained Product(s) that:
 - a. has been marketed or sold on an extensive basis by either Respondent (whichever Respondent is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or
 - b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by either Respondent;

provided however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Acquirer; *provided further, however*, that in such cases, Respondents may take a license back from the Acquirer for such intellectual property for use in connection with the Retained Products and such a license to Respondents may be perpetual, fully paid-up and royalty-free license(s) with rights to sublicense.

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ZZ. “Product Manufacturing Employees” means all salaried employees of Respondents who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product(s) (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.

AAA. “Product Manufacturing Technology” means:

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

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BBB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchases information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product(s); provided however, “Product Marketing Materials” excludes the pricing of each of the Divestiture Products to customers.

CCC. “Product Research and Development Employees” means all salaried employees of Respondents who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (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.

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

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

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

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

1. any agreement between Respondents 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, 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;
2. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents 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;

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3. any agreement between Respondents 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, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents 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.

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

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

JJJ. “Sotalol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 77-070 (Sotalol AF in 80 mg, 120 mg, and 160 mg dosage strengths); and

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2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Sotalol Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient sotalol in the dosage strengths identified above.

KKK. “Sotalol Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Sotalol Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Sotalol Products, including, without limitation, the Categorized Assets related to the Sotalol Products.

LLL. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) 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.

MMM. “Third Party(ies)” means any private entity other than the following: Respondents or the relevant Acquirer for the affected assets, rights and Divestiture Product(s).

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NNN. “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 Respondents; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey their rights, if any, therein; or (2) content unrelated to the Product(s).

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

- A. Not later than ten (10) days after the Effective Date, Respondents shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, absolutely and in good faith, to Amneal pursuant to, and in accordance with, the Generic Divestiture Product Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Amneal or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, respectively, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets,

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the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Amneal is not an acceptable purchaser of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets then Respondents shall immediately rescind the transaction with Amneal, in whole or in part, as directed by the Commission, and shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, as is relevant, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a(n) Acquirer(s) and only in a manner that receives the prior approval of the Commission;

provided further that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, 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 Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal (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.

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- B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to the relevant Acquirer(s), and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products;

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

- C. Respondents shall transfer the Product Manufacturing Technology related to the relevant Divestiture Product to the relevant Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondents shall, *inter alia*:
1. designate employees of Respondents knowledgeable with respect to such Product Manufacturing Technology to a committee for the purposes of communicating directly with such Acquirer and the Interim Monitor (if any has been appointed) for the purposes of effecting such transfer;
 2. prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the relevant Divestiture Product, such protocols and acceptance criteria to be subject to the approval of the Acquirer;
 3. prepare and implement 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 Product Manufacturing Technology to the Acquirer; and

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4. upon reasonable written notice and request from the Acquirer to Respondents, provide in a timely manner, at no greater than Direct Cost, assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to:
 - a. manufacture the relevant Divestiture Products in the same quality achieved by the Respondents and in commercial quantities;
 - b. obtain any Product Approvals necessary for the Acquirer to manufacture, sell, market or distribute the relevant Divestiture Product; and
 - c. receive, integrate, and use such Product Manufacturing Technology.

D. Respondents shall:

1. upon reasonable written notice and request from the Acquirer to Respondents, Respondents shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the relevant Divestiture Products at Respondents' Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the relevant finished drug product independently of Respondents and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components specified in the Respondents' Application(s) for the Product from entities other than Respondents;

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2. Respondents shall make representations and warranties to the Acquirer that the Product(s) supplied through Contract Manufacture pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Product(s) to be marketed or sold in the Geographic Territory, Respondents shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by Respondents to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. Any Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the ingredients and/or components in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer; *provided further* that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Products supplied to the Acquirer pursuant to such Remedial Agreement by Respondents to meet cGMP;

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3. Respondents shall make representations and warranties to the Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Products in a timely manner as required by a Remedial Agreement unless Respondents can demonstrate that their failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents; *provided, however*, that in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on Respondents' aggregate liability for such a breach;
4. during the term of the Contract Manufacture between Respondents and the Acquirer, upon request of the Acquirer or Interim Monitor (if any has been appointed), Respondents shall make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date;
5. during the term of the Contract Manufacture between Respondents and the Acquirer, maintain manufacturing facilities necessary to manufacture each of the Divestiture Products in finished form (suitable for sale to the ultimate consumer/patient); and
6. during the term of the Contract Manufacture between Respondents and the Acquirer, provide consultation with knowledgeable employees of Respondents and training, at the request of the Acquirer and at a facility chosen by

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the Acquirer, for the purposes of enabling the Acquirer (or the Designee of the Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by the Respondents 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 Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, II.D.1. - 6., shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date the relevant Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (2) the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or (3) the date of written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product.

E. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the relevant Divestiture Product(s);
2. deliver such Confidential Business Information as follows:

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- a. in good faith;
 - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
 - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to the Acquirer, provide the Acquirer and the Interim 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 relevant Divestiture Product(s) 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 research, Development, manufacturing, marketing, or sale of the relevant Divestiture Product(s) other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or
 - c. applicable Law;
5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except

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the Acquirer or other persons specifically authorized by the Acquirer to receive such information; and

6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products.
- F. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire the Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- G. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.F. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Acquirer for the relevant assets.
- H. Respondents shall:
1. for each Divestiture Product, for a period of at least twelve (12) months from the relevant Closing Date or upon the hiring of ten (10) Divestiture Product Core

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Employees by the relevant Acquirer, whichever occurs earlier, provide the relevant Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”; and

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after the relevant Closing Date, provide the relevant Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant Divestiture Product Core Employees. Failure by Respondents 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;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by the relevant Acquirer of the Divestiture Product Core Employees related to the particular Divestiture Products and assets acquired by such Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the relevant Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent (whichever Respondent is relevant to such Divestiture Product) that would affect the ability or incentive of those individuals to be employed by the relevant Acquirer. In addition, Respondents shall not

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make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Acquirer;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.H.3. shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of such employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer to such 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, and manufacture 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 such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent (whichever Respondent is relevant to such Divestiture Product) until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that, subject to those conditions of continued employment prescribed in this Order, this Order does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to

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employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the relevant Closing Date, not:
 - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the relevant Acquirer; or
 - b. hire any Divestiture Product Employee; *provided, however,* Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the relevant Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided, however, Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

- I. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement

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pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- J. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition, and or that contain the same active pharmaceutical ingredient as the relevant Divestiture Products; and/or
 3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' principal place of business within the United States and shall provide an officer's certification to the Commission stating

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that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.

K. Until Respondents complete the divestitures required by Paragraph II.A. and fully transfer the related Product Manufacturing Technology,

1. Respondents shall take such actions as are necessary to:

- a. maintain the full economic viability and marketability of the businesses associated with each Divestiture Product;
- b. minimize any risk of loss of competitive potential for such business;
- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to each Divestiture Product;
- d. ensure the assets required to be divested are transferred to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Divestiture Product;
- e. ensure the completeness of the transfer of the Product Manufacturing Technology; and

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

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- L. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) under the following:
1. any Patent owned or licensed by Respondents as of the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the respective Divestiture Product, or that claims a device relating to the use thereof;
 2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;

if such suit would have the potential to interfere with the relevant Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the relevant Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of the relevant Divestiture Products within the Geographic Territory. Respondents shall also covenant to the relevant Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the relevant Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with the relevant Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the relevant Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of the

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relevant Divestiture Products within the Geographic Territory.

- M. 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 related to the Product Intellectual Property related to the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and/or the Sotalol Product Assets.
- N. For any patent infringement suit in which either Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as such Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the relevant Acquirer's freedom to practice in the research, Development, manufacture, use, import, export, distribution or sale of any Divestiture Product, Respondents shall:
1. cooperate with the relevant Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving such Divestiture Product;
 2. waive conflicts of interest, if any, to allow either Respondents' outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Divestiture Product; and
 3. permit the transfer to the relevant Acquirer of all of the litigation files and any related attorney work-product in

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the possession of Respondents' outside counsel relating to such Divestiture Product.

O. Respondents shall not, in the Geographic Territory:

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

provided however, that this Order shall not preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

- P. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.

III.

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IT IS FURTHER ORDERED that:

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

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and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the date of completion by Respondents of the divestiture of all Divestiture Assets and the transfer of the Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
 - (1) with respect to each Divestiture Product, the date the relevant Acquirer (or the Designee(s) of such Acquirer) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
 - (2) with respect to each Divestiture Product, the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - (3) with respect to each Divestiture Product, the date of written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

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provided, however, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement(s) to Contract Manufacture such Divestiture Product.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses,

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

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order.
 8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality

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

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

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

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Mylan, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Mylan 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 Mylan

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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.
 - 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 believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
 - 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and

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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. Any delays in divestiture caused by Respondents 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 shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; and, *provided further, however*, that Respondents shall select such entity within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as

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the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim

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Monitor pursuant to the relevant provisions of 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*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

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

Respondents shall assure that, in any instance wherein their counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer(s) or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the

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Acquirer(s), that Respondents' counsel does so only in order to do the following:

- A. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. 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 assets and businesses associated with those Products; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph V, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if the relevant Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondent Mylan shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

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- B. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondents have fully complied with the following:
1. Paragraphs II.A , II.B., II.C., II.D., II.E., II.G., II.H., II.J., and II.K.; and
 2. all of their responsibilities to render transitional services to the relevant Acquirer as provided by this Order and the Remedial Agreement(s),

Respondent Mylan shall submit to the Commission a verified written report setting forth in detail the manner and form in which Respondents intend to comply, are complying, and have complied with this Order. Respondent Mylan shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent Mylan shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- A. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent Mylan 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.

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VII.

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

- A. any proposed dissolution of Respondent Mylan;
- B. any proposed acquisition, merger or consolidation of Respondent Mylan; or
- C. any other change in Respondents 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.

VIII.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by Respondents 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 a Divestiture Product, a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondents' obligations to the Acquirer(s) pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement a representation from the relevant Acquirer that such 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 and to have any such

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manufacture to be independent of Respondents, all as soon as reasonably practicable.

- E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

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

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

X.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Acebutolol Product Assets, the Flecainide Product

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Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, the transfer of the Product Manufacturing Technology related to the Acebutolol Products, the Flecainide Products, the Guanfacine Products, the Nicardipine Products, and the Sotalol Products, respectively, and the related obligations imposed on the Respondents by this Order is:

- A. to ensure the continued use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the research, Development, and manufacture of each of the respective Divestiture Products;
- B. to provide for the future use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the distribution, sale and marketing of each of the respective Divestiture Products;
- C. to create a viable and effective competitor, who is independent of the Respondents, in the research, Development, manufacture, distribution, sale and marketing of each of the respective Divestiture Products; and,
- D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on November 1, 2017.

By the Commission.

**NON-PUBLIC APPENDIX II.A.
GENERIC DIVESTITURE PRODUCT AGREEMENTS**

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

Analysis to Aid Public Comment

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 Mylan Laboratories (“Mylan”) and E. Merck oHG (“Merck”) which is designed to remedy the anticompetitive effects of the acquisition of certain assets of Merck by Mylan. Under the terms of the proposed Consent Agreement, the companies would be required to assign and divest the Merck rights and assets necessary to manufacture and market generic: (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nifedipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets to Amneal Pharmaceuticals LLC (“Amneal”).

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger executed on May 12 and 13, 2007, Mylan proposes to acquire Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries for approximately \$6.6 billion. The Commission’s Complaint alleges 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 competition in the U.S. markets for the manufacture and sale of the following generic pharmaceutical products: (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine

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hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets (the “Products”). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

Mylan is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical drugs. Headquartered in Pennsylvania, Mylan sells generic pharmaceuticals in the United States and has manufacturing facilities throughout the country. Merck is a German pharmaceutical company that develops and manufactures pharmaceutical products for sale in the United States. Merck sells generic pharmaceutical products directly to customers in the United States through its subsidiary Genpharm L.P., as well as indirectly through distribution agreements with other generic companies, including Par Pharmaceutical Companies, Inc. (“Par”).

The Products and Structure of the Markets

The proposed acquisition of certain assets of Merck by Mylan would strengthen Mylan’s worldwide position in generic pharmaceuticals and provide Mylan with a stronger pipeline of generic products. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in five of these markets.

The transaction would reduce the number of competing generic suppliers in the overlap markets. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics’ pricing.

In the market for generic acebutolol capsules, Mylan and Merck are the only companies manufacturing and selling products in the

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United States. For the four other generic products, Mylan and Merck currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors.

Generic acebutolol hydrochloride is a beta blocker used to treat hypertension. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Therefore, the proposed transaction would give Mylan a monopoly in this market.

Generic flecainide acetate is an anti-arrhythmia drug used to treat heart problems. Flecainide is produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (“Roxane”), Barr Pharmaceuticals Inc., and Ranbaxy Pharmaceuticals Inc. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. After Mylan’s acquisition of Merck Generics, Mylan’s market share would increase to approximately 78 percent and the number of suppliers of generic flecainide would decrease from five to four.

Guanfacine hydrochloride, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (“Watson”), Merck/Par, Actavis Group hf. (“Actavis”), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States, although not all six suppliers are capable of supplying all formulations. For instance, Mylan, Merck/Par, Watson and Actavis are the only suppliers of the 2 mg formulation of guanfacine. Because many customers prefer to purchase the 1 mg and 2 mg formulations of the product from one supplier, the competitive significance of the other four suppliers who do not sell these formulations is limited.

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Nicardipine hydrochloride is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (“Teva”) are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed transaction would thus result in an increase in Mylan’s market share to approximately 86 percent and reduce the number of suppliers from three to two.

Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is led by Apotex Inc. (“Apotex”). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007. Therefore, the proposed transaction would reduce the number of suppliers from three to two.

Entry

Entry into the markets for the manufacture and sale of the Products would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant markets are relatively small and in decline, so the limited sales opportunities available to a new entrant are likely insufficient to warrant the time and investment necessary to enter.

Analysis to Aid Public Comment

Effects

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic acebutolol hydrochloride capsules, flecainide acetate tablets, guanfacine hydrochloride tablets, nicardipine hydrochloride capsules, and sotalol hydrochloride AF tablets. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. Here, the evidence shows that, given the small number of suppliers, the prices of the generic pharmaceutical products at issue decrease with the entry of each additional competitor. Evidence gathered during our investigation indicates that anticompetitive effects – whether unilateral or coordinated – are likely to result from the proposed transaction due to a decrease in the number of independent competitors in the markets at issue.

The acquisition of Merck by Mylan would create a monopoly in the market for generic acebutolol hydrochloride tablets. The evidence indicates that the presence of more than one competitor allows customers to negotiate lower prices and that the reduction in the number of competitors in this market would allow the merged entity to unilaterally exercise market power with a resulting increase in prices. In the markets for generic flecainide acetate tablets, generic nicardipine hydrochloride capsules, and generic sotalol AF tablets, the proposed acquisition would leave only two significant current competitors: the combined firm and one other company. The evidence indicates that the presence of three or more independent competitors in these markets allows customers to negotiate lower prices, and that a reduction in the number of competitors in these markets would allow the merged entity and other market participants to raise prices. Likewise, in the generic guanfacine hydrochloride tablet market, the reduction in the number of competitors also would likely lead to higher prices.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products

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involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing.

The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Mylan and Merck are required to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Merck divest its assets in the Products to Amneal.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Amneal, a small but growing generic manufacturer, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Amneal develops, manufactures, sells, and distributes generic pharmaceuticals within the United States. Moreover, Amneal will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and

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experience marketing generic products, Amneal is well-positioned to replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that Amneal is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Amneal is not acceptable, the parties must unwind the sale and divest the assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Mylan and Merck to provide transitional services to enable the Commission-approved acquirer to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Merck.

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC (“Quantic”) to oversee the asset transfer and to ensure Mylan and Merck’s compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Mylan and Merck to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute

Analysis to Aid Public Comment

an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

LAWRENCE A. JORDAN
AND
STEPHANIE L. JORDAN,
TRADING AND DOING BUSINESS AS
SPRINGBOARD AND PRO HEALTH LABS

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4203; File No. 072 3140

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses the deceptive advertising and promotion of respondent's ProBalance and ProBalance Plus transdermal creams. The complaint alleged that respondent represented that ProBalance and ProBalance Plus contained, among other ingredients, natural progesterone. The complaint further alleged that respondent violated the FTC Act by advertising without substantiation that its creams were effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The consent order requires respondent to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis; in reducing the risk of estrogen-induced endometrial cancer or breast cancer; or in mitigating, treating, preventing, or curing any disease, illness, or health condition. Respondent is also barred from representing that its creams reduce the user's risk of developing breast cancer, is safe for human use, or has no side effects. The order further prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the *Commission*: Gregory A. Ashe, Laura DeMartino,
Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the *Respondents*: Not represented by counsel.