

Complaint

IN THE MATTER OF

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

Docket No. C-4590; File No. 161 0102
Complaint, July 26, 2016 – Decision, September 7, 2016

This consent order addresses the \$7.2 billion acquisition by Mylan N.V. of certain assets of Meda AB. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The consent order requires Mylan to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc., and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC, the abbreviated new drug application owner for this product.

Participants

For the *Commission*: Susan Huber, and Christina Perez.

For the *Respondents*: Yonatan Even and Margaret Segal
D'Amico, Cravath, Swaine & Moore LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Mylan N.V. (“Respondent” or “Mylan”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Meda AB (“Meda”) in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the

Complaint

public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENT

1. Respondent is a company organized, existing, and doing business under and by virtue of the laws of the Netherlands, with its principal executive offices located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, United Kingdom AL10 9UL, and its United States address for service of process of the Complaint, the Decision and Order and the Order to Maintain Assets, as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

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

II. THE ACQUIRED COMPANY

3. Meda is a company organized, existing, and doing business under and by virtue of the laws of Sweden, with its principal executive offices located at Pipers vag 2A, Box 906, SE- 107 09 Solna, Sweden.

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

III. THE PROPOSED ACQUISITION

5. Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Respondent intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately \$7.2 billion in a

Complaint

combination of cash and the Respondent's ordinary shares (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

IV. THE RELEVANT MARKETS

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

- a. 400 mg and 600 mg generic felbamate tablets; and
- b. 250 mg generic carisoprodol tablets.

7. For the purposes of this Complaint, the United States is the relevant geographic market in which to assess the competitive effects of the Acquisition in each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKETS

8. Generic felbamate tablets treat severe refractory epilepsy and are available in 400 mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—currently sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration ("FDA") approval for both strengths of generic felbamate tablets, but is not yet on the market. Entry into the markets for these strengths by other firms in the near future is unlikely. Thus, the Acquisition would reduce the number of suppliers of 400 mg and 600 mg generic felbamate tablets from four to three.

9. Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms currently market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S. marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would be the third supplier of generic carisoprodol tablets.

Complaint

Thus, the Acquisition would eliminate the entry of a third independent market participant.

VI. ENTRY CONDITIONS

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

VII. EFFECTS OF THE ACQUISITION

11. The effects of the Acquisition, if consummated, would likely be to substantially lessen competition or 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 § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Mylan and Meda and reducing the number of independent significant competitors in the markets for generic 400 mg and 600 mg felbamate tablets, thereby increasing the likelihood that: (1) Mylan would be able to unilaterally exercise market power in these markets; (2) the remaining competitors would engage in coordinated interaction between or among each other; and (3) customers would be forced to pay higher prices; and
- b. by eliminating future competition between Mylan and Meda in the market for generic carisoprodol tablets, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of the generic carisoprodol tablets to which Mylan owns the U.S. marketing rights; and (2) increasing the

Order to Maintain Assets

likelihood that the combined entity would delay, reduce, or eliminate the substantial additional price competition that would have resulted from an additional supplier of these products.

VIII. VIOLATIONS CHARGED

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

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

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-sixth day of July, 2016, issues its Complaint against said Respondent.

By the Commission.

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Mylan” or “Respondent”) of Meda AB, and Respondent having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Order to Maintain Assets

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

The Commission having thereafter considered the matter and having determined 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 N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands. Its principal executive offices are located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL109UL, England, and its United States address for service of process in this matter is as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317. Mylan Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of West Virginia, is a wholly-owned subsidiary of Mylan N.V. with its offices at 781 Chestnut Ridge Road, Morgantown, WV 26505.
2. Meda AB is a corporation organized, existing, and doing business under and by virtue of the laws of Sweden with its principal executive offices located at Box 906, SE-170 09 Solna, Sweden.

Order to Maintain Assets

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

ORDER**I.**

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

- A. “Mylan” or “Respondent” means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Mylan N.V. (including but not limited to Mylan Pharmaceuticals Inc.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Meda AB.
- B. “Commission” means the Federal Trade Commission.
- C. “Decision and Order” means the
 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- D. “Felbamate Products Business” means the Business of the Respondent within the Geographic Territory

Order to Maintain Assets

specified in the Decision and Order related to the Felbamate Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.

- E. “Meda” means Meda AB or any of Meda AB’s subsidiaries.
- F. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph V of the Decision and Order.
- G. “Transition Period” means the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Felbamate Acquirer directs the Respondent to cease the marketing, distribution, and sale of the Felbamate Products; (ii) the date on which the Felbamate Acquirer commences the marketing, distribution, and sale of the Felbamate Products; or (iii) the date four (4) months after the Felbamate Closing Date.
- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

II.**IT IS FURTHER ORDERED** that

- A. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Felbamate Products Business, to minimize any risk of loss of competitive potential for that Business and to prevent the destruction, removal, wasting, deterioration, or impairment of the Felbamate Product Assets except for ordinary wear

Order to Maintain Assets

and tear. Respondent shall not sell, transfer, encumber, or otherwise impair the Felbamate Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Felbamate Products Business.

- B. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall maintain the operations of the Felbamate Products Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic marketability, viability, and competitiveness of the Felbamate Products Business and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with the Felbamate Products Business. Respondent's responsibilities shall include, but are not limited to, the following:
1. providing the Felbamate Products Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Felbamate Product Business;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Felbamate Products Business authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;

Order to Maintain Assets

3. providing such resources as may be necessary to respond to competition against each of the Felbamate Products and/or to prevent any diminution in sales of each of the Felbamate Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Felbamate Product Assets to the Felbamate Acquirer;
 4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Felbamate Products at the related High Volume Accounts;
 5. making available for use by the Felbamate Products Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to the Felbamate Products Business; and
 6. providing such support services to the Felbamate Products Business as were being provided to the Business by Respondent as of the date the Consent Agreement was signed by Respondent.
- C. Until Respondent fully transfers and delivers the Felbamate Product Assets to the Felbamate Acquirer, Respondent shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Felbamate Products for the last fiscal year.
- D. Respondent shall deliver to the Acquirer the following information regarding each Felbamate Product Core Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:

Order to Maintain Assets

1. direct contact information for the employee, including telephone number;
2. the date of hire and effective service date;
3. job title or position held;
4. a specific description of the employee's responsibilities related to the Felbamate Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
5. the base salary or current wages;
6. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
7. employment status (i.e., active or on leave or disability; full-time or part-time);
8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, the provision of such information may be conditioned upon the Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to a Felbamate Product Core Employee the opportunity to enter into employment contracts during the Felbamate Product Core Employee Access Period, and (iii) restrict access

Order to Maintain Assets

to the information to the Acquirer's employees or representatives who need such access in connection with the specified and permitted use.

- E. For a period of twelve (12) months after the Felbamate Closing Date, Respondent shall
1. provide Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Felbamate Product Core Employees. This period is hereinafter referred to as the "Felbamate Product Core Employee Access Period";
 2. not interfere with the hiring or employing by the Felbamate Acquirer or its Manufacturing Designee of the Felbamate Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Felbamate Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Felbamate Acquirer or its Manufacturing Designee;
 3. not make any counteroffer to any Felbamate Product Core Employee who has received a written offer of employment from the Felbamate Acquirer or its Manufacturing Designee; and
 4. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Felbamate Product ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee, or hire such Covered Employee;

Order to Maintain Assets

provided, however, Respondent may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.D above within the time provided therein shall extend the time period in this Paragraph II.E in an amount equal to the delay.

- F. Until the Felbamate Closing Date, Respondent shall provide all Felbamate Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Felbamate Products consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Business related to the Felbamate Products and to ensure successful execution of the pre-Acquisition plans for the Felbamate Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Divestiture Closing Date for the Felbamate Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law).
- G. During the Transition Period, Respondent, in consultation with the Felbamate Acquirer, for the

Order to Maintain Assets

purposes of ensuring an orderly marketing and distribution transition, shall:

1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution and sale the Felbamate Products by the Felbamate Acquirer is not delayed or impaired by the Respondent;
2. designate employees of Respondent knowledgeable about the marketing, distribution and sale of the Felbamate Products who will be responsible for communicating directly with the Felbamate Acquirer, and the Monitor, for the purposes of assisting in the transfer of the Felbamate Products Business to the Felbamate Acquirer;
3. maintain and manage inventory levels of each Felbamate Product in consideration of the marketing and distribution transition to the Felbamate Acquirer;
4. continue to market, distribute and sell the Felbamate Products in the United States;
5. beginning on the Acquisition Date, allow the Felbamate Acquirer access at reasonable business hours to all Confidential Business Information related to the Felbamate Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Felbamate Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Felbamate Acquirer;
6. beginning on the Acquisition Date, provide the Felbamate Acquirer with a listing of inventory levels (weeks of supply) for each customer (i.e.,

Order to Maintain Assets

retailer, group purchasing organization, wholesaler or distributor) on a regular basis and in a timely manner;

7. beginning on the Acquisition Date, provide the Felbamate Acquirer with anticipated reorder dates for each customer on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Felbamate Acquirer in an efficient and timely manner.

H. Respondent shall:

1. pending complete delivery of all Felbamate Confidential Business Information provide the Felbamate Acquirer and the Monitor with access to the Felbamate Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Felbamate Confidential Business Information and facilitating delivery of the Felbamate Confidential Business Information in a manner consistent with this Order;
2. on or before the Felbamate Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Felbamate Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Felbamate Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete

Order to Maintain Assets

records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and

3. not later than thirty (30) days after the Felbamate Closing Date, provide written notification of the restrictions on the use and disclosure of Felbamate Confidential Business Information to all of its employees who may be in possession of or have access to Felbamate Confidential Business Information. Respondent shall give the above-described notification by email with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Felbamate Closing Date. Respondent shall provide a copy of the notification to the Felbamate Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Felbamate Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

I. Respondent shall:

1. pending complete delivery of all Carisoprodol Confidential Business Information to Indicus, provide Indicus and the Monitor with access to the Carisoprodol Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Carisoprodol Confidential Business Information and facilitating delivery of the Carisoprodol Confidential Business Information in a manner consistent with this Order;

Order to Maintain Assets

2. on or before the Carisoprodol Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Carisoprodol Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Carisoprodol Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed;
3. not later than thirty (30) days after the Carisoprodol Closing Date, provide written notification of the restrictions on the use and disclosure of Carisoprodol Confidential Business Information to all of its employees who may be in possession of, or have access to Carisoprodol Confidential Business Information. Respondent shall give the above-described notification by e mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Carisoprodol Closing Date. Respondent shall provide a copy of the notification to the Carisoprodol Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Carisoprodol Acquirer with copies of all

Order to Maintain Assets

certifications, notifications, and reminders sent to Respondent's personnel.

- J. Respondent shall not
1. use, directly or indirectly, any Confidential Business Information related to a Divestiture Product other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the terms of any related Remedial Agreement, or applicable Law;
 2. not disclose or convey any Confidential Business Information related to a Divestiture Product, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Product.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Felbamate Product Business within the Geographic Territory through its full transfer and delivery to an Acquirer, to maintain the confidentiality of the Confidential Business Information related to the Divestiture Products, and to minimize any risk of loss of competitive potential for the Felbamate Product Business within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the

Order to Maintain Assets

Divestiture Product Assets except for ordinary wear and tear.

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

- A. The Commission may appoint a monitor or monitors (“Monitor”) to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor and Respondent agree and that the Commission approves.
- B. The Commission appoints F. William Rahe of Quantic Regulatory Services, LLC as a Monitor and approves the agreement between Quantic Regulatory Services, LLC and Respondent, attached as Public Appendix C and Non-Public Appendix C-1 to the Decision and Order.
- C. The Monitor’s duties and responsibilities shall include the following:
 - 1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 - 2. The Monitor shall have the power and authority to monitor Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;

Order to Maintain Assets

3. The 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 Monitor's duties and responsibilities; and
 4. The Monitor shall evaluate the reports submitted to the Commission by any Respondent pursuant to this Order, the Decision and Order, and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning a) the performance by the submitting Respondent of its obligations under the Order, and b) the progress by the Felbamate Acquirer (or its Manufacturing Designee) toward obtaining FDA approval to manufacture (independently of Respondent) each Felbamate Product and the ability to manufacture each Felbamate Product in commercial quantities, in a manner consistent with cGMP.
- D. Respondent shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including, but not limited to, the following:
1. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;

Order to Maintain Assets

2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets; and
 4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order, the Decision and Order, or the Consent Agreement.
- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,
- provided, however, that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the*

Order to Maintain Assets

Respondent the substance of communications to or from the Commission or the Acquirer.

- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.
- J. The Monitor shall serve until the later of a) the completion of the divestitures of the Carisoprodol Product Assets and the Felbamate Product Assets, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Felbamate Acquirer (or its Manufacturing Designee) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture final finished Felbamate Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent; c) the date the Felbamate Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the Felbamate Products; d) the date of written notification

Order to Maintain Assets

from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Felbamate Acquirer has abandoned its efforts to manufacture the Felbamate Products; or e) five (5) years.

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

- A. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission and every sixty (60) days thereafter until Respondent has fully complied with this Order to Maintain Assets and Paragraphs II and III of the Decision and Order, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Orders, including:
1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations;

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

Order to Maintain Assets

V.

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

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

VI.

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

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and or electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

Order to Maintain Assets

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

VII.**IT IS FURTHER ORDERED** that

- A. The Order to Maintain Assets shall terminate as of
1. the later of the following dates:
 - 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,
 - b. the day after the later of (i) divestiture of all the Felbamate Product Assets, as required and described in the Decision and Order, or the (ii) delivery of the Carisoprodol Confidential Business Information, as required by and described in the Decision and Order, or
 - c. the day after the Product Manufacturing Technology related to the Felbamate Products has been provided to the Felbamate Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Felbamate Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transactions related to the provision of the Product Manufacturing Technology are complete;
 2. the day after Respondent provides written notice to the Commission that the Acquisition will not be consummated; or

Decision and Order

3. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

DECISION AND ORDER
[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan N.V. (“Mylan” or “Respondent”) of Meda AB, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent

Decision and Order

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 N.V. is a corporation organized, existing, and doing business under and by virtue of the laws of the Netherlands. Its principal executive offices are located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL109UL, England, and its United States address for service of process in this matter is as follows: Corporate Secretary, 1000 Mylan Boulevard, Canonsburg, Pennsylvania, 15317. Mylan Pharmaceuticals Inc., a corporation organized, existing and doing business under and by virtue of the laws of West Virginia, is a wholly-owned subsidiary of Mylan N.V. with its offices at 781 Chestnut Ridge Road, Morgantown, WV 26505.
2. Meda AB is a corporation organized, existing, and doing business under and by virtue of the laws of Sweden with its principal executive offices located at Box 906, SE-170 09 Solna, Sweden.
3. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondent, and the proceeding is in the public interest.

ORDER**I.**

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

- A. “Mylan” or “Respondent” means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled

Decision and Order

by Mylan N.V. (including but not limited to Mylan Pharmaceuticals Inc.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include Meda AB.

- B. “Commission” means the Federal Trade Commission.
- C. “Meda” means Meda AB or any of Meda AB’s subsidiaries.
- D. “Indicus” means USV Limited, a company organized under the laws of India with its principal offices at BSD Marg, Govandi East, Mumbai 400 088 or any of its subsidiaries, including Indicus Pharma LLC.
- E. “Alvogen” means Alvogen Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal executive offices located at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058, or any of Alvogen Group, Inc.’s subsidiaries.
- F. “Acquirer(s)” means the Carisoprodol Acquirer, the Felbamate Acquirer or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- G. “Acquisition” means Respondent Mylan’s acquisition of Meda AB pursuant to Mylan’s public offer to the shareholders of Meda AB to acquire all of the outstanding shares of Meda AB.
- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s),

Decision and Order

license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).

- J. “Application(s)” means any of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- K. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, importation, advertisement, and sale of a Product.
- L. “Carisoprodol Acquirer” means Indicus or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- M. “Carisoprodol Closing Date” means the later of (1) the Acquisition Date and (2) the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer,

Decision and Order

deliver, or otherwise convey the Carisoprodol Product Assets to an Acquirer.

- N. “Carisoprodol Divestiture Agreement” means the Second Amendment to the Master Collaboration and Supply Agreement by and between USV Limited, Indicus Pharma LLC and Mylan Pharmaceuticals Inc., dated as of June 22, 2016, contained in Non-Public Appendix A, or any other agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) to accomplish the requirements of this Order concerning the Carisoprodol Products, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission (except as provided under Rule §2.41(f), 16 C.F.R. §2.41(f)).
- O. “Carisoprodol Products” means all Products in Development, marketed, or sold by Mylan that are manufactured pursuant to Application ANDA No. 205126 and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, carisoprodol, at the following strengths: 250mg and 350mg.
- P. “Carisoprodol Product Assets” means all rights, title and interest in all assets of Mylan as of the Acquisition Date related to the Business of the Carisoprodol Products, including but not limited to the following related to the Business of the Carisoprodol Products:
1. rights to all Applications;
 2. all Product Intellectual Property;
 3. all Product Approvals;
 4. all Product Marketing Materials;
 5. all Product Scientific and Regulatory Material;

Decision and Order

6. all Website(s) related exclusively to the Carisoprodol Products and all content related exclusively to the Carisoprodol Products that is displayed on any Website that is not dedicated exclusively to the Carisoprodol Products;
 7. all Product Development Reports; and
 8. at the option of the Acquirer, all Product Contracts to purchase Carisoprodol Product(s).
- Q. “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.
- R. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- S. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is related to the conduct of the Business of a specified Divestiture Product(s). The term “Confidential Business Information” *excludes* the following:
1. information relating to the Respondent’s general business strategies or practices that does not discuss with particularity the specified Divestiture Product(s);
 2. information that is contained in documents, records, or books of the Respondent that is provided to an Acquirer by the Respondent that is

Decision and Order

unrelated to the specified Divestiture Product(s) acquired by that Acquirer; and

3. information prepared in connection with the Acquisition that relates to United States, state, or foreign antitrust or competition Laws and that is protected by the attorney work product, attorney-client, joint defense, or other privilege.

T. “Contract Manufacture” means the following:

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

U. “Contract Manufacture Product(s)” means the Felbamate Products and any ingredient, material, or component used in the manufacture of a Felbamate Product including the active pharmaceutical ingredient(s), excipient(s), or packaging materials (including, without limitation, drug vials),

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

Decision and Order

- V. “Development” means all preclinical and clinical drug development activities, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- W. “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 the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee,
- provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.*
- X. “Divestiture Closing Date” means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey a Divestiture Product to an Acquirer

Decision and Order

- Y. “Divestiture Product(s)” means individually and collectively the Carisoprodol Products and the Felbamate Products.
- Z. “Divestiture Product Assets” means, individually and collectively the Carisoprodol Product Assets and the Felbamate Product Assets.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- BB. “Domain Name” means the domain name(s) (uniform resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration; *provided, however*, “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- CC. “Drug Master File(s)” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- DD. “Felbamate Acquirer” means Alvogen or any other Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- EE. “Felbamate Closing Date” means the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Felbamate Product Assets to an Acquirer.
- FF. “Felbamate Divestiture Agreements” means the Asset Purchase Agreement by and between Mylan N.V. and Alvogen Pharma US, Inc. and the Supply and Technology Transfer Agreement by and between

Decision and Order

Mylan Pharmaceuticals Inc. and Alvogen Malta Operations Ltd. contained in Non-Public Appendix B, or any other agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) to accomplish the requirements of this Order concerning the Felbamate Products, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission (except as provided under Rule §2.41(f), 16 C.F.R. §2.41(f)).

- GG. “Felbamate Products” means the products manufactured, in Development, marketed, sold, owned, or controlled by Mylan pursuant to Application ANDA No. 204595 and any supplements, amendments, or revisions to this ANDA. These Products are orally administered tablets containing, as an active pharmaceutical ingredient, felbamate, at the following strengths: 400mg, and 600mg.
- HH. “Felbamate Product Assets” means all rights, title, and interest in and to all assets of Mylan as of the Acquisition Date that are related to the Business of the Felbamate Products, to the extent legally transferable, including but not limited to the following related to the Business of the Felbamate Products:
1. rights to all Applications;
 2. all Product Intellectual Property;
 3. all Product Approvals;
 4. all Product Manufacturing Technology;
 5. all Product Marketing Materials;
 6. all Product Scientific and Regulatory Material;
 7. all Website(s) related exclusively to the Felbamate Products and all content related exclusively to the

Decision and Order

Felbamate Products that is displayed on any Website that is not dedicated exclusively to the Felbamate;

8. a list of all of the NDC Numbers related to each Felbamate Product (“Felbamate NDC Numbers”), and, to the extent permitted by Law, the right to
 - a. require Respondent to discontinue the use of the Felbamate NDC Numbers in the sale or marketing of the Felbamate Products *except* (i) for returns, rebates, allowances, and adjustments for such Products sold prior to the Felbamate Closing Date, (ii) as may be required by applicable Law, or (iii) as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement,
 - b. prohibit Respondent from seeking from any customer any type of cross- referencing of the Felbamate NDC Numbers with any Retained Product(s) *except* for returns, rebates, allowances, and adjustments for the Felbamate Products sold prior to the Felbamate Closing Date and *except* as may be required by applicable Law,
 - c. seek to change any cross-referencing by a customer of the Felbamate NDC Numbers with a Retained Product and to receive notification from the Respondent of any such cross-referencing that is discovered by the Respondent,
 - d. seek cross-referencing by a customer of the Respondent’s NDC Numbers related to a Felbamate Product with the Acquirer’s NDC Numbers related to the Felbamate Product,

Decision and Order

- e. approve the timing of Respondent's discontinued use of the Felbamate NDC Numbers in the sale or marketing of the Felbamate Products *except* (i) for returns, rebates, allowances, and adjustments for Felbamate Products sold prior to the Felbamate Closing Date, (ii) as may be required by applicable Law, or (iii) as is necessary to give effect to the transactions contemplated under any applicable Remedial Agreement, and
 - f. approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of the Felbamate NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
9. all Product Development Reports;
10. at the option of the Acquirer, all Product Contracts related a Felbamate Product;
11. all patient registries related to the Felbamate Products, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data, and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the Felbamate Products (including, without limitation, any Risk Evaluation Mitigation Strategy as defined by the FDA);
12. the following information for each High Volume Account for a Felbamate Product:
- a. the name and business contact information for the employee(s) of the High Volume Account that is or has been responsible for the purchase of the specified Felbamate Product,

Decision and Order

- b. net sales (in either units or dollars) on an annual, quarterly, or monthly basis of each Felbamate Product, and
 - c. separately for each SKU or NDC Number of a Felbamate Product purchased by such customer, (i) the final price as of the Felbamate Closing Date, i.e., the final price charged by Respondent net of all discounts, rebates, or promotions, (ii) all adjustments made to the net price during the one (1) year period immediately prior to the Felbamate Closing Date, (iii) any supply outages (failures to supply) during the one (1) year period immediately prior to the Felbamate Closing Date, and (iv) to the extent known by the Respondent, the status of the product on the customer's respective formulary (i.e., primary, secondary, or backup),
 - d. inventory levels (weeks of supply) of each Felbamate Product as of the Felbamate Closing Date, and
 - e. the anticipated reorder dates for each customer as of the Felbamate Closing Date;
13. the following information for each customer and targeted customer for a Felbamate Product (other than High Volume Accounts):
- a. the net sales (in either units or dollars) for each Felbamate Product on either an annual, quarterly, or monthly basis,
 - b. inventory levels (weeks of supply) of each Felbamate Product as of the Felbamate Closing Date, and
 - c. the anticipated reorder dates for each customer as of the Felbamate Closing Date;

Decision and Order

14. the wholesale acquisition cost for each Felbamate Product for each of the twelve (12) months immediately prior to the Felbamate Closing Date;
15. the following information for each Felbamate Product that has had any batch determined to be out-of-specification during the five (5) year period immediately preceding the Felbamate Closing Date: (i) a detailed description of the deficiencies (e.g., impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure) with respect to any out-of-specification batch; (ii) the corrective actions taken to remediate the cGMP deficiencies in the Felbamate Product; and (iii) to the extent known by Respondent, the employees (whether current or former) responsible for taking such corrective actions;
16. a list of all active pharmaceutical ingredient suppliers identified on an Application of a Retained Product that is the Therapeutic Equivalent of a Felbamate Product;
17. copies of all unfilled customer purchase orders for the Felbamate Products as of the Felbamate Closing Date, to be provided to the Acquirer no later than five (5) days after the Felbamate Closing Date;
18. at the option of the Acquirer and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Felbamate Closing Date including, but not limited to, raw materials, packaging materials, work-in-process, and finished goods related to the Felbamate Products;
19. at the option of the Acquirer, all unfilled customer purchase orders for the Felbamate Products; and

Decision and Order

20. all of the Respondent's books, records, and files directly related the Felbamate Products, including all books, records and files directly related to the foregoing items,

provided, however, that the Felbamate Product Assets shall not include: (i) documents relating to the Respondent's general business strategies or practices relating to the conduct of its Business of generic pharmaceutical Products, where such documents do not discuss with particularity the Felbamate Products; (ii) administrative, financial, and accounting records; (iii) quality control records that are determined not to be material to the manufacture of the Felbamate Products by the Monitor or the Acquirer; (iv) information that is exclusively related to the Retained Products; and (v) 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 assets to be divested contain information: (i) that relates both to the Felbamate Products and to Retained Products and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Felbamate Products; or (ii) for which Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, Respondent shall provide Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

Decision and Order

- II. “Felbamate Product Core Employee” means a salaried employee or former employee of the Respondent who directly participated in any of the following activities within the eighteen (18) month period immediately prior to the Felbamate Closing Date (irrespective of the portion of working time involved) unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance:
1. research, Development, regulatory approval process, or clinical studies of the Felbamate Products; or
 2. planning, design, implementation, or operational management of the Product Manufacturing Technology of the Felbamate Products.
- JJ. “Felbamate Product License” means a perpetual, non-exclusive, fully paid-up, and royalty-free license(s) with rights to sublicense to the following as of the Felbamate Closing Date:
1. all Patents owned, licensed or controlled by Respondent related to a Felbamate Product that the Respondent can demonstrate were being used prior to the Acquisition Date for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;
 2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information owned, licensed or controlled by Respondent, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product that Respondent can demonstrate were being used prior to the Acquisition Date for any Retained Product that is the subject of an active (not discontinued) NDA or ANDA as of the Acquisition Date;

Decision and Order

3. all Product Manufacturing Technology related to general manufacturing know-how (i.e. manufacturing know-how not exclusively related to a Felbamate Product) owned, licensed, or controlled by Respondent to:
 - a. research and Develop the Felbamate Products for marketing, distribution, or sale within the Geographic Territory,
 - b. use, make, have made, distribute, offer for sale, promote, advertise, or sell the Felbamate Product(s) within the Geographic Territory,
 - c. import or export the Felbamate Product(s) to or from the Geographic Territory to the extent related to the marketing, distribution, or sale of the Felbamate Products in the Geographic Territory, and
 - d. have the Felbamate Product(s) made anywhere in the world for distribution or sale within or import into the Geographic Territory; and
4. a full, complete, and unlimited Right of Reference or Use to the Drug Master File related to the NDA for any Retained Product that is the Therapeutic Equivalent of a Felbamate Product to reference or use in any Application related to a Felbamate Product,

provided, however, that for any intellectual property that is licensed by Respondent from a Third Party under a license entered prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to the Respondent.

KK. “Geographic Territory” means the United States of America, including all of its territories and possessions, unless otherwise specified.

Decision and Order

- LL. “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.
- MM. “High Volume Accounts” mean any customer (retailer, wholesaler or distributor) whose annual or projected annual aggregate purchase amount (on a company-wide level), in units or in dollars, of a specified Divestiture Product in the Geographic Territory from the Respondent was, or is projected to be, among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (i) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (ii) the end of the last quarter that immediately preceded the Acquisition Date; or (iii) the end of the last quarter that immediately preceded the Divestiture Closing Date.
- NN. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- OO. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- PP. “Monitor” means any monitor appointed pursuant to Paragraph V of this Order or Paragraph III of the related Order to Maintain Assets.
- QQ. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code for a specific Product.
- RR. “Orders” means this Decision and Order and the related Order to Maintain Assets.

Decision and Order

- SS. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- TT. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the specified Divestiture 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.
- UU. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups, or affiliates thereof.
- VV. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- WW. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefore, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in

Decision and Order

connection with any Application related to that Product.

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

1. pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, only the specified Divestiture Product from the Respondent (for avoidance of doubt, this provision does not include contracts or agreements that include products other than Divestiture Products);
2. pursuant to which the Respondent had as of the Acquisition Date the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party, for use in connection with the manufacture of the specified Divestiture Product;
3. relating to any Clinical Trials involving the specified Divestiture Product;
4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or plans to manufacture the specified Divestiture Product as a finished Product on behalf of the Respondent;

Decision and Order

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

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

Decision and Order

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

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

Decision and Order

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

ZZ. “Product Development Reports” means:

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

Decision and Order

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

Decision and Order

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

AAA. “Product Intellectual Property” means all of the intellectual property related to a Product (other than intellectual property licensed under the Felbamate Product License) that is owned, licensed, or controlled by the Respondent as of the specified Divestiture Closing Date:

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

provided, however, that “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Mylan” or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof; or general

Decision and Order

registered images or symbols by which Mylan can be identified or defined.

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

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of that Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;
2. all ingredients, materials, or components used in the manufacture of that Product including the active pharmaceutical ingredient, excipients, or packaging materials; and
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer’s option, all such equipment used to manufacture that Product.

CCC. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the specified Divestiture Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales

Decision and Order

materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters, and other similar materials related to the specified Divestiture Product.

- DDD. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and Clinical Trial materials and information.
- EEE. “Product Trade Dress” means the current trade dress of a Product, including but not limited to, Product packaging and the lettering of the Product trade name or brand name.
- FFF. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefore (and all renewals, modifications, and extensions thereof), and all common law rights, and the goodwill symbolized thereby and associated therewith, for a Product.
- GGG. “Remedial Agreement(s)” means any Carisoprodol Divestiture Agreement or Felbamate Divestiture Agreement that has been approved by the Commission.
- HHH. “Retained Product(s)” means any Product(s) other than a Divestiture Product.

Decision and Order

- III. “Right of Reference or Use” means the authority to rely upon, and otherwise use, (i) an investigation of the quality, safety, or efficacy of a Product (including any or all such investigations conducted *in vitro*, *in vivo*, or *in silico* and any and all Clinical Trials); (ii) Product Development Reports; or (iii) Product Scientific and Regulatory Material for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation, Product Development Reports, or Product Scientific and Regulatory Material for FDA audit, if necessary.
- JJJ. “Supply Cost” means a cost not to exceed (i) the Respondent’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date, or (ii) the lowest average net price per unit (i.e., the final price per SKU or NDC Number charged by the Respondent net of all discounts, rebates, or promotions) charged for the specified Divestiture Product during the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit;
- provided, however*, that in each instance where: (i) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- KKK. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and

Decision and Order

meaningful manner. Such standards and requirements shall include, *inter alia*:

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

Decision and Order

quantities and to meet all Agency-approved specifications for such Divestiture Product, and

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

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

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

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 the Respondent,

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

II.

IT IS FURTHER ORDERED that

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall divest the Felbamate Product Assets and grant the Felbamate Product License, absolutely and in good faith, to Alvogen to, and in accordance with, the Felbamate Divestiture Agreements,

Decision and Order

provided, however, if Respondent has divested the Felbamate Product Assets and granted the Felbamate Product License to Alvogen prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Alvogen is not an acceptable purchaser of the Felbamate Product Assets or licensee of the Felbamate Product License, then Respondent shall immediately rescind the transaction with Alvogen, in whole or in part, as directed by the Commission, and shall divest the Felbamate Product Assets and grant the Felbamate Product License (as applicable) within one hundred eighty (180) days after the date this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

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

- B. Prior to the Felbamate Closing Date, Respondent shall
1. provide the Felbamate Acquirer with the opportunity to review all Product Contracts related to the Felbamate Products for the purposes of

Decision and Order

determining whether to assume such contracts or agreements; and

2. secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Felbamate Product Assets and grant the Felbamate Product License to the Felbamate Acquirer, and to permit the Felbamate Acquirer to continue the Business of the Felbamate Products,

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

- C. Within five (5) days after the Felbamate Closing Date, Respondent shall provide to the Felbamate Acquirer

1. copies of all unfilled customer purchase orders for the Felbamate Products as of the Felbamate Closing Date; and
2. the information included in the Felbamate Product Assets at Paragraphs I.HH(12), I.HH(13), I.HH(14), I.HH(15) and I.HH(16).

- D. Respondent shall provide, or cause to be provided, to the Felbamate Acquirer all Product Manufacturing Technology related to the Felbamate Products in a manner consistent with the Technology Transfer Standards.

- E. Respondent shall

1. not enforce any agreement that limits or otherwise impairs the ability of the Felbamate Acquirer to use or to acquire the Felbamate Product Assets and the Felbamate Product License, including but not limited to, all Product Manufacturing Technology, and Confidential Business Information related to the Felbamate Products

Decision and Order

2. No later than ten (10) days after the Felbamate Closing Date, grant to each Third Party subject to an agreement that limits or otherwise impairs the ability of the Felbamate Acquirer to use or to acquire the Felbamate Product Assets or Felbamate Product License (including but not limited to Product Manufacturing Technology and related intellectual property and Felbamate Confidential Business Information), a release that allows the Third Party to provide the relevant information to the Felbamate Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer and the Monitor (if one has been appointed).

F. Respondent shall:

- a. upon reasonable written notice and request from the Felbamate Acquirer to Respondent, Contract Manufacture and deliver, or cause to be manufactured and delivered, in a timely manner and under reasonable terms and conditions, a supply of any requested Contract Manufacture Product at the Supply Cost, for a period of time sufficient to allow the Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent, and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Application(s) of the Respondent from Persons other than the Respondent;
- b. make representations and warranties to the Felbamate Acquirer that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract

Decision and Order

Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend, and hold the Felbamate Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Felbamate Acquirer pursuant to a Remedial Agreement by that Respondent to meet cGMP. This obligation may be made contingent upon the Felbamate Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim,

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

provided further, however, that where (i) an agreement to divest the Felbamate Product Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement to meet cGMP;

Decision and Order

- c. give priority to supplying a Contract Manufacture Product to the Felbamate Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
- d. make representations and warranties to the Felbamate Acquirer that Respondent shall hold harmless and indemnify the Felbamate Acquirer for any liabilities or loss of profits resulting from the failure of the Contract Manufacture Products to be delivered in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that the failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent,

provided, however, that where (i) an agreement to divest the Felbamate Product Assets or Contract Manufacture is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for a Divestiture Product, the agreement may contain limits on the Respondent's aggregate liability for such a failure;

- e. during the term of any agreement to Contract Manufacture, upon written request of the Felbamate Acquirer or the Monitor (if any has been appointed), make available to the Felbamate Acquirer and the Monitor (if any has been appointed) all records that relate directly to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Felbamate Closing Date;
- f. during the term of any agreement to Contract Manufacture, take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Products;
- g. in the event Respondent becomes unable to supply or produce a Contract Manufacture Product from

Decision and Order

the facility or facilities originally contemplated under a Remedial Agreement with the Felbamate Acquirer: provide Product that is the Therapeutic Equivalent of such Contract Manufacture Product from the facility(ies) that Respondent uses or has used to source its own supply of the Product that is the Therapeutic Equivalent of the Contract Manufacture Product, where such facility(ies) is still suitable for use for such manufacturing;

- h. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Monitor to monitor compliance with the obligations to Contract Manufacture;
- i. during the term of any agreement to Contract Manufacture, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Felbamate Acquirer and at a facility chosen by the Felbamate Acquirer, for the purposes of enabling the Felbamate Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the Contract Manufacture Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Felbamate Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the Contract Manufacture Products; and
- j. notify the Commission and the Monitor in writing at least sixty (60) days prior to exercising any right under a Divestiture Agreement to terminate an agreement to Contract Manufacture any Contract Manufacture Products.

Decision and Order

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

G. Respondent shall:

1. submit to the Felbamate Acquirer, at Respondent's expense, all Confidential Business Information related to the Felbamate Products or the Business of the Felbamate Products ("Felbamate Confidential Business Information");
2. deliver all Felbamate Confidential Business Information to the Felbamate Acquirer in good faith, in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information, and in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all Felbamate Confidential Business Information provide the Felbamate Acquirer and the Monitor (if any has been appointed) with access to the Felbamate Confidential Business Information and employees who possess or are able to locate such information

Decision and Order

for the purposes of identifying the books, records, and files that contain Felbamate Confidential Business Information and facilitating delivery of the Felbamate Confidential Business Information in a manner consistent with this Order;

4. on or before the Felbamate Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Felbamate Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Felbamate Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed; and
5. not later than thirty (30) days after the Felbamate Closing Date, provide written notification of the restrictions on the use and disclosure of Felbamate Confidential Business Information to all of its employees who may be in possession of or have access to Felbamate Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Felbamate Closing Date. Respondent shall provide a copy of the notification to the Felbamate Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall

Decision and Order

provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Felbamate Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

- H. Respondent shall deliver to the Acquirer the following information regarding each Felbamate Product Core Employee no later than ten (10) days after such information is requested by either the Acquirer or staff of the Commission:
1. direct contact information for the employee, including telephone number;
 2. the date of hire and effective service date;
 3. job title or position held;
 4. a specific description of the employee's responsibilities related to the Felbamate Products; provided, however, in lieu of this description, the Respondent may provide the employee's most recent performance appraisal;
 5. the base salary or current wages;
 6. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, and current target or guaranteed bonus, if any;
 7. employment status (i.e., active or on leave or disability; full-time or part-time);
 8. all other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and

Decision and Order

9. at the Acquirer's option, a copy of all applicable employee benefit plans and summary plan descriptions (if any),

provided that, the provision of such information may be conditioned upon the Acquirer's written confirmation that it will (i) treat the information as confidential and, more specifically, (ii) use the information solely in connection with considering whether to provide, or providing to a Felbamate Product Core Employee the opportunity to enter into employment contracts during the Felbamate Product Core Employee Access Period, and (iii) restrict access to the information to the Acquirer's employees or representatives who need such access in connection with the specified and permitted use.

- I. For a period ending twelve (12) months after the Felbamate Closing Date, Respondent shall
 1. provide Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Felbamate Product Core Employees. This period is hereinafter referred to as the "Felbamate Product Core Employee Access Period";
 2. not interfere with the hiring or employing by the Felbamate Acquirer or its Manufacturing Designee of the Felbamate Product Core Employees, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any non-compete or nondisclosure provision of employment with respect to a Felbamate Product or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Felbamate Acquirer or its Manufacturing Designee;

Decision and Order

3. not make any counteroffer to any Felbamate Product Core Employee who has received a written offer of employment from the Felbamate Acquirer or its Manufacturing Designee; and
4. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Felbamate Product ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee, or hire such Covered Employee;

provided, however, Respondent may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the terms of the Order, and

provided further, that Respondent may advertise for employees in newspapers, trade publications, or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent;

Failure by Respondent to provide any information requested in Paragraph II.H above within the time provided therein shall extend the time period in this Paragraph II.I in an amount equal to the delay.

- J. Until the Felbamate Closing Date, Respondent shall provide all Felbamate Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Felbamate Products consistent with past practices and/or as may be necessary to preserve

Decision and Order

the marketability, viability, and competitiveness of the Business related to the Felbamate Products and to ensure successful execution of the pre-Acquisition plans for the Felbamate Products. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent until the Divestiture Closing Date for the Felbamate Product Assets has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law),

- K. Until Respondent completes the divestiture of the Felbamate Product Assets (including fully providing Product Manufacturing Technology to the Felbamate Acquirer) Respondent shall take all actions necessary to:
1. maintain the full economic viability and marketability of the Business associated with the Felbamate Products;
 2. minimize any risk of loss of competitive potential for that Business;
 3. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Felbamate Products;
 4. ensure the assets related to the Felbamate Products are provided to the Felbamate Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the associated Business; and
 5. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology.
- L. Respondent shall not sell, transfer, encumber, or otherwise impair the Felbamate Product Assets (other than in the manner prescribed in this Order), nor take

Decision and Order

any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to the Divestiture Products.

III.**IT IS FURTHER ORDERED** that

- A. Not later than ten (10) days after the Acquisition Date, Respondent shall terminate the Addendum to the Master Collaboration and Supply Agreement between USV Limited, Indicus Pharma LLC and Mylan Pharmaceuticals dated January 9, 2013, pursuant to the Carisoprodol Divestiture Agreement and shall divest the Carisoprodol Product Assets, absolutely and in good faith, to Indicus in accordance with the Carisoprodol Divestiture Agreement;

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

- B. Prior to the Carisoprodol Closing Date, Respondent shall provide the Carisoprodol Acquirer with the opportunity to review all Product Contracts related to the Carisoprodol Products for the purposes of the Acquirer determining whether to assume such contracts or agreements.

Decision and Order

C. Respondent shall:

1. submit to Indicus, at Respondent's expense, all Confidential Business Information related to the Carisoprodol Products or the Business of the Carisoprodol Products ("Carisoprodol Confidential Business Information");
2. deliver all Carisoprodol Confidential Business Information to Indicus in good faith, in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all Carisoprodol Confidential Business Information to Indicus, provide Indicus and the Monitor (if any has been appointed) with access to the Carisoprodol Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files that contain Carisoprodol Confidential Business Information and facilitating delivery of the Carisoprodol Confidential Business Information in a manner consistent with this Order;
4. on or before the Carisoprodol Closing Date, and as a condition of continued employment, require that each employee whose responsibilities (in whole or part) include sales or marketing and who has or may have had access to Carisoprodol Confidential Business Information, and the direct supervisor(s) of each such employee, sign a confidentiality agreement pursuant to which the employee is required to maintain the confidentiality of the Carisoprodol Confidential Business Information and not disclose it to other employees, executives, or other personnel of the Respondent (other than as necessary to comply with the requirements of this

Decision and Order

Order). Respondent shall maintain complete records of signed confidentiality agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming that all confidentiality agreements have been signed;

5. not later than thirty (30) days after the Carisoprodol Closing Date, provide written notification of the restrictions on the use and disclosure of Carisoprodol Confidential Business Information to all of its employees who may be in possession of, or have access to Carisoprodol Confidential Business Information. Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Carisoprodol Closing Date. Respondent shall provide a copy of the notification to the Carisoprodol Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgement program. Respondent shall provide the Carisoprodol Acquirer with copies of all certifications, notifications, and reminders sent to Respondent's personnel.

IV.**IT IS FURTHER ORDERED** that

- A. Respondent shall not
 1. use, directly or indirectly, any Confidential Business Information related to a Divestiture Product other than as necessary to comply with the requirements of this Order, Respondent's obligations to each respective Acquirer under the

Decision and Order

terms of any related Remedial Agreement, or applicable Law;

2. not disclose or convey any Confidential Business Information related to a Divestiture Product, directly or indirectly, to any Person except (i) the Acquirer of the relevant Divestiture Product, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, or (iv) the Monitor (if any has been appointed); and
 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of a Divestiture Product to the marketing or sales employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Product.
- B. Respondent shall not join, file, prosecute, or maintain any suit, in law or equity, against an Acquirer, any Person controlled by or under common control with the Acquirer, the Manufacturing Designee of the Acquirer, or any Person that has an agreement with the Acquirer to commercialize, distribute, market or import a Divestiture Product:
1. under any Patent owned by or licensed to the Respondent as of the day after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter of a Product, or that claims a device relating to the use thereof; or
 2. under any Patent that was filed or in existence on or before the Acquisition Date that is acquired by or licensed to the Respondent at any time after the Acquisition Date that claims a method of making, using, or administering, or a composition of matter

Decision and Order

of a Product, or that claims a device relating to the use thereof;

if such suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The Respondent shall also covenant to that Acquirer that as a condition of any assignment or license from the Respondent to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential directly to limit or interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer. The provisions of this Paragraph do not apply to any Patent owned by, acquired by, or licensed to or from the Respondent that claims inventions conceived by and reduced to practice after the Acquisition Date.

- C. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or

Decision and Order

otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Product(s) acquired by that Acquirer, if such litigation would have the potential to interfere with that Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer.

- D. For any patent infringement suit filed prior to the relevant Divestiture Closing Date in which the Respondent is alleged to have infringed a Patent of a Third Party or any potential patent infringement suit from a Third Party that the Respondent has prepared or is preparing to defend against as of such Divestiture Closing Date, and where such a suit would have the potential directly to limit or interfere with the relevant Acquirer's freedom to practice the following: (i) the research, Development, or manufacture anywhere in the world of the Divestiture Product(s) acquired by that Acquirer for the purposes of marketing, sale, or offer for sale within the United States of America of such Divestiture Product(s); or (ii) the use within, import into, export from, or the supply, distribution, sale or offer for sale within, the United States of America of the Divestiture Product(s) acquired by that Acquirer, the Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from the Respondent in connection with obtaining resolution of any pending patent litigation related to that Divestiture Product;

Decision and Order

2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent that Acquirer in any ongoing patent litigation related to that Divestiture Product; and
 3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondent's outside counsel related to that Divestiture Product.
- E. The purpose of the divestiture of the Divestiture Product Assets, the provision of the related Product Manufacturing Technology for the Contract Manufacture Products and the related obligations imposed on the Respondent by this Order is:
1. to ensure the continued use of such assets for the purposes of the Business associated with each Divestiture Product within the Geographic Territory;
 2. to create a viable and effective competitor that is independent of the Respondent in the Business of each Divestiture Product within the Geographic Territory; and
 3. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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

- A. The Commission may appoint a monitor or monitors ("Monitor") to assure that Respondent expeditiously complies with all obligations and performs all responsibilities required by this Order, the Order to Maintain Assets and the Remedial Agreements. The Monitor shall serve, without bond or other security, at

Decision and Order

the expense of Respondent, on such reasonable and customary terms and conditions to which the Monitor and Respondent agree and that the Commission approves.

- B. The Commission appoints F. William Rahe of Quantic Regulatory Services, LLC as a Monitor and approves the agreement between Quantic Regulatory Services, LLC and Respondent, attached as Public Appendix C and Non-Public Appendix C-1 to this Order.
- C. The Monitor's duties and responsibilities shall include the following:
 - 1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 - 2. The Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;
 - 3. The 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 Monitor's duties and responsibilities; and
 - 4. The Monitor shall evaluate the reports submitted to the Commission by the Respondent pursuant to this Order, the Order to Maintain Assets, and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning a) the performance by the submitting Respondent of its obligations under the Order, and b) the progress by the Felbamate Acquirer (or its Manufacturing

Decision and Order

Designee) toward obtaining FDA approval to manufacture (independently of Respondent) each Felbamate Product and the ability to manufacture each Felbamate Product in commercial quantities, in a manner consistent with cGMP.

- D. Respondent shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including, but not limited to, the following:
1. Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor;
 2. Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with the Orders;
 3. Subject to any demonstrated legally recognized privilege, the Respondent shall provide the Monitor with full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets; and

Decision and Order

4. Respondent shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to this Order, the Order to Maintain Assets or the Consent Agreement.
- E. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; however such agreement shall not limit the ability of the Monitor to provide information to the Commission without the consent of Respondent.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Respondent's materials and information received in connection with the performance of the Monitor's duties,
- provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to the Respondent the substance of communications to or from the Commission or the Acquirer.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff

Decision and Order

of the Commission to Respondent of the identity of any proposed substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor.

- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of the this Order.
- J. The Monitor shall serve until the later of a) the completion of the divestitures of the Carisoprodol Product Assets and the Felbamate Product Assets, including the transfer and delivery of the related Product Manufacturing Technology; b) the date the Felbamate Acquirer (or its Manufacturing Designee) is approved by the FDA to manufacture and sell that Divestiture Product and is able to manufacture final finished Felbamate Products in commercial quantities, in a manner consistent with cGMP, independently of Respondent; c) the date the Felbamate Acquirer notifies the Commission and Respondent of its intention to abandon its efforts to manufacture the Felbamate Products; d) the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Felbamate Acquirer has abandoned its efforts to manufacture the Felbamate Products; or e) five (5) years.

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

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the

Decision and Order

Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and

Decision and Order

conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the

Decision and Order

delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power

Decision and Order

shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Divestiture Trustee

Decision and Order

from providing any information to the Commission.

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

VII.**IT IS FURTHER ORDERED** that

- A. It shall not be violation of this Order for Respondent's counsel (including in house counsel under appropriate confidentiality arrangements) to retain documents or other materials provided to an Acquirer, or access original documents provided to an Acquirer to
 - 1. assure such Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable

Decision and Order

Government Entity, or any taxation requirements;
or

2. to defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and Businesses associated with those Divestiture Products,

so long as copies of such documents are insufficient or otherwise unavailable, Respondent requires those who view such un-redacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably), and Respondent uses best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VIII.

IT IS FURTHER ORDERED that:

- A. Any Remedial Agreement shall be incorporated by reference into this Order and made a part hereof, and Respondent shall comply with all terms of the Remedial Agreement. A breach by Respondent of any term of a Remedial Agreement shall constitute a violation of this Order.
- B. A Remedial Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order and nothing in this Order shall be construed to reduce any rights or benefits of the Acquirer or to reduce any obligations of Respondent under any Remedial Agreement. To the extent that any term of a Remedial Agreement conflict with a term of this Order such that Respondent cannot fully comply with both, Respondent shall comply with the term of this Order.

Decision and Order

- C. Respondent shall not modify, replace or extend the terms of a Remedial Agreement without the prior approval of the Commission, except as otherwise provided under Rule §2.41(f), 16 C.F.R. §2.41(f).
- D. Respondent shall include in each Remedial Agreement related to the Felbamate Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligation to the Acquirer pursuant to this Order.
- E. Respondent shall include in the Remedial Agreement related to the Felbamate Products a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, the Felbamate Products, and to have any such manufacture to be independent of the Respondent, all as soon as reasonably practicable.
- F. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products, a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

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

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Respondent shall submit to the Commission and to the Monitor verified written reports within thirty (30) days after the date this Order becomes final and every sixty

Decision and Order

(60) days thereafter until Respondent has fully complied with Paragraphs II and III, setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including:

1. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the Respondent to the relevant Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
 2. a detailed description of the timing for the completion of such obligations.
- C. One (1) year after 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 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.

X.

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

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

Decision and Order

XI.

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

- A. Access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all business and other records and all documentary material and or electronically stored information as defined in Rule 2.7(a)(1) and (2), 16 C.F.R. § 2.7(a)(1) and (2), books, ledgers, accounts, correspondence, memoranda and all other records and documents (in whatever form such records and documents are kept) in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. To interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

XII.

IT IS FURTHER ORDERED that this Order shall terminate on September 7, 2026.

By the Commission.

Decision and Order

In re Mylan N.V.

Non-Public Appendix A

Carisoprodol Divestiture Agreement

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

In re Mylan N.V.

Non-Public Appendix B

Felbamate Divestiture Agreements

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

In re Mylan N.V.

Public Appendix C

Monitor Agreement

Analysis to Aid Public Comment

In re Mylan N.V.

Non-Public Appendix C-1

Confidential Appendix A to the Monitor Agreement

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

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

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Mylan N.V. (“Mylan”) that is designed to remedy the anticompetitive effects resulting from Mylan’s acquisition of Meda AB (“Meda”). Under the terms of the proposed Consent Agreement, Mylan is required to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. (“Alvogen”), and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC (“Indicus”) the abbreviated new drug application owner for this product.

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

Analysis to Aid Public Comment

Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Mylan intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately \$7.2 billion. The Commission alleges in its Complaint that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. §45, by lessening current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

The proposed acquisition would reduce the number of current suppliers in the markets for 400 mg and 600 mg generic felbamate tablets and reduce the number of future suppliers in the market for 250 mg generic carisoprodol tablets.

Generic felbamate tablets treat severe refractory epilepsy and are available in 400mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration (“FDA”) approval for each strength of generic felbamate tablets, but it is not yet on the market

Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S. marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

Analysis to Aid Public Comment

II. Entry

Entry into the three relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the proposed acquisition. The combination of drug development times and regulatory requirements, including approval by the United States Food and Drug Administration (“FDA”), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

Analysis to Aid Public Comment

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the proposed acquisition. If the Commission determines that Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that

Analysis to Aid Public Comment

gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

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

Complaint

IN THE MATTER OF

FORTILINE, LLCCONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4592; File No. 151 0000**Complaint, September 23, 2016 – Decision, September 23, 2016*

This consent order addresses Fortiline, LLC's invitation to collude while in both a horizontal (interbrand) and a vertical (intra-brand) relationship with the invitee. The complaint alleges that Fortiline violated Section 5 of the Federal Trade Commission Act by inviting a competing seller of ductile iron pipe to raise and fix prices. The consent order prohibits Fortiline from entering into, attempting to enter into, participating in, maintaining, organizing, implementing, enforcing, inviting, encouraging, offering or soliciting an agreement or understanding with any competitor to raise or fix prices or any other pricing action, or to allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

Participants

For the *Commission*: Mark Taylor.

For the *Respondent*: Timothy Muris, Kirkland & Ellis LLP.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41, *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Fortiline, LLC (hereinafter sometimes referred to as "Fortiline" or "Respondent"), has violated the provisions of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

Nature of the Case

1. Fortiline, a distributor of ductile iron pipe ("DIP"), invited a rival to raise and fix prices in North Carolina and Virginia. By