

**COMMISSIONERS:**        **Rebecca Kelly Slaughter, Acting Chair**  
                                  **Joseph J. Simons**  
                                  **Noah Joshua Phillips**  
                                  **Rohit Chopra**  
                                  **Christine S. Wilson**

The Federal Trade Commission initiated an investigation of Respondent Pfizer Inc.’s (“Pfizer”) proposal to spin off its Upjohn division and combine it with the assets of Respondent Mylan N.V. Upon consummation, the combination is expected to be renamed Viatris Inc. and will be comprised of certain legacy Pfizer assets held by Upjohn Inc. and its subsidiaries, Respondent Pfizer’s Greenstone LLC business, and all of the assets of Respondent Mylan N.V. The Commission’s Bureau of Competition prepared and furnished to each Respondent the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

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

The Commission considered the matter and determined that it had reason to believe that Respondents have violated the said Acts, and that a complaint should issue stating its charges in that respect. The Commission accepted the Consent Agreement and placed it on the public record for a period of 30 days for the receipt and consideration of public comments; at the same time, it issued and served its Complaint and Order to Maintain Assets. The Commission duly considered any comments received from interested persons pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34. Now, in further conformity with the procedure described in Rule 2.34, the Commission makes the following jurisdictional findings, and issues the following Decision and Order (“Order”):

1. Respondent Pfizer Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017.
2. Respondent Upjohn Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017. Upon completion of the combination, Upjohn Inc. is expected to be renamed Viatriis Inc. and will become Respondent Viatriis Inc. with its executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
3. Respondent Mylan N.V. is a public limited liability company organized, existing, and doing business under and by virtue of the laws of the Kingdom of the Netherlands with its executive offices and principal place of business located at Building 4, Trident Place, Mosquito Way, Hatfield, Hertfordshire, AL10 9UL, England. Mylan N.V.’s United States address for service of process in this matter is as follows: 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.
4. Respondent Utah Acquisition Sub Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its executive offices and principal place of business located at 235 East 42<sup>nd</sup> Street, New York, New York 10017. Upon completion of the combination, Utah Acquisition Sub Inc. will become a subsidiary of Respondent Viatriis Inc. with its

executive offices and principal place of business located at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

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

## **ORDER**

### **I. Definitions**

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

- A. “Pfizer” means Pfizer Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Pfizer Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- B. “Upjohn” means Upjohn Inc., its directors, officers, employees, agents, representatives, successors (including Viatrix Inc.), and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Upjohn Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- C. “Viatrix” means Viatrix Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Viatrix Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- D. “Mylan” means Mylan N.V., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Mylan N.V., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- E. “Utah Acquisition Sub” means Utah Acquisition Sub Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Utah Acquisition Sub Inc., and the respective directors, officers, general partners, employees, agents, representatives, successors, and assigns of each.
- F. “Commission” means the Federal Trade Commission.
- G. “Respondents” means Pfizer, Upjohn, Viatrix, Mylan, and Utah Acquisition Sub.
- H. “Acquirer(s)” means:
  - 1. A Person specified by name in this Order to acquire particular assets or rights pursuant to this Order; or
  - 2. Any other Person that the Commission approves to acquire particular assets or

rights pursuant to this Order.

- I. “Acquisition” means the transactions contemplated by *Separation and Distribution Agreement* by and between Pfizer Inc. and Upjohn Inc., dated as of July 29, 2019, and the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019, as filed with the Commission.
- J. “Acquisition Date” means the date the parties close on the *Business Combination Agreement* by and among Pfizer Inc., Upjohn Inc., Utah Acquisition Sub Inc., Mylan N.V., Mylan I B.V., and Mylan II B.V. dated as of July 29, 2019.
- K. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes the FDA.
- L. “Authorized Generic Products” mean the authorized generic versions of each of the following products:
  - 1. “Medroxyprogesterone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorizations: NDA No. 02046 and NDA No. 012541, and any supplements, amendments, or revisions to these NDAs;
  - 2. “Amlodipine/Atorvastatin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021540, and any supplements, amendments, or revisions to this NDA;
  - 3. “Phenytoin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 084427, and any supplements, amendments, or revisions to this ANDA;
  - 4. “Prazosin Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 017442, and any supplements, amendments, or revisions to this NDA; and
  - 5. “Spironolactone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 012616, and any supplements, amendments, or revisions to this NDA.
- M. “Authorized Generic Product License” means an exclusive, royalty-free, fully paid-up right to market, promote, distribute, sell, and offer for sale a non-branded version of each of the Authorized Generic Products in the United States under the applicable FDA Authorization for a term of at least 10 years.

- N. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale of a Product.
- O. “Business Information” means all written information, wherever located or stored, relating to or used in a Divestiture Product Business, including documents, graphic materials, and data and information in electronic format. Business Information includes records and information relating to research and development (including copies of Product Development Reports), manufacturing, process technology, engineering, product formulations, production, sales, marketing (including Product Marketing Materials), logistics, advertising, personnel, accounting, business strategy, information technology systems, customers, customer purchasing histories, customer preferences, delivery histories, delivery routing information, suppliers and all other aspects of the Divestiture Product Business. For clarity, Business Information includes any Respondent’s rights and control over information and material provided by that Respondent to any other Person. Business Information includes Confidential Business Information.
- P. “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.
- Q. “Confidential Business Information” means all Business Information that is not in the public domain.
- R. “Customer” means any Person that is either a direct purchaser or who negotiates price on behalf of a direct purchaser (e.g., group purchasing organization) of any Divestiture Product from a Respondent or the Acquirer.
- S. “Development” means all new chemical entity research, and all studies of the safety or efficacy of a Product, including test method development and stability testing; toxicology; bioequivalency; bioavailability; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting studies of the safety or efficacy of a Product for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, labeling, and sale of a Product (including any government price or reimbursement approvals); Product Approval and registration; and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of a Respondent’s employees shall not exceed then-current average hourly wage rate for such employee.
- U. “Divestiture Agreements” mean:
1. Asset Purchase Agreement by and between Mylan Pharmaceuticals Inc. and Prasco, LLC dated as of September 18, 2020; Authorized Generic License,

Distribution, and Supply and Product Transfer Agreement by and between Pfizer Inc. and Prasco, LLC, dated as of September 18, 2020; Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020; Product Transition Agreement by and between Upjohn Inc. and Prasco, LLC, dated as of September 18, 2020; Technology Transfer Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; Amendment to the Form of Manufacturing and Supply Agreement between Pfizer Inc., Upjohn Inc., and Mylan N.V. dated as of September 18, 2020; Amendment No. 3 to the Separation and Distribution Agreement by and between Pfizer Inc. and Upjohn Inc. dated as of September 18, 2020; and all amendments, exhibits, attachments, agreements to the above referenced agreements; and

2. Any other agreement between a Respondent(s) and the Acquirer (or between a Divestiture Trustee and the Acquirer, or between Respondents for the benefit of the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.

V. “Divestiture Assets” mean Respondents’ equitable and legal right, title, and interests in and to all tangible and intangible assets that are not Excluded Assets, wherever located, relating to a Divestiture Product Business, including the following:

1. All Product Approvals and authorizations for the Divestiture Products, including all FDA Authorizations;
2. All studies of the safety or efficacy of the Product;
3. All Product Intellectual Property;
4. At the option of the Acquirer, Product Manufacturing Equipment;
5. All technological, scientific, chemical, biological, pharmacological, toxicological, regulatory materials and information, including studies of the safety, efficacy, stability, bioequivalency, bioavailability, and toxicology of a Product;
6. All website(s), Domain Names, and social media sites related exclusively to the Divestiture Product and the content thereon related exclusively to the Divestiture Product, and the content related exclusively to the Divestiture Product that is displayed on any website that is not dedicated exclusively to the Divestiture Product;
7. At the option of the Acquirer, Product Contracts;
8. All Business Information;
9. At the option of the Acquirer, all inventory and all ingredients, materials, or components used in the manufacture of the specified Divestiture Product in existence as of the Divestiture Date including, the active pharmaceutical ingredient(s), excipient(s), raw materials, packaging materials, work-in-process, and finished goods related to that Divestiture Product; and
10. At the option of the Acquirer, the right to fill any or all unfilled Customer purchase

orders for the specified Divestiture Product as of the Divestiture Date.

- W. “Divestiture Date” means the date on which a Respondent (or a Divestiture Trustee) closes on a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey rights or assets related to a Divestiture Product to the Acquirer as required by Paragraph II of this Order.
- X. “Divestiture Products” means the:
1. Authorized Generic Products;
  2. Eplerenone Products; and
  3. Gatifloxacin Products.
- Y. “Divestiture Product Business” means the Business related to a Divestiture Product.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph X of this Order or Paragraph IX of the Order to Maintain Assets.
- AA. “Domain Name” means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.
- BB. “Employee Information” means the following, for each Relevant Employee, as and to the extent permitted by law:
1. With respect to each such employee, the following information:
    - a. Name, job title or position, date of hire, and effective service date;
    - b. Specific description of the employee’s responsibilities;
    - c. Base salary or current wages;
    - d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent’s last fiscal year, and current target or guaranteed bonus, if any;
    - e. Employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
    - f. All other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
  2. At the option of the Acquirer, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the Relevant Employees.
- CC. “Eplerenone Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA 203896, and any supplements, amendments, or revisions to this ANDA.
- DD. “Eplerenone Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to the Eplerenone Products, including all of the Divestiture Assets related to the Eplerenone Products.

EE. “Excluded Assets” mean:

1. Any real estate and the buildings and other permanent structures located on such real estate;
2. Corporate names or corporate trade dress of a Respondent or the related corporate logos thereof; or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by a Respondent or the related corporate logos thereof; or general registered images or symbols by which a Respondent can be identified or defined;
3. The portion of any Business Information that contains information about any of a Respondent’s business other than a Divestiture Product Business, in those cases in which the redaction does not impair the usefulness of the information related to the Divestiture Product Business;
4. Any original document that a Respondent has a legal, contractual, or fiduciary obligation to retain the original; *provided, however*, that Respondents shall provide copies of the document to the Acquirer and shall provide that Acquirer access to the original document if copies are insufficient for regulatory or evidentiary purposes;
5. (i) Any tax asset relating to (a) the Divestiture Assets for pre-Divestiture Date tax periods or (b) any tax liability that any Respondent is responsible for arising out of the divestiture of the Divestiture Assets, (ii) all accounts receivable, notes receivable, rebates receivable and other miscellaneous receivables of any Respondent that are related to the Divestiture Product Business and arising out of the operation of the Divestiture Product Business prior to the Divestiture Date, and (iii) all cash, cash equivalents, credit cards and bank accounts of any Respondent; and
6. Any records or documents reflecting attorney-client, work product or similar privilege of any Respondent or otherwise relating to the Divestiture Assets as a result of legal counsel representing any Respondent in connection with the divestiture of the Divestiture Assets pursuant to this Order or the Divestiture Agreements.

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

GG. “FDA Authorization(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto. “FDA Authorization” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the



preparation thereof, and all correspondence between the holder and the FDA related thereto.

- HH. “Gatifloxacin Product AG Assignment Agreement” means the Partial Assignment and Assumption Agreement by and between Upjohn US 2 LLC and Prasco, LLC, dated as of September 18, 2020.
- II. “Gatifloxacin Products” mean an authorized generic version of the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA #022548, and any supplements, amendments, or revisions to this NDA.
- JJ. “Levothyroxine Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021301, and any supplements, amendments, or revisions to these NDAs
- KK. “Licensed Intellectual Property” means; (i) all Product Manufacturing Technology that is used (but not exclusively, predominantly, or primarily used) in the manufacture of a Divestiture Product, and (ii) copyrights used (but not exclusively, predominantly, or primarily used), to commercialize, distribute, market, advertise, or sell any Divestiture Product as of the applicable Divestiture Date.
- LL. “Manufacturing Designee” means any Person other than a Respondent that has been designated by the Acquirer to perform any part of the manufacturing process, including the finish or packaging of a Divestiture Product on behalf of that Acquirer.
- MM. “Monitor” means any monitor appointed pursuant to Paragraph IX of this Order or Paragraph VIII of the Order to Maintain Assets, hereinafter, Monitor Paragraphs.
- NN. “NDC Number(s)” means the National Drug Code number, including both the labeler code assigned by the FDA and the additional numbers assigned by the labeler as a product code and package size code for a specific Product.
- OO. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.
- PP. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.
- QQ. “Orders” means this Decision and Order and the Order to Maintain Assets.
- RR. “Patent(s)” means all patents and patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention, and statutory invention registrations, in each case filed, or in existence, on or before the Divestiture Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions.
- SS. “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.

- TT. “Prasco” means (i) Prasco, LLC, a limited liability company organized, existing and doing business under the laws of the State of Ohio with its executive offices and principal place of business located at 6125 Commerce Court, Mason, Ohio 45040; and (ii) any Person controlled by or under common control of Prasco, LLC.
- UU. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient, or that is the subject of an FDA Authorization.
- VV. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other regulatory approvals, and pending applications and requests therefor, required by applicable Agencies, related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage, or transport of a Product, and includes, without limitation, all approvals, registrations, licenses, or authorizations granted in connection with any FDA Authorization related to that Product.
- WW. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:
1. Pursuant to which any third party, including a Customer, purchases, or has the option to purchase, a Product from a Respondent or negotiates the purchase price on behalf of another Customer;
  2. Pursuant to which a Respondent had, or has as of the Divestiture Date, the ability to independently purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s), from any third party for use in connection with the manufacture of a Product;
  3. Relating to any study of the safety or efficacy of a Product;
  4. With universities or other research institutions for the use of a Product in scientific research;
  5. For the marketing of a Product or educational matters relating solely to the Products;
  6. Pursuant to which a third party manufactures or plans to manufacture a Product as a finished dosage form on behalf of a Respondent;
  7. Pursuant to which a third party provides or plans to provide any part of the manufacturing process, including, without limitation, the finish or packaging of a Product on behalf of a Respondent;
  8. Pursuant to which a third party licenses any Product Intellectual Property or Product Manufacturing Technology related to a Product to a Respondent;

9. Pursuant to which a third party is licensed by a Respondent to use any of the Product Intellectual Property or Product Manufacturing Technology;
10. Constituting confidentiality agreements involving a Product;
11. Involving any royalty, licensing, covenant not to sue, or similar arrangement related to a Product;
12. Pursuant to which a third party provides any specialized services necessary to the research, Development, manufacture, or distribution of a Product to a Respondent including, consultation arrangements; and
13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.

XX. “Product Development Reports” means information related to the Development of a Product, including:

1. Pharmacokinetic study reports;
2. Bioavailability study reports;
3. Bioequivalence study reports;
4. All correspondence, submissions, notifications, communications, registrations, or other filings made to, received from, or otherwise conducted with the FDA relating to the FDA Authorization(s);
5. Annual and periodic reports related to the above-described FDA Authorization(s), including any safety update reports;
6. FDA approved labeling or other Agency-approved labeling;
7. Currently used or planned product package inserts (including historical change of controls summaries);
8. FDA approved patient circulars;
9. Adverse event reports, adverse experience information, and descriptions of material events and matters concerning safety or lack of efficacy;
10. Summaries of complaints from physicians or other health care providers;
11. Summaries of complaints from ultimate users of the Product;
12. Summaries of complaints from Customers;
13. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;
14. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;
15. Reports from any Person (e.g., any consultant or outside contractor) engaged to

investigate or perform testing for the purposes of resolving any Product or process issues, including, without limitation, identification and sources of impurities or defects;

16. Reports from vendors of the component(s), active pharmaceutical ingredient(s), excipient(s), packaging component(s), and detergent(s) used to produce any Product that relate to the specifications, degradation, chemical interactions, testing, and historical trends of the production of any Product;
17. Analytical methods development records;
18. Manufacturing batch or lot records;
19. Stability testing records;
20. Change in control history; and
21. Executed validation and qualification protocols and reports.

YY. “Product Intellectual Property” means intellectual property of any kind (other than Licensed Intellectual Property), that is owned, licensed, held, or controlled by a Respondent as of the Divestiture Date, including Patents, patent applications, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.

ZZ. “Product Manufacturing Equipment” means equipment that is being used, or has been used to manufacture the specified Divestiture Product.

AAA. “Product Manufacturing Technology” means all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including the following: all product specifications, processes, analytical methods, product designs, plans, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the conformance of any Product Approvals, conformance with any Agency requirements, and cGMP compliance, labeling and all other information related to the manufacturing process, and supplier lists.

BBB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the United States as of the Divestiture Date that are owned or controlled by a Respondent, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), Customer information (including Customer net purchase information to be provided on the basis of dollars and units for each month, quarter or year), sales forecasting models, educational materials, advertising and display materials, speaker lists, promotional and marketing materials, website content, artwork

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

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

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

DDD. “Relevant Employees” includes:

1. Manufacturing Employees means all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition Date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: (i) Developing and validating the commercial manufacturing process, (ii) formulating the manufacturing process performance qualification protocol, (iii) controlling the manufacturing process to assure performance Product quality, (iv) assuring that during routine manufacturing the process remains in a state of control, (v) collecting and evaluating data for the purposes of providing scientific evidence that the manufacturing process is capable of consistently delivering quality Products, (vi) managing the operation of the manufacturing process, or (vii) managing the transfer of the Product Manufacturing Technology to a different facility; and
2. Marketing Employees means all management-level employees of a Respondent who have participated at any time during the 3-year period immediately prior to the Acquisition date (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax, or financial compliance) in any of the following related to the specified Divestiture Product: sales management, brand management, sales training, market research, or marketing and contracting with any of the following: drug wholesalers or distributors, group purchasing organizations, pharmacy benefit organizations, managed care organizations, or hospitals, *excluding* administrative assistants.

EEE. “Retained Product(s)” means any Product(s) other than a Divestiture Product that is manufactured, in Development, marketed, sold, owned, controlled, or licensed by a Respondent anywhere in the world on or before the Acquisition Date and that has not been discontinued or permanently withdrawn from the market.

FFF. “Sucralfate Products” mean the Products in Development or manufactured anywhere in the world and authorized for marketing or sale in the United States pursuant to the following FDA Authorization: ANDA No. 074415, and any supplements, amendments, or revisions to this ANDA.

GGG. “Supply Cost” means the actual cost of materials, ingredients, packaging, direct labor, and direct overhead *excluding* any allocation or absorption of costs for excess or idle capacity, and *excluding* any intracompany transfer profits *plus* the actual cost of shipping and transportation in cases in which those costs are incurred by a Respondent.

HHH. “Technology Transfer Standards” mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, as related to the specified Divestiture Product(s), *inter alia*:

1. Designating employees or other Persons working on behalf of a Respondent knowledgeable about the Product Manufacturing Technology who will be responsible for communicating directly with the receiving Person, and a Monitor, for the purpose of effecting such delivery;
2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Product that are acceptable to the receiving Person;
3. Preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology to the receiving Person;
4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the receiving Person to visit the Respondent’s facility where that process occurs for the purposes of evaluating and learning that process or discussing the process with employees of the Respondent involved in that process (including, without limitation, use of equipment and components, manufacturing steps, time constraints for completion of steps, and methods to ensure batch or lot consistency); and
5. Providing, in a timely manner, assistance and advice to enable the receiving Person to:
  - a. Manufacture the Product in the quality and quantities achieved by a Respondent prior to the Acquisition Date;
  - b. Obtain any Product Approvals necessary for the receiving Person to manufacture the Product for the Acquirer in a manner that allows that Acquirer to distribute, market, and sell the Product in commercial quantities and to meet all Agency-approved specifications for the Product; and
  - c. Receive, integrate, and use all Product Manufacturing Technology used in, and all Product Intellectual Property that is related to, the manufacture of the Product.

III. “Therapeutic Equivalent” means a drug product that is classified by the FDA as being therapeutically equivalent to another drug product or that otherwise meets the FDA’s

criteria for such classification.

JJJ. “Varenicline Products” mean the Products in Development or authorized for marketing or sale in the United States pursuant to the following FDA Authorization: NDA No. 021928 and any supplements, amendments, or revisions to this NDA.

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

## **II. Divestitures**

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

A. No later than 10 days after the Acquisition Date, Respondents shall, absolutely and in good faith, pursuant to the Divestiture Agreements:

1. Divest the Eplerenone Divestiture Assets and grant a perpetual, non-exclusive, fully paid up, fully transferable, and royalty-free license to use the related Licensed Intellectual Property in the related Divestiture Product Business to Prasco;
2. Grant the Authorized Generic Product License for each of the Authorized Generic Products to Prasco; and
3. Assign all rights granted to any Respondent to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products to Prasco;  
*provided, however* that Respondents may satisfy this requirement by providing an executed copy of a direct agreement between Prasco and the holder of the FDA Authorization of Gatifloxacin Products granting Prasco exclusive rights to market, promote, distribute, sell, and offer for sale an authorized generic of the Gatifloxacin Products;

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

B. With respect to the Authorized Generic Product License, Respondents shall:

1. Permit the Acquirer to terminate the license on a product-by-product basis without penalty;
2. Not terminate the license due to (i) a breach by the Acquirer, or (ii) the Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;
3. Not withdraw or discontinue the FDA Authorization for any of the Authorized

Generic Products other than as permitted under this Order; and

4. Permit the Acquirer to acquire the FDA Authorization from the holder at no cost should the holder withdraw or discontinue the FDA Authorization for any reason.

C. If Respondents have divested any of the Divestiture Assets or granted or assigned rights to the Divestiture Products to the Acquirer who is named in this Order prior to the Order Date, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:

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

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

*provided, however,* that in cases in which any Product Contract also relates to a Retained Product the Respondent shall, at the option of that Acquirer, assign or otherwise make available to that Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

E. Prior to the Divestiture Date, Respondents shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondents to divest the Divestiture Assets and to grant or assign rights to the Divestiture Products to the Acquirer, and to permit that Acquirer to continue in the related Divestiture Product Business in the United States without interruption or impairment.

F. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, Respondents shall not enforce any agreement against a third party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the third party a license or other right to the Product Manufacturing Technology or any ingredient, material, or component used in the manufacture of the Divestiture



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

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

- G. Respondents shall transfer the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer, with the consent of the Acquirer, or at the Acquirer's option, to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Respondent Pfizer shall be responsible for validating and qualifying the manufacture of these Products at either a facility that is retained by Respondent Pfizer after the Acquisition Date or at a facility owned or controlled by the Manufacturing Designee in order to obtain FDA Approvals to manufacture these Products from such facilities and Respondents shall bear all costs related to these transfers.
- H. If, at any time during the term of the Authorized Generic Product License, the Acquirer notifies the Respondents that the Acquirer wants to move manufacturing of an Authorized Generic Product out of a facility owned or controlled by a Respondent, then such Respondent shall transfer the Product Manufacturing Technology to that Acquirer, or to its Manufacturing Designee, in a manner consistent with the Technology Transfer Standards. Such Respondent shall be responsible for ensuring the validation and qualification of the manufacture of these Products at the facility chosen by that Acquirer in order to obtain FDA Approvals to manufacture these Products from that facility. Such Respondent shall bear all costs related to this transfer.
- I. No later than 10 days after the Divestiture Date, Respondents shall designate employees of Respondents knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.
- J. No later than 10 days after the Divestiture Date, Respondents shall provide the following to the relevant Acquirer of each of the Divestiture Products:
  - 1. A list of any finished batch or lot of the relevant Divestiture Product that any Respondent, any manufacturer for a Respondent, or regulatory Agency determined to be out-of-specification at any time during the three-year period immediately preceding the Divestiture Date, and, for each such batch or lot: (i) a detailed description of the known deficiencies or defects (e.g., impurity content, incorrect levels of the active pharmaceutical ingredient, stability failure); (ii) the corrective

actions taken to remediate any cGMP deficiencies in that Divestiture Product; and (iii) to the extent known by any Respondent, the employees (whether current or former) responsible for taking such corrective actions;

2. A list by stock-keeping unit by Customer that contains the current net price per unit as packaged for sale (*i.e.*, the price net of all customer-level discounts, rebates, or promotions) for the relevant Divestiture Product for each order sold to that Customer during the two-year period prior to the Divestiture Date;
3. A list of the inventory levels (weeks of supply) of the relevant Divestiture Product in the possession of each Customer to the extent known or available to any Respondent, as of the date prior to and closest to the Divestiture Date as is available;
4. A list of any pending reorder dates for the relevant Divestiture Product by Customer as of the Divestiture Date to the extent known by any Respondent;
5. A list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by law, to control, prohibit, or otherwise limit the use, including the use in Customer cross-referencing, of such NDC numbers by the Respondents, *unless* that Divestiture Product has not been marketed or sold in the United States prior to the Divestiture Date; and
6. The quantity and delivery terms in all unfilled Customer purchase orders for the relevant Divestiture Product as of the Divestiture Date.

K. Respondents shall not join, file, prosecute, or maintain any suit, in law or equity, against the Product Releasees under any Patent that was pending or issued on or before the Acquisition Date if such suit would limit or impair the Acquirer's freedom to research and Develop, or manufacture anywhere in the world the Divestiture Product(s), or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.

L. Upon reasonable written request from the Acquirer to a Respondent, that Respondent shall provide, in a timely manner, assistance of knowledgeable employees of that Respondent (*i.e.*, employees of that Respondent that were involved in the Development of the Divestiture Products) to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a third party related to the Product Intellectual Property for the Divestiture Products acquired by that Acquirer from a Respondent. A Respondent shall make its employees available to that Acquirer for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than Direct Cost.

M. For any patent infringement suit that is filed or to be filed within the United States that is (i) filed by, or brought against, a Respondent prior to the Divestiture Date related to any Divestiture Product or (ii) any potential patent infringement suit that a Respondent has prepared, or is preparing, to bring or defend against as of the Divestiture Date that is related to any Divestiture Product, that Respondent shall:

1. Cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation, and witnesses from that Respondent in connection with obtaining resolution of such patent infringement suit;
2. Waive conflicts of interest, if any, to allow that Respondent's outside legal counsel to represent the Acquirer in any such patent infringement suit; and
3. Permit the transfer to the Acquirer of all of the litigation files and any related attorney work product in the possession of that Respondent's outside counsel related to such patent infringement suit.

### **III. Divestiture Agreements**

**IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreements shall be incorporated by reference into this Order and made a part hereof, and any failure by a Respondent to comply with any term of the Divestiture Agreements shall constitute a violation of this Order; *provided however*, that the Divestiture Agreements shall not limit, or be construed to limit, the terms of this Order. To the extent any provision in the Divestiture Agreements varies from or conflicts with any provision in this Order such that the Respondents cannot fully comply with both, Respondents shall comply with this Order.
- B. Respondents shall include in the Divestiture Agreements a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.
- C. Respondents shall not modify or amend any of the terms of any Divestiture Agreement without the prior approval of the Commission, *except* as otherwise provided in Rule 2.41(f)(5) of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.41(f)(5).

### **IV. Transition Services and Manufacturing by Respondents**

**IT IS FURTHER ORDERED** that:

- A. At the request of the Acquirer, in a timely manner, at no greater than Direct Cost or at such cost as provided in a Divestiture Agreement, Respondents shall provide transition services sufficient to enable the Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondents have operated that Business prior to the Acquisition Date.
- B. Upon reasonable written notice and request from the Acquirer of the rights to the Authorized Generic Products, Respondents shall manufacture, deliver and supply, or cause to be manufactured, delivered, and supplied, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, that Acquirer's requested supply of each of the Authorized Generic Products and any of the active pharmaceutical ingredients used in the Authorized Generic Products that are made by a Respondent, as applicable, hereinafter "Supplied Products." For the initial 10-year term of the Authorized Generic

Agreement, the requested supply of Supplied Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement.

- C. The Respondents shall make representations and warranties to the Acquirer that the Supplied Products meet the relevant Agency-approved specifications.
- D. The Respondents shall agree to indemnify, defend, and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Supplied Products to meet cGMP, but the Respondents may make this obligation contingent upon the Acquirer giving the Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

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

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

- E. The Respondents shall agree to hold harmless and indemnify the Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of the Respondents to deliver the Supplied Products to the Acquirer in a timely manner *unless* (i) Respondents can demonstrate that the failure was beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents, and (ii) Respondents are able to cure the supply failure no later than 30 days after the receipt of notice from that Acquirer of a supply failure.
- F. The Respondents shall give priority to supplying the Acquirer over the supplying of Products for any Respondent's own use or sale.
- G. During the term of any agreement for a Respondent to supply the Supplied Products, upon written request of the Acquirer or a Monitor, the Respondent shall make available to the supplied Acquirer and a Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of the applicable Supplied Products.
- H. The Respondents shall provide the Acquirer with the actual costs incurred or the price paid for active ingredients, components, and excipients the Respondents use to manufacture the applicable Supplied Products.
- I. During the term of any agreement for a Respondent to supply the Supplied Products, Respondents shall take all actions as are reasonably necessary to ensure an uninterrupted supply of each of the Supplied Products.
- J. Respondents shall not be entitled to terminate any agreement to supply the Supplied

Products due to (i) a breach by the Acquirer of a Divestiture Agreement, or (ii) that Acquirer filing a petition in bankruptcy, or entering into an agreement with its creditors, or applying for or consenting to appointment of a receiver or trustee, or making an assignment for the benefit of creditors, or becoming subject to involuntary proceedings under any bankruptcy or insolvency law;

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

- K. The Respondents shall permit the Acquirer to terminate the agreement for the supply of the Supplied Products on a product-by-product basis, at any time, upon commercially reasonable notice, and without cost or penalty (other than costs or penalties due by the Respondent to third parties pursuant to the termination of such agreement, which may be the responsibility of that Acquirer).
- L. In the event that that a Respondent becomes (i) unable to supply or produce a Supplied Product from the facility that has been supplying the Acquirer, and (ii) any Respondent has a different facility that is listed on the FDA Authorization for that Supplied Product and is still suitable for use to manufacture the Supplied Product, or any Respondent has a facility that manufactures the Therapeutic Equivalent of such Supplied Product, then such Respondent shall, at the option of the supplied Acquirer, provide a supply of either the Therapeutic Equivalent or the Supplied Product from the other facility under the same terms and conditions as contained in the Divestiture Agreement to supply.
- M. During the term of any agreement for a Respondent to supply the Supplied Products, the Respondents shall provide consultation with knowledgeable employees of Respondents and training, at the written request of the supplied Acquirer and at a facility chosen by the supplied Acquirer, for the purposes of enabling that Acquirer (or its Manufacturing Designee) to obtain all Product Approvals to manufacture the applicable Supplied Products in final form in the same quality achieved by, or on behalf of, Respondents and in commercial quantities, in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of that Acquirer that its personnel (or its Manufacturing Designee's personnel) are adequately trained in the manufacture of the applicable Supplied Products.
- N. For any Supplied Product that, after the Acquisition Date, is made in a facility owned by Respondent Upjohn or Respondent Viatriis, Respondents shall transfer such manufacturing to a facility owned, controlled, or operated by Respondent Pfizer or, at the option of the Acquirer, to its Manufacturing Designee. Respondents shall bear all costs for this transfer including the cost to validate the Supplied Products at the changed facility and the costs for any changes in the specifications for any Supplied Product required by the FDA prior to the FDA's granting approval to market such Product from the changed site of manufacture.
- O. For any Authorized Generic Product that, after the Acquisition Date, has as its source of the active pharmaceutical ingredient either Respondent Upjohn or Respondent Viatriis:

(i) Respondents shall give priority to supplying the active pharmaceutical ingredients for use in such Authorized Generic Product over supplying the active pharmaceutical ingredients for any Product for any Respondent's own use or sale, and (ii) at the Acquirer's option, Respondents shall bear the costs to qualify and obtain FDA regulatory approval to change the source of the active pharmaceutical ingredient(s).

## **V. Asset Maintenance**

**IT IS FURTHER ORDERED** that, until the Respondents have physically transferred the Eplerenone Divestiture Assets, granted the Authorized Generic Product License and assigned the rights to the Gatifloxacin Products to the Acquirer pursuant to Paragraph II of this Order, Respondents shall operate and maintain each of the respective Divestiture Assets and each of the respective Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondents shall:

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

another of Respondents' businesses.

- G. Maintain and preserve the Business Information of such Divestiture Product Businesses.
- H. Provide the resources necessary for such Divestiture Product Businesses to respond to competition, prevent diminution in sales, and maintain its competitive strength.
- I. Continue providing customary levels of support services to such Divestiture Product Businesses.
- J. Maintain all licenses, permits, approvals, authorizations, or certifications used in the operation of such Divestiture Product Businesses, and operate such Divestiture Product Businesses in accordance and compliance with all regulatory obligations and requirements.
- K. Maintain the levels of production, quality, pricing, service, or customer support typically associated with such Divestiture Product Businesses.

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

## **VI. Employees**

**IT IS FURTHER ORDERED** that:

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

that Acquirer or its Manufacturing Designee; *provided, however*, that nothing in the Orders shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by that Acquirer or its Manufacturing Designee of any Relevant Employees, not offer any incentive to such employees to decline employment with that Acquirer or its Manufacturing Designee, and not otherwise interfere with the recruitment of any Relevant Employees by that Acquirer.
- C. Respondents shall continue to provide Relevant Employees compensation and benefits, including regularly scheduled raises and bonuses, until the Divestiture Date or as may be necessary to comply with the provisions of the Orders to provide manufacturing and supply of Divestiture Products or transition services to the Acquirer.
- D. Respondents shall provide reasonable financial incentives for Relevant Employees to continue in their positions, and as may be necessary, to facilitate the employment of such Relevant Employees by the Acquirer.
- E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and a Monitor, determines in its sole discretion that the Acquirer or its Manufacturing Designee should have the ability to interview, make offers of employment to, or hire any of Respondents' employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided manufacturing and supply of Divestiture Products or transition services to the Acquirer, then the Commission may notify Respondents that such employees are to be designated as Relevant Employees, and Paragraph VI of this Order shall apply to such employees as of that notification date.
- F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate his or her employment with the Acquirer or its Manufacturing Designee; *provided, however*, Respondents may:
1. Hire an employee whose employment has been terminated by the Acquirer;
  2. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at one or more of Relevant Employees; and
  3. Hire an employee who has applied for employment with Respondents, as long as such application was not solicited or induced in violation of this Paragraph.



## **VII. Business Information**

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

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

- b. Do not solicit, access, or use any such Confidential Business Information that they are prohibited from receiving for any reason or purpose; and
  - 7. Take all actions necessary and appropriate to prevent access to, and the disclosure or use of, such Confidential Business Information by or to any Person(s) not authorized to access, receive, or use such information pursuant to the terms of the Orders or the Divestiture Agreements, including:
    - a. Establishing and maintaining appropriate firewalls, confidentiality protections, internal practices, training, communications, protocols, and system or network controls and restrictions;
    - b. To the extent practicable, maintaining such Confidential Business Information separate from other data or information of any Respondent; and
    - c. Ensuring by other reasonable and appropriate means that such Confidential Business Information is not shared with a Respondent's personnel engaged in any Business related to the same or substantially the same type of Business as the Divestiture Products, including a Respondent's personnel engaged in the marketing and sale within the United States of Products Developed or in Development for the same or similar indications as the Divestiture Products or that use the same active pharmaceutical ingredients as the Divestiture Products.
- B. As a condition of continued employment after the Divestiture Date, Respondents shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one-year period prior to the Divestiture Date, and each employee that has responsibilities related to the Development, marketing, or sales of those Retained Products that are Developed or in Development for the same or similar indications as the Divestiture Products, in each case who have or may have had access to Confidential Business Information, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which that employee shall be required to maintain all such Confidential Business Information as strictly confidential, including the nondisclosure of that information to all other employees, executives, or other personnel of any Respondent (other than as necessary to comply with the requirements of the Orders).
- C. No later than 30 days after the Divestiture Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information. Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for 2 years after the Divestiture Date. Respondents shall provide a copy of their notifications to the Acquirer. Respondents shall maintain complete records of all such notifications at the respective Respondent's principal executive offices within the United States and shall provide an officer's certification to

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

- D. Each Respondent shall assure that its own counsel (including its own in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to the Acquirer or access original documents provided to that Acquirer, except under circumstances in which copies of documents are insufficient or otherwise unavailable, and for the following purposes:

1. To assure such Respondent's compliance with any Divestiture Agreement, the Orders, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or
2. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena, or other proceeding relating to the divestiture or any other aspect of an Divestiture Product, the Divestiture Assets, or the Divestiture Product Business;

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

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

## **VIII. Additional Obligations**

**IT IS FURTHER ORDERED** that, during the term of the license of any Authorized Generic Product to the Acquirer pursuant to Paragraph II of this Order, Respondent Pfizer shall retain and maintain each FDA Authorization that is the FDA Authorization for an Authorized Generic Product unless:

- A. Respondent Pfizer transfers such FDA Authorization to the Acquirer;
- B. The FDA requires the withdrawal of the FDA Authorization for safety or efficacy reasons;
- C. Respondent Pfizer demonstrates, in consultation with that Acquirer and a Monitor, that a withdrawal of the FDA Authorization is necessary due to safety issues based on adverse events, serious adverse events, unexpected adverse events, or other pharmacovigilance reported to the FDA since the Divestiture Date; or

- D. The Acquirer consents to the Respondent Pfizer's withdrawal of the FDA Authorization.

**IX. Monitor**

**IT IS FURTHER ORDERED** that:

- A. The Commission appoints F. William Rahe and William Hitchings of Quantic Regulatory Services Inc. as Monitors to observe and report on Respondents' compliance with the terms of the Orders. The Monitors shall serve pursuant to the agreement contained in the Monitor Agreement Appendix to the Orders, *provided, however*, such agreement shall not limit, or be construed to limit, the terms of the Monitor Paragraphs of the Orders.
- B. No later than one day after the Commission issues the Order to Maintain Assets, Respondents shall:
1. Confer on the Monitors all rights, power, and authorities necessary to permit the Monitors to monitor Respondents' compliance with the terms of the Orders as set forth in the Monitor Paragraphs of the Orders; and
  2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitors set forth in the Monitor Paragraphs of the Orders.
- C. The Monitors:
1. Shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders;
  2. Shall act in consultation with the Commission or its staff;
  3. Shall serve as an independent third party and not as an employee, or agent of the Respondents or of the Commission;
  4. Shall serve the expense of Respondents, without bond or other security;
  5. May employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out that Monitor's duties and responsibilities;
  6. Shall enter into a confidentiality agreement related to Commission materials and information received in connection with the performance of that Monitor's duties and each of that Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;
  7. Shall notify Respondents and staff of the Commission, in writing, of any potential financial, professional, personal, or other conflicts of interest within 5 days should they arise;
  8. Within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission, shall report in writing to the Commission regarding Respondents' compliance with their obligations under the Orders; and

9. Shall serve until that Monitor, in conjunction with Commission staff, determines that all obligations for the Respondents to provide manufacturing and supply of Divestiture Products have expired or been terminated and a final report is filed within 30-days after that date or until such other time as may be determined by the Commission or its staff.
- D. Respondents shall (i) provide the Monitors full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the Monitors to monitor Respondents' compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitors to perform their duties pursuant to the Orders.
  - E. Respondents shall indemnify and hold the Monitors harmless against losses, claims, damages, liabilities, or expenses (including attorney's fees and out of pocket costs) that arise out of, or in connection with, any claim concerning the Monitors' performance of the Monitors' duties under the Orders, whether or not such claim results in liability, *except*, to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitors' gross negligence or willful misconduct. For purposes of this Paragraph, the term "Monitor" shall include all persons retained by the Monitors in the performance of their duties under the Orders.
  - F. Respondents may require the Monitors and each of the Monitors' consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; *provided, however*, that such agreement does not restrict the Monitors from providing any information to the Commission.
  - G. Respondents shall not require nor compel the Monitors to disclose to Respondents the substance of communications with the Commission, including the Monitors' written reports submitted to the Commission, or any other Person with whom the Monitors communicate in the performance of their duties.
  - H. If the Commission determines that the Monitors have ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor and such substitute Monitor shall be afforded all rights, powers, and authorities and subject to all obligations of a Monitor under the Monitor Paragraphs of the Orders:
    1. The Commission shall select the substitute Monitor, subject to the consent of Respondents which consent shall not be unreasonably withheld. Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor if, upon notice by staff of the Commission of the identity of the substitute Monitor to Respondents, Respondents have not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within 10 days after such notice; and
    2. Not later than 5 days after the Commission appoints a substitute Monitor, Respondents shall enter into an agreement with the substitute Monitor that (i) contains substantially the same terms as the agreement attached as Monitor Agreement Appendix to the Orders or (ii) is approved by the Commission and

confers on the substitute Monitor the rights, powers, and authority of a Monitor under the Monitor Paragraphs of the Orders.

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

## **X. Divestiture Trustee**

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

- A. If the Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets or the rights to the Divestiture Products as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under 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 a Respondent to comply with the Orders.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within 10 days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. No later than 10 days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order. Any failure by Respondents to comply with a trust agreement approved by the Commission shall be a violation of this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee’s powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
2. The Divestiture Trustee shall have one year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one-year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture(s) can be achieved within a reasonable time, the divestiture period may be extended by the Commission;

*provided, however,* the Commission may extend the divestiture period only two (2) times.

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

*provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission;

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

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants,

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

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

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

- E. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to 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(s) required by this Order.



## **XI. Prior Approvals**

**IT IS FURTHER ORDERED** that,

- A. Each Respondent (other than Respondent Pfizer) shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any rights or interests in the Levothyroxine Products, the Sucralfate Products or the Varenicline Products, or the Therapeutic Equivalent of any of these Products without the prior approval of the Commission.
- B. Respondent Pfizer shall not, directly or indirectly, through subsidiaries, partnerships, or otherwise, acquire any voting or non-voting stock, equity, notes convertible into any voting or non-voting stock rights or interests, or debt in Respondent Viatrix, Respondent Upjohn, or Respondent Mylan without the prior approval of the Commission.

## **XII. Compliance Reports**

**IT IS FURTHER ORDERED** that:

- A. Respondents shall:
  - 1. Notify Commission staff via email at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) of the Acquisition Date and the Divestiture Dates no later than 5 days after the occurrence of each; and
  - 2. Submit the complete copies of each of the Divestiture Agreements to the Commission at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov) no later than 30 days after the Divestiture Date.
- B. Respondents shall file verified written reports (“Compliance Reports”) in accordance with the following:
  - 1. Respondents shall submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondents have completed all of the following: (i) the transfer and delivery of the Divestiture Assets and the rights to the Divestiture Products to the Acquirer, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer’s designated third-party contract manufacturer, (iii) the transfer and delivery of all Business Information to the Acquirer, and (iv) Respondent Pfizer or a third-party contract manufacturer (non-Respondent) designated by Pfizer is FDA approved to manufacture each of the Authorized Generic Products at a facility that is owned or controlled by Pfizer after the Acquisition Date or by Pfizer’s designated third-party contract manufacturer; and Respondents shall submit annual Compliance Reports one year after the Order Date, and annually for the following 9 years on the anniversary of the Order Date; and additional Compliance Reports as the Commission or its staff may request;
  - 2. Respondent Pfizer shall continue to submit interim Compliance Reports every 6

months regarding Respondent Pfizer's provision of manufacturing and supply of the Authorized Generic Products to the Acquirer, including a detailed explanation of any manufacturing disruptions or any failures to supply the quantity of ordered Product to that Acquirer, and any other related requirements of the Orders;

3. Each Respondent's Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether the Respondent is in compliance with the Orders. Conclusory statements that the Respondent has complied with its obligations under the Orders are insufficient. Respondents shall include in their Compliance Reports, among other information or documentation that may be necessary to demonstrate compliance:
  - a. A detailed description of all substantive contacts, negotiations, or recommendations related to the transfer and delivery to the Acquirer of (i) the Divestiture Assets and the rights to the Divestiture Products, (ii) the Business Information related to each of the Divestiture Product Businesses, and (iii) the provision of manufacturing and supply of Authorized Generic Products to that Acquirer;
  - b. A detailed description of the transfer of the Product Manufacturing Technology related to the Spironolactone Products, the Prazosin Products, and the Phenytoin Products to Respondent Pfizer or to Pfizer's designated third-party contract manufacturer and progress toward the manufacturing of these products at a facility retained by Pfizer or Pfizer's designated third-party contract manufacturer; and
  - c. A detailed description of the timing for the completion of such obligations.
4. Each annual Compliance Report shall include the previous year's market information for each market alleged in the Complaint including the aggregate size of the market in units and in dollars; the monthly sales in units and in dollars, separately for each strength, for each market participant; the market share for each market participant calculated based on units and on dollars; and, to the extent known, an explanation of any significant changes in the total size of the market and any significant adverse impacts to the manufacture or supply of competing products to the market;
5. Respondents shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondents' obligations under the Orders and provide copies of these documents to Commission staff upon request.

- C. Respondents shall verify each Compliance Report in the manner set forth in 28 U.S.C. § 1746 by the Chief Executive Officer or other officer or employee specifically authorized to perform this function. Respondents shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic

copies to the Secretary at [ElectronicFilings@ftc.gov](mailto:ElectronicFilings@ftc.gov) and to the Compliance Division at [bccompliance@ftc.gov](mailto:bccompliance@ftc.gov). In addition, Respondents shall provide a copy of each Compliance Report to each Monitor.

### **XIII. Change in Respondents**

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

- A. The dissolution of: Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.;
- B. Any proposed acquisition, merger, or consolidation of Pfizer Inc., Upjohn Inc., Viatris Inc., and Mylan N.V.; or
- C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

### **XIV. Access**

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

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

### **XV. Purpose**

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

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

**XVI. Term**

**IT IS FURTHER ORDERED** that this Order shall terminate on January 25, 2031.

By the Commission, Acting Chairwoman Slaughter and Commissioner Chopra  
dissenting.

April J. Tabor  
Secretary

SEAL  
ISSUED: January 25, 2021

**NON-PUBLIC APPENDIX I**  
**AGREEMENTS RELATED TO THE DIVESTITURES**  
**[cover page]**

**NON-PUBLIC APPENDIX  
MONITOR COMPENSATION  
[cover page]**

**PUBLIC APPENDIX  
MONITOR AGREEMENT**

## MONITOR AGREEMENT

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Quantic"), and Mylan N.V. ("Mylan") and Pfizer Inc. ("Pfizer") (together with Mylan, the "Merging Parties"), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in *In the Matter of Mylan N.V.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders* (the "Consent Agreement"), incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with the Merging Parties (collectively, the "Orders"), which, among other things, require the Merging Parties to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that the Merging Parties comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic, and in particular William Hitchings and William Rahe, as such monitor (the "Monitor") pursuant to the Orders to monitor the Merging Parties' compliance with the terms of the Consent Agreement and Orders and with the Remedial (Divestiture) Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

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

WHEREAS, this Monitor Agreement, although executed by the Monitor and the Merging Parties, is not effective for any purpose, including but not limited to imposing rights and responsibilities on the Merging Parties or the Monitor under the Orders, until it has been approved by the Commission; and

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

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means, individually and collectively, amlodipine besylate/atorvastatin calcium tablets, eplerenone tablets, gatifloxacin ophthalmic solution, medroxyprogesterone acetate injectable suspension, phenytoin chewable tablets, prazosin hydrochloride capsules, spironolactone/hydrochlorothiazide tablets, and mesalamine delayed release capsules, and any other Divestiture Product as required in the Orders.



2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Orders, including but not limited to:
  - a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;
  - b. supervising any redaction of Confidential Business Information retained by the Merging Parties as required by the Orders; and
  - c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.
3. The Merging Parties hereby agrees that it will fully and promptly comply with all terms of the Orders requiring it to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon itself any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.
4. The Merging Parties further agrees that:
  - a. it will use its best efforts to ensure that Prasco LLC ("Prasco") or any other Commission-approved Acquirer enters into an agreement with the Monitor at or about the Closing Date governing the facilitation of the Monitor's duties under the Orders and the exchange of information between Prasco or any other Commission-approved Acquirer and the Monitor;
  - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, it will provide the Monitor with the following, as applicable:
    - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
    - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
    - (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to the Merging Parties' compliance with the Orders, including processes and process

- validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;
- (4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Prasco or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;
  - (5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and
  - (6) such other information as reasonably requested by the Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.
- c. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to Prasco, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
  - d. it will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
  - e. it will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Merging Parties;
  - f. it will provide the Monitor with all correspondence, meeting minutes, telephone summaries, and reports, sent to or received from

the FDA relating to the Divestiture Products;

- g. it will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing the Merging Parties' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:
  - (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
  - (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with Prasco related to the manufacture, supply, and technology transfer of the Divestiture Products;
  - (3) all significant activities concerning the assistance, advice and consultation provided to Prasco generally as provided in the Decision and Order; and
  - (4) on request, the Merging Parties will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

*provided, however*, that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that the Merging Parties files the Merging Parties' reports with the Commission as required pursuant to the Decision and Order;

- i. it will comply with the Monitor's reasonable requests for onsite visits and audits of the Merging Parties' facilities (or any Respondent's or contract manufacturer's facility, to the extent within the Merging Parties' control) used to manufacture the Products identified in the

Divestiture Products;

- j. it will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Monitor Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of any Divestiture Product(s) and, further including, actions necessary to maintain all necessary FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products (to the extent within the Merging Parties' control), and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Monitor with access to and hard copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and
  - k. it will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA.
- 5. The Merging Parties shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and the Merging Parties related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Monitor, of such communications.
  - 6. The Merging Parties agrees that to the extent authorized by the Orders, the Monitor shall have the authority to employ, at the expense of the Merging Parties, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
  - 7. The Merging Parties and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning the Merging Parties' compliance with the Merging Parties' obligations to maintain assets pursuant

to the Orders.

8. The Monitor shall maintain the confidentiality of all information provided to the Monitor by the Merging Parties. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Monitor Agreement and the Orders. Such information shall not be disclosed by the Monitor to any third party other than:
  - a. persons employed by, or working with, the Monitor under this Monitor Agreement; or
  - b. persons employed at the Commission and working on this matter.
9. Upon written request, the Monitor will inform the Commission and the Merging Parties of all persons employed by, or working with, the Monitor under this Monitor Agreement (other than, for the avoidance of doubt, representatives of the Commission, the Merging Parties or Prasco) to whom confidential information related to this Monitor Agreement has been disclosed.
10. Upon (i) termination of the Monitor's duties under this Monitor Agreement and the Orders, and (ii) written request by the Merging Parties, the Monitor shall promptly return to the Merging Parties all material provided to the Monitor by the Merging Parties that is confidential to the Merging Parties and that it is entitled to have returned to it under the Orders, and shall destroy any written material prepared by the Monitor that contains or reflects any confidential information of the Merging Parties, provided, that, notwithstanding the foregoing, the Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;
11. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than the Merging Parties,



or any director, officer, employee, agent, consultant or affiliate of the Merging Parties, when such source is entitled to make such disclosure to such recipient or such information was independently developed by the Monitor as evidenced by written records.

12. Nothing in this Monitor Agreement shall require the Merging Parties to disclose any material or information that is subject to a legally recognized privilege or that the Merging Parties is prohibited from disclosing by reason of law.
13. The Monitor shall be responsible for monitoring Respondents' compliance with their obligations as set forth in the Orders and the Divestiture Agreements (Remedial Agreements). In doing so, the Monitor shall act in consultation with the Commission or its staff, and shall serve as an independent third party and not as an employee or agent of the Respondents or the Commission. The Monitor shall have all rights, duties, powers and authorities as required by the Orders, and nothing in the Monitor Agreement shall change, amend, modify, or otherwise limits those rights, duties, powers, and authorities. .
14. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to the Merging Parties.
15. Mylan will pay the Monitor within thirty (30) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of Prasco with respect to the Divestiture Products (including any and all such activities performed prior to the date of this Monitor Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months such hourly rates should be reviewed and may be adjusted by agreement with the Merging Parties.
  - a. In addition, Mylan will pay within thirty days of receipt of an invoice (i) all reasonable and customary out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train or air travel in the performance of the Monitor's duties, and international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties.
  - b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and

any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.

- c. The Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
  - d. To the extent that the Monitor is requested to travel in the performance of the Monitor's duties, the Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process.
16. Mylan hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Mylan shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Monitor's duties and obligations 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 are determined by final arbitration to result from the gross negligence or the willful misconduct of the Monitor.

17. The Monitor's maximum liability to the Merging Parties relating to services rendered pursuant to this Monitor Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the lesser of \$75,000 or the total sum of the fees paid to the Monitor by the Mylan, except to the extent resulting from the gross negligence or the willful misconduct of the Monitor determined by final arbitration. IN NO CIRCUMSTANCES WHATSOEVER SHALL THE MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.
18. The Merging Parties agrees that Mylan's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and Prasco and relates to the Monitor's responsibilities under this Monitor Agreement and/or the Orders.

19. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Mylan shall be required, to notify Prasco and potential future Acquirers with respect to its appointment as the Monitor.
20. In the event of a disagreement or dispute between the Merging Parties and the Monitor concerning the Merging Parties' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between the Merging Parties and the Monitor not relating to the Merging Parties' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Merging Parties' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.
21. This Monitor Agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdiction's choice of law principles).
22. This Monitor Agreement shall terminate no later than: (i) the date set forth in the relevant provision of the Orders; or (ii) on the date on which the Commission has appointed a substitute monitor pursuant to the Orders. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.
23. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that it has a conflict of interest that could adversely affect the performance by the designated lead monitor for the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both the Merging Parties and the Commission of such conflict.
24. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Monitor and the Merging Parties.
25. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
26. This Monitor Agreement and the Orders contains the entire agreement between the parties hereto with respect to the matters described herein and



replaces and supersedes any and all prior agreements or understandings, whether written or oral. Any amendment, waiver, or modification of this Monitor Agreement shall not be valid unless in writing and signed by the parties, and approved by the Commission. Any such amendment, modification, or waiver may only be made in a manner consistent with the terms of the Orders. Purchase Order terms and conditions shall not be applicable.

27. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Quantic Regulatory Services, LLC  
Bethanne Seel  
Office Manager  
5N Regents Street  
Suite 502  
Livingston, NJ 07039

If to Mylan:

Mylan N.V.  
Building 4, Trident Place  
Mosquito Way, Hatfield  
Hertfordshire, United Kingdom, AL10 9UL, or

1000 Mylan Boulevard, Canonsburg, PA 15317

Attention: Global General Counsel

With a copy to:

Cravath, Swaine & Moore LLP  
Worldwide Plaza  
825 Eighth Avenue  
New York, NY 10019

Attention: Margaret D'Amico

If to Pfizer:

Pfizer Inc.  
235 East 42nd Street

New York, New York 10017, USA

Attention: Global General Counsel

With a copy to:

Morgan, Lewis & Bockius LLP  
101 Park Ave  
New York, NY 10178

Attention: Harry T. Robins

If to the Commission:

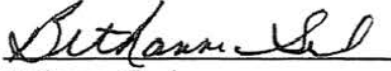
Federal Trade Commission  
601 Pennsylvania Avenue, N.W.  
Washington, DC 20001  
Attn.:  
Telephone:  
Fax:

28. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.
29. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

**[Remainder of Page Intentionally Left Blank.]**

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 14th of September 2020.

Quantic Regulatory Services, LLC



Bethanne Seel  
Office Manager

Mylan N.V.



Thomas D. Salus  
Assistant Secretary

~~Pfizer Inc.~~



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Marc Brotman  
Vice President & Assistant General Counsel Secretary

## **Confidential Appendix A**

