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

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

1. Respondent Elanco Animal Health Incorporated is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Indiana with its executive offices and principal place of business located at 2500 Innovation Way, Greenfield, Indiana 46140.

2. Respondent Bayer Aktiengesellschaft is a corporation organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany with its executive offices and principal place of business located at Kaiser-Wilhelm-Allee 1, Leverkusen, Germany 51368. Bayer’s United States address for service of process of the Complaint, the Decision and Order, and the Order to Maintain Assets solely in this matter is as follows: Bayer Corporation ("Bayer Corp"), a corporation organized, existing, and doing business under and by virtue of the laws of the State of Indiana, with its executive offices and principal place of business at 100 Bayer Boulevard Whippany, NJ 07981.

3. 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. “Elanco” means Elanco Animal Health Incorporated, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates controlled by Elanco Animal Health Incorporated, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

B. “Bayer” means Bayer Aktiengesellschaft, its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Bayer Aktiengesellschaft, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.


D. “Respondents” means Elanco and Bayer.

E. “Acquirer(s)” means:
1. A Person specified by name in this Order to acquire particular Divestiture Assets pursuant to this Decision and Order; or

2. Any other Person the Commission approves to acquire particular Divestiture Assets pursuant to this Decision and Order.

F. “Acquisition Agreement” means the Share and Asset Purchase Agreement between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated, dated August 20, 2019. The Acquisition Agreement is contained in Non-Public Appendix IV.

G. “Acquisition Date” means the earlier of (i) the date on which Elanco acquires any ownership interest in any of the Persons or assets that are identified in the Acquisition Agreement for acquisition by Elanco, or (ii) the date on which Bayer acquires any ownership interest in the voting securities of Elanco pursuant to the Acquisition Agreement.

H. “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.

I. “Business” means the research, Development, manufacture, commercialization, distribution, marketing, advertisement, importation, and sale of a Product.

J. “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 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 Respondent’s right and control over information and material provided to any other Person.

K. “Capstar Divestiture Agreement” mean the Asset Purchase Agreement between Elanco US Inc. and PetIQ, LLC, and, for the purposes of Section 9.16 only, PetIQ, Inc., dated as of January 13, 2020, and all amendments, exhibits, attachments, contracts, agreements, and schedules attached to and submitted to this Order and contained in Non-Public Appendix I.

L. “Capstar Divestiture Assets” mean all rights, title and interest in the Divestiture Product Business related to each of the Capstar Products, including all of the Divestiture Assets related to each of the Capstar Products, including the Capstar trademark.

M. “Capstar Products” mean the Products in Development or manufactured anywhere in the world for marketing or sale in the United States pursuant to the following FDA Authorization: NADA No. 141175, and any supplements, amendments, or revisions to
this NADA.

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

O. “Confidential Business Information” means all Business Information that is not in the public domain.

P. “Customer” means any Person that is a direct purchaser of any Divestiture Product from a Respondent or an Acquirer.

Q. “Dechra” means: (i) Dechra Limited, a private limited company organized under the laws of England and Wales with its executive offices and principal place of business located at 24 Cheshire Avenue, Cheshire Business Park, Lostock Gralam, Northwich, UK, CW9 7UA; (ii) Dechra Veterinary Products LLC, a limited liability company organized under the laws of the State of Delaware, with its executive offices and principal place of business located at 7015 College Blvd., Suite 525, Overland Park, Kansas 66211; and (iii) any Person controlled by or under common control of either Dechra Limited and Dechra Veterinary Products LLC.

R. “Development” means all new chemical entity research, and all studies in animals of the safety or efficacy of a Product, including test method development and stability testing; toxicology; formulation; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; conducting studies in animals 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.

S. “Divestiture Agreement” means:

1. The Capstar Divestiture Agreement;
2. The Osurnia Divestiture Agreement;
3. The StandGuard Divestiture Agreement; or
4. Any other agreement between a Respondent(s) and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order.

T. “Divestiture Assets” mean Respondent Elanco’s 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 in animals 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 in animals of the safety or efficacy 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.

U. “Divestiture Date” means, for each of the respective Divestiture Assets (i.e., the Capstar Divestiture Assets, the Osurnia Divestiture Assets, or the StandGuard Divestiture Assets), the date on which a Respondent (or a Divestiture Trustee) closes on the sale of those Divestiture Assets to an Acquirer.

V. “Divestiture Product” means:
   1. The Capstar Products;
   2. The Osurnia Products; or
   3. The StandGuard Products.

W. “Divestiture Product Business” means the Business related to a Divestiture Product.

X. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph IX of this Order.

Y. “Domain Name” means the domain name(s) and the related uniform resource locator(s) and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration.

Z. “Employee Information” means the following, for each Relevant Employee, as and to the extent permitted by law:
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 proposed or approved Acquirer, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the Relevant Employees.

AA. “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 Respondent Elanco shall provide copies of the document to the Acquirer and shall provide the 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;
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; and

7. Assets specifically identified as excluded assets in Non-Public Appendix V.

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


DD. “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.

EE. “Manufacturing Designee” means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.

FF. “Monitor” means any monitor appointed pursuant to this Decision and Order or the related Order to Maintain Assets issued by the Commission.

GG. “Neogen” means (i) Neogen Corporation, a corporation organized under the laws of the State of Michigan with its executive offices and principal place of business located at 620 Lesher Place, Lansing, Michigan 48912; and (ii) any Person controlled by or under common control of Neogen Corporation.

HH. “Order Date” means the date on which the final Decision and Order in this matter is issued by the Commission.

II. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Consent Agreement.

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

KK. “Osurnia Divestiture Agreement” means the Asset Purchase Agreement between Elanco Tiergesundheit AG and Dechra Limited, dated as of January 3, 2020, and all amendments, exhibits, attachments, agreements, and schedules attached to this Order and contained in Non-Public Appendix II.

LL. “Osurnia Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to each of the Osurnia Products, including all of the Divestiture Assets
related to each of the Osurnia Products, including the Osurnia trademark.

MM. “Osurnia Products” means: the Products identified on Schedule 1.1.32 of the Osurnia Divestiture Agreement, including Product in Development, manufactured, marketed, or sold pursuant to the following FDA Authorization: NADA No. 141437, and any supplements, amendments, or revisions to this NADA.

NN. “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.

OO. “PetIQ” means (i) PetIQ, LLC, a limited liability company organized under the laws of the State of Idaho with its executive offices and principal place of business located at 923 South Bridgeway Place, Eagle, Idaho 83616; (ii) PetIQ, Inc., a corporation organized under the laws of the State of Delaware, with its executive offices and principal place of business located at 923 South Bridgeway Place, Eagle, Idaho 83616; and (iii) any Person controlled by or under common control of either PetIQ, LLC and PetIQ, Inc.

PP. “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.

QQ. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound that is referenced as its pharmaceutically, biologically, or genetically active ingredient, or that is the subject of an FDA Authorization, or both.

RR. “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.

SS. “Product Contracts” means all contracts, agreements, mutual understandings, arrangements, or commitments related to the Divestiture Product Business, including those:

1. Pursuant to which any Customer purchases, or has the option to purchase, a Product from a Respondent;

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 in animals 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 intellectual property 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;

10. Constituting confidentiality agreements related to 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; or

13. Pursuant to which any third party collaborates with a Respondent in the performance of research, Development, marketing, distribution, or selling of a Product.

TT. “Product Development Reports” mean Business Information, as 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 circulars for animal owners or breeders;
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 veterinarians;
11. Summaries of complaints from Customers;
12. Product recall reports filed with the FDA or any other Agency, and all reports, studies, and other documents related to such recalls;
13. Investigation reports and other documents related to any out of specification results for any impurities or defects found in any Product;
14. 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;
15. 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;
16. Analytical methods development records;
17. Manufacturing batch or lot records;
18. Stability testing records;
19. Change in control history; and
20. Executed validation and qualification protocols and reports.

UU. “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, mask works, trademarks, service marks, copyrights, trade dress, commercial names, internet web sites, internet domain names, inventions, discoveries, know-how, trade secrets, and proprietary information.

VV. “Product Manufacturing Equipment” means equipment that is being used, or has been used at any time since Respondents entered into the Acquisition Agreement to manufacture the specified Divestiture Product.

WW. “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.

XX. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product 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.

YY. “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.

ZZ. “Relevant Employees” means:

1. Manufacturing Employees - all employees of a Respondent who have participated at any time during the 3-year period immediately prior to the termination of any contract to provide Transition Manufacturing (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;
2. Marketing Employees - all management-level employees of a Respondent who have participated (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 within the 18 month period immediately prior to the Divestiture Date; and

3. Research and Development Employees - all employees of a Respondent who have participated (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: research, Development, regulatory approval process, or studies in animals of the safety or efficacy of the Divestiture Product, within the 18 month period immediately prior to the Divestiture Date.

AAA. “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.

BBB. “Shared Intellectual Property” means all Product Intellectual Property of any kind (other than trademarks, Domains Names, and FDA Authorizations related to a Divestiture Product) (i) that is primarily or predominantly used (but not exclusively used) in connection with a Divestiture Product Business as of the Divestiture Date, and (ii) that has been used, and continues to be used, in connection with the manufacture of any Retained Product.

CCC. “StandGuard Divestiture Agreement” mean the Asset Purchase Agreement by and between Elanco US Inc. and Neogen, dated as of February 20, 2020, and all amendments, exhibits, attachments, agreements, and schedules attached to this Order and contained in Non-Public Appendix III.

DDD. “StandGuard Divestiture Assets” mean all rights, title and interest in the Divestiture Product Business related to each of the StandGuard Products, including all of the Divestiture Assets related to each of the StandGuard Products, including the StandGuard trademark.

EEE. “StandGuard Products” mean the following Products in Development or manufactured anywhere in the world for marketing or sale in the United States:

1. The pour-on insecticide known as StandGuard (containing .50% gamma-cyhalothrin, corn oil, silicone fluid and butylated hydroxytoluene);
2. The gammacyhalothrin ear tag (containing 2.0% gamma-cyhalothrin); and
3. The controlled-release premised insecticide known as StandGuard Premise
Insecticide (containing 5.9% gamma-cyhalothrin.

**FFF.** “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.

**GGG.** “Technology Transfer Standards” mean requirements and standards sufficient to ensure that the information and assets required to be transferred and delivered to an Acquirer pursuant to this Order are delivered to that Acquirer 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 Divestiture Product(s) acquired by that Acquirer, *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 that Acquirer or its Manufacturing Designee, and the 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 that Acquirer;

3. Preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology to that Acquirer or its Manufacturing Designee;

4. For any part of the manufacturing process that is performed by a Respondent, permitting employees of the Acquirer and/or its Manufacturing Designee 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 that Acquirer or its Manufacturing Designee to:
   
   a. Manufacture the Product in the quality and quantities achieved by a Respondent or the manufacturer or developer of the Product;
   
   b. Obtain any Product Approvals necessary for that Acquirer or its Manufacturing Designee to manufacture, 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.
“Transition Manufacture” and “Transition Manufacturing” mean the following:

1. To manufacture, or to cause to be manufactured, a Capstar Product on behalf of the Acquirer (including, for the purposes of studies in animals or commercial sales); or

2. To provide, or to cause to be provided, any part of the manufacturing process including, the finish and packaging of a Capstar Product on behalf of the Acquirer.

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

II. Divestitures

IT IS FURTHER ORDERED that:

A. Not later than 10 days after the Acquisition Date, Respondent Elanco shall divest the Capstar 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, absolutely and in good faith, to PetIQ pursuant to, and in accordance with, the Capstar Divestiture Agreements;

provided, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and the Monitor, the Acquirer needs one or more Excluded Assets to operate the Capstar Divestiture Assets or the related Divestiture Product Business in a manner that achieves the purposes of the Order, Respondent Elanco shall divest, absolutely and in good faith, the needed Excluded Assets to the Acquirer.

B. Not later than 10 days after the Acquisition Date, Respondent Elanco shall divest the Osurnia 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, absolutely and in good faith, to Dechra pursuant to, and in accordance with, the Osurnia Divestiture Agreements;

provided, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and the Monitor, the Acquirer needs one or more Excluded Assets to operate the Osurnia Divestiture Assets or the related Divestiture Product Business in a manner that achieves the purposes of the Order, Respondent Elanco shall divest, absolutely and in good faith, the needed Excluded Assets to the Acquirer.

C. Not later than 10 days after the Acquisition Date, Respondent Elanco shall divest the StandGuard 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, absolutely and in good faith, to Neogen pursuant to, and in accordance with, the StandGuard Divestiture Agreements;

provided, however, that, if within 12 months after the Order Date, the Commission determines, in consultation with the Acquirer and the Monitor, the Acquirer
needs one or more Excluded Assets to operate the StandGuard Divestiture Assets or the related Divestiture Product Business in a manner that achieves the purposes of the Order, Respondent Elanco shall divest, absolutely and in good faith, the needed Excluded Assets to the Acquirer.

D. The Order does not prohibit Respondent Elanco from receiving a non-exclusive license from the relevant Acquirer of each of the Divestiture Products to use the Shared Intellectual Property in the manufacture of (i) any Product that is marketed, distributed, or sold that is not indicated for the same treatment in the same animal species as such Divestiture Products, or (ii) with respect to Shared Intellectual Property included in the Capstar Assets or the StandGuard Assets, any Product that is not commercialized, distributed, marketed, advertised, or sold within the United States.

E. If Respondent Elanco has divested any of the Divestiture Assets to an 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 Respondent Elanco that:

1. The named Acquirer is not an acceptable purchaser of any of the Divestiture Assets, then Respondent Elanco shall immediately rescind the transaction with that Acquirer as directed by the Commission, and shall divest the respective Divestiture Assets 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 Respondent Elanco shall make such modifications to the manner of divestiture of the Divestiture Assets 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.

F. Prior to the Divestiture Date, Respondent Elanco shall provide the relevant Acquirer of each of the Divestiture Products with the opportunity to review each Product Contract related to such Divestiture Products so that the relevant 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 the relevant Acquirer, assign or otherwise make available to the relevant Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product.

G. Respondent Elanco:

1. Prior to the Divestiture Date, shall secure all approvals, consents, ratifications, waivers, or other authorizations from all non-governmental third parties that are necessary to permit Respondent Elanco to divest the Divestiture Assets to each of the relevant Acquirers, and to permit the relevant Acquirer to continue in the related Divestiture Product Business in the United States without interruption or
impairment; and

2. As related to the Product Manufacturing Technology and any ingredient, material, or component used in the manufacture of the Divestiture Product, shall not enforce any agreement against a third party or the relevant Acquirer to the extent that such agreement may limit or otherwise impair the ability of the relevant 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 relevant Acquirer. Not later than 10 days after the Divestiture Date, Respondent Elanco 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 relevant Acquirer. Within 5 days of the execution of each such release, Respondent Elanco shall provide a copy of the release to the relevant Acquirer;

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

H. Respondent Elanco shall deliver to the relevant Acquirer of each of the Divestiture Products the related Product Manufacturing Technology and shall deliver it in a manner consistent with the Technology Transfer Standards.

I. Not later than 10 days after the Divestiture Date, Respondent Elanco shall designate employees of Respondent Elanco knowledgeable about the marketing, distribution, warehousing, and sale of each of the Divestiture Products to assist the relevant Acquirer of each of the Divestiture Products to transfer and integrate the related Divestiture Product Business.

J. Not later than 10 days after the Divestiture Date, Respondent Elanco 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 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; and
5. 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:
   1. Use any of the trademarks divested pursuant to this Order or any mark confusingly similar to those trademarks as a trademark, tradename, or service mark, except as may be agreed upon with the relevant Acquirer of each of the Divestiture Products for the purposes of selling inventory, finished goods, packaging or similar materials bearing the relevant trademarks for the benefit of the relevant Acquirer during a transition period;
   2. Attempt to register the divested trademarks;
   3. Attempt to register any mark confusingly similar to the divested trademarks;
   4. Challenge or interfere with the use and registration of the divested trademarks by the relevant Acquirer of each of the Divestiture Products; or
   5. Challenge or interfere with efforts to enforce its trademark registrations for, and trademark rights in, the divested trademarks against third parties by the relevant Acquirer of each of the Divestiture Products,

   provided, however, the prohibitions in this paragraph II.K shall apply only to actions in the United States with respect to trademarks including in the Capstar Assets and the StandGuard Assets.

L. 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 each Acquirer’s freedom to research, Develop, or manufacture anywhere in the world the Divestiture Product(s) acquired by that Acquirer, or to distribute, market, sell, or offer for sale within the United States any such Divestiture Product.

M. Upon reasonable written request from an Acquirer, Respondent Elanco shall, in a timely manner, make available knowledgeable employees of Respondent Elanco (i.e., employees of Respondent Elanco that were involved in the Development of the Divestiture Products) to assist the Acquirer in defending against, responding to, or otherwise participating in any infringement action brought by a third party against the Acquirer related to the Product Intellectual Property acquired by that Acquirer from
Respondent Elanco. Respondent Elanco shall make their employees available for the fee provided in the relevant Divestiture Agreement, or if no fee is provided, at no greater than the then-current average hourly wage rate for such employee.

N. 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 a 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 a Divestiture Product, Respondents shall:

1. Cooperate with the relevant Acquirer of that Divestiture Product 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 Respondents’ outside legal counsel to represent that Acquirer in any such patent infringement suit; and

3. Permit the transfer to that Acquirer of all of the litigation files and any related attorney work product in the possession of the Respondents’ 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 Transition Manufacturing

IT IS FURTHER ORDERED that:

A. At the request of an Acquirer, in a timely manner, at no greater than the cost of labor, material, travel, and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service, or at such cost as provided in a Divestiture
Agreement, Respondent Elanco shall provide transition services sufficient to enable the relevant Acquirer of each of the Divestiture Products to operate the related Divestiture Product Business in substantially the same manner that Respondent Elanco has operated that Business prior to the Acquisition Date.

B. Upon reasonable written notice and request by the Acquirer of the Capstar Products (“Capstar Acquirer”) or the Acquirer of the StandGuard Products (“StandGuard Acquirer”), Respondent Elanco shall Transition Manufacture and deliver, or cause to be manufactured and delivered, to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, the requested supply of Capstar Products or StandGuard Products, as applicable. The requested Divestiture Products shall be provided at no greater than Supply Cost or at such cost as provided in a Divestiture Agreement and for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, (and, for the Capstar Products, in a manner consistent with cGMP), the finished dosage form of the Divestiture Product independently of Respondent Elanco, and to secure sources of supply of the active ingredients, excipients, other ingredients, and necessary components from Persons other than Respondent Elanco.

C. Respondent Elanco shall make representations and warranties to the Capstar Acquirer and StandGuard Acquirer that the Divestiture Products Elanco is supplying to each meet the relevant Agency-approved specifications.

D. For the Capstar Product(s), the supplying Respondent shall agree to indemnify, defend, and hold the relevant Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses, or losses alleged to result from the failure of the Capstar Product(s) supplied to that Acquirer pursuant to a Divestiture Agreement to meet cGMP, but the supplying Respondent may make this obligation contingent upon that Acquirer giving the supplying Respondent prompt written notice of such claim and cooperating fully in the defense of such claim;

provided, however, that the supplying Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with the supplying Respondent’s responsibilities to supply the Capstar Products in the manner required by this Order;

provided further, however, that this obligation shall not require the supplying Respondent to be liable for any negligent act or omission of that Acquirer or for any representations and warranties, express or implied, made by that Acquirer that exceed the representations and warranties made by the supplying Respondent to that Acquirer in an agreement to Transition Manufacture.

E. Respondent Elanco shall agree to hold harmless and indemnify the Capstar Acquirer and the StandGuard Acquirer for any liabilities, loss of profits, or consequential damages resulting from the failure of Respondent Elanco to deliver Divestiture Products to the requesting Acquirer in a timely manner unless (i) Respondent Elanco can demonstrate
that the failure was beyond the control of Respondent Elanco and in no part the result of negligence or willful misconduct by Respondent Elanco, and (ii) Respondent Elanco is able to cure the supply failure not later than 30 days after the receipt of notice from that Acquirer of a supply failure.

F. Respondent Elanco shall give at least the same level of priority to supplying requested Divestiture Products to the Capstar Acquirer and the StandGuard Acquirer as Respondent Elanco gives to the manufacturing and supplying of Products for Respondent Elanco’s own use or sale.

G. During the term of any agreement to Transition Manufacture, upon written request of the Capstar Acquirer, the StandGuard Acquirer, or the Monitor, Respondent Elanco shall make available to the requesting Acquirer and the Monitor all records generated or created after the Divestiture Date that relate directly to the manufacture of Divestiture Products for the Capstar Acquirer or StandGuard Acquirer, as applicable.

H. Respondent Elanco shall provide the following to the Capstar Acquirer regarding Capstar Products and to the StandGuard Acquirer regarding the StandGuard Products: the actual costs incurred or the price paid for active ingredients, components, and excipients Respondent Elanco uses to manufacture the relevant Divestiture Products supplied to the relevant Acquirer.

I. During the term of any agreement to Transition Manufacture, Respondent Elanco shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Capstar Products to the Capstar Acquirer and StandGuard Product to the StandGuard Acquirer.

J. Respondent Elanco shall not be entitled to terminate any agreement to Transition Manufacture due to (i) a breach by the relevant 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 Respondent Elanco from seeking compensatory damages from that Acquirer for that Acquirer’s breach of its payment obligations to Respondent Elanco under the agreement.

K. Respondent Elanco shall permit the Capstar Acquirer or the StandGuard Acquirer to terminate its agreement with Respondent Elanco to Transition Manufacture at any time upon commercially reasonable notice and without cost or penalty (other than costs or penalties due by a Respondent to third parties pursuant to the termination of such agreement, which shall be the responsibility of that Acquirer).

L. During the term of any agreement to Transition Manufacture, Respondent Elanco shall provide consultation with knowledgeable employees of Respondent Elanco and training, at the written request of the Capstar Acquirer or the StandGuard Acquirer and at a facility chosen by the requesting Acquirer, for the purposes of enabling that Acquirer (or the
Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in final form in the same quality achieved by, or on behalf of, Respondent Elanco and in commercial quantities, (and, for the Capstar Products, in a manner consistent with cGMP), independently of Respondent Elanco and sufficient to satisfy management of the requesting Acquirer that its personnel (or its Manufacturing Designee’s personnel) are adequately trained in the manufacture of the relevant Divestiture Products.

V. Asset Maintenance

IT IS FURTHER ORDERED that, until the Capstar Divestiture Assets, the Osurnia Divestiture Assets, and the StandGuard Divestiture Assets have been physically transferred to each of the relevant Acquirers, Respondent Elanco shall operate and maintain each of the respective Divestiture Assets and related Divestiture Product Businesses in the ordinary course of business consistent with past practices. Included in these obligations, Respondent Elanco 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 the related 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 workforce 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 Respondent Elanco’s 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 an Acquirer has requested or agreed to in writing and that has been approved in advance by the Monitor (in consultation with Commission staff), in all cases to facilitate the relevant Acquirer’s acquisition of the Divestiture Assets and consistent with the purposes of the Orders.

VI. Employees

IT IS FURTHER ORDERED that:

A. Until 2 years after the Divestiture Date, Respondent Elanco shall cooperate with and assist each Acquirer to evaluate independently and offer employment to the Relevant Employees for the Divestiture Products acquired by that Acquirer.

B. Respondent Elanco shall, for each Acquirer:

1. No later than 10 days after a request from an 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 an 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 Respondent Elanco 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 Respondent Elanco that may deter Relevant Employees from accepting employment with the relevant Acquirer or its Manufacturing Designee, including, but not limited to, removal of any non-compete or confidentiality provisions of employment or other contracts with Respondent Elanco that may affect the ability or incentive of those individuals to be employed by the 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 this Order shall be construed to require Respondent Elanco to terminate the employment of any employee or prevent Respondent Elanco from continuing the employment of any employee; and

4. Not interfere, directly or indirectly, with the hiring or employing by the relevant 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 the Acquirer.

C. Respondent Elanco 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 this Order to provide Transition Manufacturing or transition services.

D. Respondent Elanco 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 relevant Acquirer.

E. If, at any point within 6 months of the Divestiture Date, the Commission, in consultation with the Acquirer and the 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 Respondent Elanco’s employees who were not included as Relevant Employees, but who either (i) were involved with any of the Divestiture Products, or (ii) provided Transition Manufacturing or transition services to an Acquirer, then the Commission may notify Respondent Elanco that such employees are to be designated as Relevant Employees, and the provisions of this Paragraph V shall apply to such employees as of that notification date.

F. Respondents shall not, for a period of one year following the Divestiture Date, directly or indirectly, solicit or otherwise attempt to induce any of the Relevant Employees who have accepted offers of employment with the Acquirer or its Manufacturing Designee to terminate 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; or

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. Respondent Elanco shall transfer and deliver all Business Information related to a Divestiture Product Business to the Acquirer of that Divestiture Product Business pursuant to the following:

1. Respondent Elanco shall deliver the Business Information to the Acquirer, at Respondent Elanco’ 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, Respondent Elanco shall provide the 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 this Order;

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. Respondent Elanco’s 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, Transition Manufacturing, or who are engaged in the transfer and delivery of the Product Manufacturing Technology to that Acquirer), (iii) the Commission, or (iv) the Monitor or except as 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 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 relevant 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 a 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 (e.g., commercialization of Products Developed, in Development, marketed, or sold for the same or similar indications and in the same geographic territory as the Divestiture Products).

B. As a condition of continued employment after the Divestiture Date, Respondent Elanco shall require each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the 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 and for commercialization, in each case who have or may have had access to Confidential Business Information related to those Products, 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 Respondent Elanco (other than as necessary to comply with the requirements of this Order).

C. Not later than 30 days after the Divestiture Date, Respondent Elanco shall provide written notification of the restrictions on the use and disclosure of the above-described Confidential Business Information by that Respondent Elanco’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. Respondent Elanco 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. Respondent Elanco shall provide a copy of the notification to the Acquirer. Respondent Elanco shall maintain complete records of all such notifications at that 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. Respondent Elanco shall provide the 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 an Acquirer or access original documents provided to an 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, this Order, any law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable government entity, or any taxation requirements; or

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 relevant 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. Monitor

IT IS FURTHER ORDERED that:

A. The Commission appoints Francis J. Civille as the Monitor to observe and report on Respondents’ compliance with the terms of the Orders. The Monitor shall serve pursuant to the agreement between the Monitor and Respondent Elanco 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 Paragraph of the Orders.

B. No later than one day after the Commission issues the Order to Maintain Assets, Respondent Elanco shall:

1. Confer on the Monitor all rights, power, and authorities necessary to permit the Monitor to monitor Respondent Elanco’s compliance with the terms of the Orders as set forth in Monitor Paragraph of the Orders; and
2. Consent to the terms and conditions regarding such rights, powers, and authorities of the Monitor set forth in the Monitor Paragraph of the Orders.

C. The Monitor:

1. Shall have the authority to monitor Respondent Elanco’s 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, agent, or fiduciary of Respondent Elanco or of the Commission;
4. Shall serve at the expense of Respondent Elanco, without bond or other security;
5. May employ, at the cost and expense of Respondent Elanco, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the 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 the Monitor’s duties and each of the Monitor’s consultants, accountants, attorneys, and other representatives and assistants shall enter into such a confidentiality agreement;
7. Shall notify Respondent Elanco 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, the Monitor shall report in writing to the Commission regarding Respondent Elanco’s compliance with its obligations under the Orders and, where relevant, each Acquirer’s or its Manufacturing Designee’s progress toward obtaining the Product Approvals necessary to manufacture each Divestiture Product acquired by that Acquirer, independently of Respondent Elanco; and
9. Shall serve until 30 days after all Divestiture Agreements to provide Transition Manufacturing or transition services have expired or been terminated or until such other time as may be determined by the Commission or its staff.

D. Respondent Elanco shall (i) provide the Monitor full and complete access to all information and facilities, and, as necessary, make such arrangements with third parties, to allow the monitor to monitor Respondent Elanco’s compliance with its obligations under the Orders; and (ii) cooperate with, and take no action to interfere with or impede the ability of, the Monitor to perform his/her duties pursuant to the Orders.

E. Respondent Elanco shall indemnify and hold the Monitor 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 Monitor’s performance of the Monitor’s 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 Monitor’s gross negligence or willful misconduct. For purposes of this Paragraph, the term “Monitor” shall include all persons retained by the Monitor in the performance of his or her duties under the Orders.

F. Respondent Elanco may require the Monitor and each of the Monitor’s consultants, accountants, attorneys, and other representatives and assistants to enter into a customary confidentiality agreement; provided, however, that such agreement does not restrict the Monitor from providing any information to the Commission.

G. Respondent Elanco shall not require nor compel the Monitor to disclose to Respondent Elanco the substance of communications with the Commission, including the Monitor’s written reports submitted to the Commission, or any Person with whom the Monitor communicates in the performance of the Monitor’s duties.

H. If the Commission determines that the Monitor has 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 the Monitor Paragraph of the Orders:

1. The Commission shall select the substitute Monitor, subject to the consent of Respondent Elanco which consent shall not be unreasonably withheld. Respondent Elanco 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 Respondent Elanco, Respondent Elanco has 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, Respondent Elanco 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 Paragraph of the Orders.

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

IX. Divestiture Trustee

IT IS FURTHER ORDERED that:

A. If Respondent Elanco has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver, or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15
U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent Elanco 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 this Order.

B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Elanco, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Elanco has 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 Respondent Elanco of the identity of any proposed Divestiture Trustee, Respondent Elanco shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

C. Not later than 10 days after the appointment of a Divestiture Trustee, Respondent Elanco 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 Respondent Elanco 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, Respondent Elanco 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 1 year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one-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. Respondent Elanco shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Elanco 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 Respondent Elanco’s absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an Acquirer 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 Respondent Elanco from among those approved by the Commission;

   provided further, however, that Respondent Elanco 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 Respondent Elanco, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Elanco, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee’s duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee’s services, all remaining monies shall be paid at the direction of Respondent Elanco, 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. Respondent Elanco 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 Respondent Elanco and to the Commission every 30 days concerning the Divestiture Trustee’s efforts to accomplish the divestiture.

9. Respondent Elanco 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.

X. Compliance Reports

IT IS FURTHER ORDERED that:

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

B. Respondent Elanco shall file verified written reports (“Compliance Reports”) in accordance with the following:
   1. Respondent Elanco shall:
a. Submit interim Compliance Reports within 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter until Respondent Elanco has completed all of the following: (i) the transfer and delivery of the Capstar Divestiture Assets, the Osurnia Divestiture Assets and the StandGuard Divestiture Assets to each of the relevant Acquirers, (ii) the transfer and delivery of all of the Product Manufacturing Technology related to the Divestiture Products to each of the relevant Acquirers, (iii) the transfer and delivery of all Business Information to each of the relevant Acquirers, and (iv) the provision of Transition Manufacturing to the Acquirer of the Capstar Divestiture Assets;

b. Annual Compliance Reports one year after the Order Date and annually for the next 4 years on the anniversary of that date; and

c. Additional Compliance Reports as the Commission or its staff may request.

2. Each Compliance Report shall contain sufficient information and documentation to enable the Commission to determine independently whether Respondent Elanco is in compliance with the Orders. Conclusory statements that Respondent Elanco has complied with its obligations under the Orders are insufficient. Respondent Elanco shall include in its 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 each of the relevant Acquirers of (i) the Capstar Divestiture Assets, the Osurnia Divestiture Assets, and the StandGuard Divestiture Asset (ii) the related Product Manufacturing Technology, (iii) the related Business Information, and (iv) the provision of Transition Manufacturing to the Acquirer of the Capstar Divestiture Assets; and

b. A detailed description of the timing for the completion of such obligations.

3. Respondent Elanco shall retain all material written communications with each party identified in the Compliance Report and all non-privileged internal memoranda, reports, and recommendations concerning fulfilling Respondent Elanco’s obligations under the Orders and provide copies of these documents to Commission staff upon request.

C. Respondent Elanco 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. Respondent Elanco shall submit an original and 2 copies of each Compliance Report as required by Commission Rule 2.41(a), 16 C.F.R. § 2.41(a), including a paper original submitted to the Secretary of the Commission and electronic copies to the Secretary at ElectronicFilings@ftc.gov and to the Compliance Division at bcompliance@ftc.gov. In addition, Respondent Elanco shall provide a copy of each Compliance Report to the Monitor.
XI. Change in Respondents

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

A. The dissolution of: Elanco Animal Health Incorporated or Bayer Aktiengesellschaft;
B. Any proposed acquisition, merger, or consolidation of Elanco Animal Health Incorporated or Bayer Aktiengesellschaft; or
C. Any other change in Respondents including, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

XII. Access

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, 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.

XIII. Purpose

IT IS FURTHER ORDERED that the purpose of this Order is to remedy in a timely and sufficient manner the lessening of competition resulting from the proposed acquisition by Elanco of certain assets and shares comprising the animal health business of Bayer as alleged in the Commission’s Complaint by:

C. Ensuring the continued use of the Capstar Divestiture Assets, Osurnia Divestiture Assets, and StandGuard Divestiture Assets for the purposes of each of the respective Divestiture Product Businesses within the United States; and
D. Creating viable and effective competitors that are independent of Respondents in the respective Divestiture Product Businesses within the United States.
XIV. Term

IT IS FURTHER ORDERED that this Order shall terminate on September 1, 2030.

By the Commission, Commissioner Slaughter not participating.

April J. Tabor
Acting Secretary

SEAL

ISSUED: September 1, 2020
PUBLIC APPENDIX
MONITOR AGREEMENT

(Monitor compensation redacted)
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