

Complaint

IN THE MATTER OF

**ELANCO ANIMAL HEALTH, INCORPORATED,
AND
BAYER AKTIENGESELLSCHAFT**

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

*Docket No. C-4725; File No. 191 0198
Complaint, July 14, 2020 – Decision, September 1, 2020*

This consent order addresses the \$7.6 billion acquisition by Elanco Animal Health, Inc. of certain assets of Bayer Animal Health, GmbH. The complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the U.S. market for low-dose prescription treatments for canine otitis externa, fast-acting oral treatments that kill adult fleas on canines, and brand name cattle pour-on insecticides. Under the order respondent must divest its canine otitis externa treatment product, Osumnia, to Dechra Pharmaceuticals PLC, its fast-acting oral treatment that kills adult fleas on canines, Capstar, to PetIQ, Inc., and its brand name cattle pour-on product, StandGuard, to Neogen Corporation.

Participants

For the *Commission*: *Stuart Hirschfeld, Joe Lipinsky, and Connor Shively.*

For the *Respondents*: *Rick Rule, Paul, Weiss, Rifkind, Wharton & Garrison; Tom McGrath, Linklaters LLP.*

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Elanco Animal Health, Inc. (“Elanco”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire all of the assets of Bayer Animal Health, GmbH, a division of Bayer AG (“Bayer”), a corporation subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating it charges as follows:

I. RESPONDENTS

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

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2. Respondent Bayer is a corporation organized, existing, and doing business under and by virtue of the laws of the Federal Republic of Germany with its principal executive offices 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, 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. Each Respondent is, and at all times relevant herein has been, engaged in commerce, as "commerce" is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and engages in business that is in or affects commerce, as "commerce" is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

II. THE PROPOSED TRANSACTION

4. Pursuant to a Share and Asset Purchase Agreement dated August 20, 2019, Respondent Elanco proposes to purchase all of the assets of Bayer Animal Health, GmbH, a division of Bayer, for approximately \$7.6 billion (the "Acquisition"). The Acquisition is subject to Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

III. THE RELEVANT MARKETS

5. A relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of low-dose prescription treatments for canine otitis externa. Canine otitis externa is an inflammation of the outer ear caused by bacteria and/or yeast. Bayer's prescription otitis externa treatment product, Claro, is a single-dose otic solution, while Elanco's product, Osumnia, is an otic gel given in two doses seven days apart. While older prescription products can be used to treat canine otitis externa, these products require numerous applications to the ear canal, up to twice daily for 14 consecutive days. Consequently, these older prescription products are not a reasonable substitute for the parties' low-dose prescription products for canine otitis externa.

6. A relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of fast-acting oral treatments that kill adult fleas on canines. Elanco's Capstar and Bayer's Advantus are tablets that start killing adult fleas quickly (within 30 minutes for Capstar, and within 60 minutes for Advantus) and eliminate all adult fleas within four hours. Medicated shampoos and sprays that can be used to kill adult fleas on canines are less convenient to administer and are slower-acting. Consequently, medicated shampoos and sprays are not a reasonable substitute for the parties' fast-acting oral treatments that kill adult fleas on canines.

7. A relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of brand name cattle pour-on insecticides. Cattle pour-on insecticides are liquid parasitocides administered directly to cattle's skin that kill and deter biting flies, lice and mites. Many customers trust and rely on brand name cattle pour-on

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insecticides rather than generic products. Consequently, generic cattle pour-on insecticides are not a reasonable substitute for the parties' brand name cattle pour-on insecticides.

8. The United States is the relevant geographic area in which to assess the competitive effects of the Acquisition in each relevant line of commerce.

IV. MARKET STRUCTURE

9. Bayer's Claro and Elanco's Osumnia are the only low-dose prescription products for the treatment of canine otitis externa. Consequently, the Acquisition would create a monopoly by combining the only two low-dose prescription products that treat canine otitis externa.

10. Elanco's Capstar and Bayer's Advantus are the only fast-acting oral treatments that kill adult fleas on canines. Consequently, the Acquisition would create a monopoly for fast-acting oral treatments that kill adult fleas on canines.

11. The market for brand name cattle pour-on insecticides is highly concentrated. Bayer, with its three brand name cattle pour-on insecticides products (Clean-Up II, Cylence, and Permethrin), is the market leader. The only other competitors with meaningful sales in the market are Merck & Co., Inc., which sells four products, and Elanco, which sells StandGuard. The Acquisition would allow the third largest competitor, Elanco, to acquire the market leader, greatly increasing concentration in brand name cattle pour-on insecticides.

V. ENTRY CONDITIONS

12. Entry into each relevant market described in Paragraphs 5 – 8 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. *De novo* entry would require significant investment to, among other things, develop products, obtain regulatory approval, where needed, and establish recognized brand names. Entry would be unlikely because the required investment would be difficult to justify given the sales opportunities in the affected markets. Entry would also not be timely because drug development times and U.S. Food and Drug Administration and U.S. Environmental Protection Agency approval requirements, where needed, would be lengthy. In addition, no other entry is likely to occur such that it would be timely and sufficient to deter or counteract the competitive harm likely to result from the Acquisition.

VI. EFFECTS OF THE ACQUISITION

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

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- a. combining the only two providers of low-dose prescription treatments for canine otitis externa, thereby eliminating actual, direct, and substantial competition between Bayer and Elanco;
- b. combining the only two providers of fast-acting oral treatments that kill adult fleas on canines, thereby eliminating actual, direct, and substantial competition between Bayer and Elanco;
- c. combining the market leader and one of the only two other providers of brand name cattle pour-on insecticides, thereby eliminating actual, direct, and substantial competition between Bayer and Elanco;
- d. increasing the likelihood that Elanco would unilaterally exercise market power in the relevant markets; and
- e. increasing the likelihood that customers would be forced to pay higher prices for the relevant products.

VII. VIOLATIONS CHARGED

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

15. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fourteenth day of July, 2020 issues its Complaint against said Respondents.

By the Commission, Commissioner Slaughter not participating.

DECISION

The Federal Trade Commission initiated an investigation of (i) the proposed acquisition by Respondent Elanco Animal Health Incorporated of certain assets and shares comprising the animal health business of Respondent Bayer Aktiengesellschaft, collectively “Respondents,” and (ii) the proposed acquisition by Respondent Bayer of voting securities of Respondent Elanco. The Commission’s Bureau of Competition prepared and furnished to Respondents the Draft Complaint, which it proposed to present to the Commission for its consideration. If issued by the Commission, the Draft Complaint would charge Respondents with violations of Section 7 of the

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Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

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

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

I. ORDER**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

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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.
- C. “Commission” means the Federal Trade Commission.
- 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

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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.

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- 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 Osumia 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

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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 Osumia 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 Osumia 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;

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- 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

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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.

CC. “FDA Authorization(s)” means all of the following, as defined in the United States Federal Food, Drug and Cosmetic Act, as amended: “Investigational New Animal Drug Application (“INADA”), “New Animal Drug Application” (“NADA”), “Abbreviated New Animal Drug Application” (“ANADA”), or “Conditional New Animal Drug Application” (“CNADA”) for a drug filed or to be filed with the FDA, 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.

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 Leshar 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.

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- 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. “Osumnia 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. “Osumnia Divestiture Assets” means all rights, title and interest in the Divestiture Product Business related to each of the Osumnia Products, including all of the Divestiture Assets related to each of the Osumnia Products, including the Osumnia trademark.
- MM. “Osumnia Products” means: the Products identified on Schedule 1.1.32 of the Osumnia 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.

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- 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;

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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;

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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

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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

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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);

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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:

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- 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.

HHH. “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.

III. “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 Osumia 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

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good faith, to Dechra pursuant to, and in accordance with, the Osumnia 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 Osumnia 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

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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;

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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.

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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

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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).

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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;

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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;

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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.

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- 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 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

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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

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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's expense, in good faith, in a timely manner (*i.e.* as

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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

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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

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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. Civile 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*,

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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

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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

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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

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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.

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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.

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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 bccompliance@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 bccompliance@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:

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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 Osumnia 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 Osumnia 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.

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- 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 bccompliance@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.

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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:

- A. Ensuring the continued use of the Capstar Divestiture Assets, Osumnia Divestiture Assets, and StandGuard Divestiture Assets for the purposes of each of the respective Divestiture Product Businesses within the United States; and
- B. 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 the date 10 years after the Order Date.

By the Commission.

NON-PUBLIC APPENDIX I**AGREEMENTS RELATED TO THE CAPSTAR DIVESTITURE**

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NON-PUBLIC APPENDIX II**AGREEMENTS RELATED TO THE OSURNIA PRODUCT DIVESTITURE**

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NON-PUBLIC APPENDIX III

AGREEMENTS RELATED TO THE STANDGUARD PRODUCT DIVESTITURE

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NON-PUBLIC APPENDIX IV

THE ACQUISITION AGREEMENT

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NON-PUBLIC APPENDIX V

excluded assets

[cover page]

NON-PUBLIC APPENDIX

MONITOR COMPENSATION

[cover page]

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PUBLIC APPENDIX**MONITOR AGREEMENT**

This Monitor Agreement ("Monitor Agreement") entered into this 24th day of June 2020 between Francis J. Civile and Elanco Animal Health Inc. ("Respondent"), provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), in connection with an Agreement Containing Consent Order incorporating an Order To Maintain Assets and a Decision and Order (the "Order"), relating to the Respondent's acquisition of certain assets comprising the animal health business of Bayer AG (*Commission File No. 191-0198*), has accepted or will shortly accept the Order for public comment, which, among other things, requires Respondent to divest or transfer certain defined assets and to ensure that Respondent complies with its obligations under the Order provides for the appointment of a Monitor;

WHEREAS, the Commission may appoint Francis J. Civile as such Monitor (the "Monitor") pursuant to the Order to monitor Respondent's compliance with the terms of the Order and with the Remedial Agreements referenced in the Order, and Francis J. Civile has consented to such appointment;

WHEREAS, the Order further provides or will provide that Respondent 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 Order;

WHEREAS, this Monitor Agreement, although executed by the Monitor and Respondent, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondent or the Monitor under the Order, 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 Order. The term "Monitored Assets" means the categorized assets, as defined in the Order, divested to each Commission-approved Acquirer.
2. The Monitor shall have all of the powers and responsibilities conferred upon the Monitor by the Order, including but not limited to:
 - a. supervising the divestiture of the Monitored Assets;
 - b. supervising compliance pertaining to the submission and delivery of Confidential Business Information to each Commission-approved Acquirer and the retention, non-disclosure, or use of Confidential Business Information by the Respondent as set forth in the Order; and

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- c. supervising the performance of any transition required by the Order.
3. Respondent hereby agrees that it will fully and promptly comply with all terms of the Order requiring them 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 hereunder.
 4. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondent shall be required, to notify all Commission-approved Acquirers of his appointment as Monitor.
 5. Respondent further agrees that:
 - a. it will use reasonable best efforts to ensure that each relevant Commission-approved Acquirer for their respective assets enters into a separate Monitor Agreement with the Monitor governing the facilitation of the Monitor's duties under the Order and the Remedial Agreements and the exchange of information between each 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 copy of the Remedial Agreements (or drafts thereof) relating to the Monitored Assets, including any exhibits, schedules and appendices;
 - (2) a copy of the offering or information memoranda (if any), or similar documents and information, provided to each Commission-approved Acquirer relating to the sale of the Monitored Assets;
 - (3) copies of relevant correspondence with and written reports or minutes of meetings of all substantive contacts and discussions with any Commission-approved Acquirer relating to the Monitored Assets or Remedial Agreements;
 - (4) an inventory and description of the Monitored Assets, including a complete inventory of any existing FDA approvals and pending FDA approvals for the products included in the Monitored Assets and identifying the person(s) responsible for taking such actions as are required to maintain or complete such approvals; and
 - (5) copies of any other relevant documents, as requested by the Monitor, including but not limited to significant product development

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and manufacturing reports, FDA correspondence/minutes, marketing assessments, annual sales reports for current year-to-date and last year, related to the Monitored Assets.

- 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 Monitored Assets to each Commission-approved Acquirer, together with their locations, telephone numbers, electronic mail address, and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
- d. it will use reasonable efforts to provide the Monitor with prompt notification (but not later than such notification is available to other meeting participants) of significant meetings, included but not limited to transfer steering committee and project team meetings or their equivalent, with the date, time and venue or phone-in coordinates, scheduled after the execution of this Monitor Agreement, relating to the manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Monitored Assets, and such meetings may be attended by the Monitor, at the Monitor's option, or at the request of the Commission or its staff;
- 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 when those minutes are available to any employee of the Respondent;
- f. it will provide the Monitor with all relevant correspondence, meeting minutes, telephone summaries, reports, sent to or received from the Food and Drug Administration ("FDA") after the execution of this Monitor Agreement relating to the Monitored Assets, and will provide prompt notice of all meetings or communications with the FDA relating to or affecting the Monitored Assets;
- g. it will provide the Monitor with electronic copies of all reports submitted to the Commission pursuant to the Order, simultaneous with the submission of such reports to the Commission, as well as any other significant written or oral communications with the Commission related to the Monitored Assets;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Order, it will provide every three (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or on a schedule as reasonably requested by the Monitor, full and detailed electronic reports to the Monitor reasonably describing all of Respondent's activities and obligations under the Order during that period concerning the Monitored Assets including, without limitation to the extent applicable:

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- (1) all significant activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer, as required in the relevant provisions of the Order and Remedial Agreements;
- (2) as applicable, all significant activities and interactions concerned with the development, regulatory aspects, manufacture, supply and technology transfer of the products included in the Monitored Assets including, without limitation, negotiation and execution of any supply agreements and actual supply and inventory; and
- (3) as applicable, all minutes and records of significant meetings, action plans and updates thereof, and follow-ups to action plans and meetings, with each Commission-approved Acquirer related to the research, development, regulatory aspects, manufacture and supply, and technology transfer of the products included in the Monitored Assets and, upon request, Respondent shall provide the Monitor with any records exchanged at such meetings, or such other information that the Monitor may reasonably require relating to the research, development, regulatory aspects, manufacture and supply, and technology transfer of the products included in the Monitored Assets for the Monitor's reporting to the Commission;

provided however, that, at the time the 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 Respondent file their reports with the Commission as required pursuant to the relevant provision(s) of the Order;

- i. it will comply with the Monitor's reasonable requests for onsite visits to Respondent's facilities (or to any contract manufacturer's facility) used to manufacture the products included in the Monitored Assets; and
- 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 involved in any activities relating to research, development, regulatory, manufacture, sale and/or divestiture of the Monitored Assets or any product comprised therein and, further including, actions necessary to maintain all necessary FDA approvals to develop, manufacture and sell any of the products included in the Monitored Assets in the United States and to prevent the destruction, removal, wasting, deterioration or impairment of the Monitored Assets, and will provide the Monitor with access to copies of all other data, records or other information that the Monitor reasonably believes are necessary to the proper discharge of his responsibilities under the Order.

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6. Respondent 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 Respondent related to the Monitored Assets in the Order or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be reasonably requested by the Monitor, of such communications.
7. Respondent agrees that to the extent authorized by the Order, the Monitor shall have the authority to employ, at the expense of the Respondent, and with the consent of Respondent, which will not unreasonably be withheld, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
8. The Monitor and any other parties employed pursuant to Paragraph 7 above (the "Designees") shall maintain the confidentiality of all information provided to the Monitor by Respondent. Such information shall be used by the Monitor and his Designees only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitor or his Designees to any third party, other than:
 - a. persons employed by, or working with, the Monitor under this Monitor Agreement and who have executed a confidentiality agreement consistent with the provisions of this Monitor Agreement; or
 - b. persons employed at the Commission and working on this matter.
9. The Monitor shall maintain a record and inform the Commission and the Respondent of all persons (other than staff of the Commission) to whom confidential information related to this Monitor Agreement has been disclosed.
10. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor shall return, at Respondent's expense, to Respondent all material provided to the Monitor by Respondent that is confidential to Respondent and that it is entitled to have returned to them under the Order, or shall have it destroyed, at Respondent's request and expense. Monitor shall destroy any materials prepared by the Monitor and shall delete any electronic files that contain or reflect any confidential information of Respondent. 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. The Monitor shall keep confidential for a period of ten (10) years all other aspects of the performance of his duties under this Monitor Agreement and shall not disclose any confidential or proprietary information relating thereto. 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 Order, the Monitor shall ensure that such persons have executed a confidentiality agreement in a form agreed upon by the Monitor and Respondent.

Decision and Order

For the purpose hereof, 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, 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 from a source other than the Monitor, Respondent, or any director, officer, employee, agent, consultant or affiliate of the Monitor or Respondent, when such source is entitled to make such disclosure to such recipient.

12. Nothing in this Monitor Agreement shall require Respondent to disclose any material or information that is subject to a legally recognized privilege or that Respondent is prohibited from disclosing by reason of law, court order or an agreement with a third party.
13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Order as it relates to Respondent.
14. Respondent will pay the Monitor the hourly fee, as listed and under the terms and conditions specified in the Fee Schedule in the attached "Exhibit to the Monitor Agreement" for the performance of the Monitor's duties and responsibilities under the Monitor Agreement and the Order.
15. Respondent hereby confirms its obligation to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Order. Respondent shall indemnify the Monitor and any subcontractor and their respective agents, partners, principals, officers 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 reasonably required under this Monitor Agreement of the Monitor's duties and obligations including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
16. The Monitor's maximum liability to the Respondent 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 total sum of the fees paid to the Monitor by Respondent, except to the extent resulting from the misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor or any of his subcontractors, agents, partners, principals, officers or employees, in which case the liability is not so limited.

Decision and Order

17. Respondent agrees that the Respondent's obligations to indemnify the Monitor extend to any agreement that is entered between the Monitor and any Commission-approved Acquirer and relates to the Monitor's responsibilities under the Monitor Agreement and/or the Order.
18. In the event of a disagreement or dispute between Respondent and the Monitor concerning Respondent's obligations under the Order and, in the event that such disagreement or dispute cannot be resolved by the parties, any party may seek the assistance of the responsible individual in the Commission's Compliance Division to resolve the issue. In the case of any disagreement or dispute between Respondent and the Monitor not relating to Respondent's obligations under the Order, 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 a single arbitrator) 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 Respondent's obligations pursuant to the Order.
19. This Monitor Agreement shall be subject to the substantive law of the State of New Jersey (regardless of any other jurisdiction's choice of law principles).
20. This Monitor Agreement shall terminate no later than the date set forth in the relevant provision of the Order or the date on which the Commission has appointed a substitute monitor pursuant to the Order, provided however, that the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Order. The confidentiality obligations of this Monitor Agreement shall survive its termination.
21. In the event that, during the term of this Monitor Agreement, the Monitor becomes aware that he has or may have a conflict of interest that may affect or could have the appearance of affecting the performance by the Monitor, or persons employed by, or working with, the Monitor, of any duty under this Monitor Agreement, the Monitor shall promptly inform both Respondent and the Commission of such conflict or potential conflict.
22. In the performance of his functions and duties under this Monitor Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs.
23. It is understood that the Monitor will be serving under this Monitor Agreement, in consultation with the Commission or its staff, as an independent third party contractor and not as an employee or agent of the Respondent or the Commission.
24. 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

Decision and Order

shall give or be construed to give any other person any legal or equitable rights hereunder.

25. This Monitor Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.
26. Any notices or other communications required to be given hereunder shall be deemed to have been properly given, if sent by mail, 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:

Francis J. Civile
1 Corda Lane
Warren, New Jersey 07059

Telephone: (732) 428-7012
Facsimile: (732) 428-7240
Mobile: (973) 727-6832
Email: fjciville@aol.com

If to Respondent, to:

Michael-Bryant Hicks
EVP, General Counsel, Corporate Secretary
Elanco Animal Health
2500 Innovation Way, Greenfield, IN 46140

Telephone: (317) 651-9498
Email: hicksmb@elanco.com

If to the Commission, to:

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
Attn.: David von Nirschl

Telephone: (202) 326-3213
Email: dnirschl@ftc.gov

27. This Monitor Agreement shall not become binding until it has been approved by

Decision and Order

the Commission and the Order has been accepted for public comment.

28. This Monitor Agreement may be signed in counterparts.

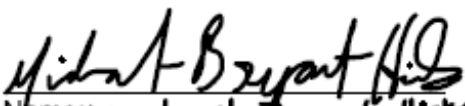
[signature page follows; remainder of this page is blank]

Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written,

Francis J. Civile

Elanco Animal Health Inc.

By: 
Name: Michael Bryant Hicks
Title: EVP General Counsel

Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

Francis J. Civile



Elanco Animal Health Inc.

By: _____
Name:
Title:

ANALYSIS OF CONSENT ORDERS TO AID PUBLIC COMMENT**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) with Elanco Animal Health, Inc. (“Elanco”), and Bayer Animal Health, GmbH (“Bayer”). The proposed Consent Agreement is intended to remedy the anticompetitive effects that likely would result from Elanco’s proposed acquisition of Bayer (the “Proposed Acquisition”).

Pursuant to a Share and Asset Purchase Agreement dated August 20, 2019, Elanco proposes to acquire all of the Bayer Animal Health assets for approximately \$7.6 billion. Both parties sell low-dose prescription treatments for canine otitis externa, fast-acting oral treatments that kill adult fleas on canines, and brand name cattle pour-on insecticides. The Commission alleges in its Complaint that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by lessening competition in the U.S. market for these three product categories.

The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Proposed Acquisition. Specifically, under the terms of the proposed Consent Agreement, Elanco is required to divest its canine otitis externa treatment product, Osrurnia, to Dechra Pharmaceuticals PLC (“Dechra”), its fast-acting oral treatment that kills adult fleas on canines, Capstar, to PetIQ, Inc. (“PetIQ”), and its brand name cattle pour-on product, StandGuard, to Neogen Corporation (“Neogen”).

II. The Relevant Products and Competitive Effects

The Commission’s Complaint alleges three relevant product markets within which to analyze the Proposed Acquisition.

The first relevant product market is low-dose prescription treatments for canine otitis externa. Canine otitis externa is an inflammation of the outer ear caused by bacteria and/or yeast. Common symptoms of otitis externa include pain, itching, redness, scaling, and swelling of the ear canal, and may result in serious complications if left untreated. Numerous prescription products treat canine otitis externa, but only the parties’ products—Elanco’s Osrurnia and Bayer’s Claro—require only one or two doses to treat the condition. Bayer’s prescription otitis externa treatment product, Claro, is a single-dose otic solution, while Elanco’s product, Osrurnia, is an otic gel given in two doses seven days apart. While other prescription products can be used to treat canine otitis externa, these other products require numerous applications to the ear canal, up to twice daily for 14 consecutive days, and are thus not reasonable substitutes for the parties’ products, which are considerably more convenient to use. As such, the Proposed Acquisition would create a monopoly by combining the only two low-dose prescription products that treat canine otitis externa.

Analysis to Aid Public Comment

A second relevant product market is fast-acting oral treatments that kill adult fleas on canines. While there are numerous products that kill and prevent fleas on dogs, most are slower-acting or preventative, targeting flea larvae. In contrast, Elanco's Capstar and Bayer's Advantus start killing adult fleas quickly (within 30 minutes for Capstar, and within 60 minutes for Advantus), and eliminate all adult fleas within four hours. Medicated shampoos and sprays that can be used to kill adult fleas are much less convenient to administer and are slower-acting. As Elanco's Capstar and Bayer's Advantus are the only fast-acting oral treatments that kill adult fleas on canines, the Proposed Acquisition would also create a monopoly for fast-acting oral treatments that kill adult fleas on canines.

A third relevant product market is brand name cattle pour-on insecticides. Cattle pour-on insecticides are liquid parasiticides administered directly to cattle's skin that kill and deter biting flies, lice, and mites. Many customers trust and rely on brand name cattle pour-on insecticides rather than generic products. As a result, generic cattle pour-on insecticides are not a reasonable substitute for the parties' brand-name cattle pour-on insecticides. The market for brand name cattle pour-on insecticides is highly concentrated. Bayer is the market leader, selling three cattle pour-on insecticide products (Clean-Up II, Cylence, and Permethrin). The only other competitors with meaningful sales in the market are Merck & Co., Inc., which sells four products, and Elanco, which sells StandGuard. Thus, the Proposed Acquisition would allow the third largest competitor, Elanco, to acquire the market leader, Bayer, significantly increasing concentration in brand name cattle pour-on insecticides. Moreover, to avoid insects becoming resistant to the active ingredients in insecticides, cattle producers typically cycle through different pour-on insecticides. Elanco's StandGuard and Bayer's Cylence have similar chemical structures and may compete for and occupy the same slot in cattle producers' pour-on insecticide rotation.

The United States is the relevant geographic market in which to assess the competitive effects of the Proposed Acquisition. Each of these products must be approved by the FDA and/or EPA before being sold in the United States. Thus, products sold outside the United States, but not approved for sale in the United States, are not alternatives for U.S. consumers.

III. Entry

Entry into the U.S. market for low-dose prescription treatments for canine otitis externa, fast-acting oral treatments that kill adult fleas on canines, and brand name cattle pour-on insecticides would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. Several major obstacles stand in the way of a prospective entrant. *De novo* entry would require significant investment to, among other things, develop products, obtain regulatory approval, where needed, and establish recognized brand names. Moreover, entry would be unlikely because the required investment would be difficult to justify given the sales opportunities in the affected markets.

IV. The Agreement Containing Consent Order

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the three relevant product markets by requiring the parties to divest the rights and assets related to Elanco's products in each of the markets. The proposed Consent

Analysis to Aid Public Comment

Agreement requires Elanco to divest Osumnia to Dechra, Capstar to PetIQ, and StandGuard to Neogen. The Order requires Elanco to divest the relevant rights and interests in these products no later than ten days after the consummation of the Proposed Acquisition.

Dechra, headquartered in Northwich, England, is a global animal health company and is publicly traded on the London Stock Exchange. Dechra has significant presence and experience in the United States, operating in the United States for over 15 years and offering more than 80 U.S. products, including both prescription and non-prescription companion animal products. Osumnia will complement Dechra's broad dermatology portfolio, which includes Animax Ointment, an antibacterial, antifungal, and anti-inflammatory skin application that is a daily-dose treatment and is indicated for multiple skin conditions, anal gland infections in dogs, as well as canine otitis externa. Although Animax can treat canine otitis externa, it is not a direct competitor to Osumnia given it is an older generation product requiring daily application to treat the condition.

PetIQ, headquartered in Boise, Idaho, is a rapidly growing pet health and wellness company. It has served as Elanco's exclusive distributor of Capstar to retailers since 2018. Capstar aligns well with the other products for dogs in PetIQ's portfolio. PetIQ's products include complementary flea and tick products for dogs that offer longer lasting treatments to kill eggs and larvae and are sold under the Sergeant's, Advecta, and Sentry brand names. PetIQ sells products through all the companion animal retail channels through which Elanco currently sells Capstar and also sells its current product lines to pet specialty retailers, mass merchandisers/grocers, club stores, and e-commerce sites.

Neogen, headquartered in Lansing, Michigan, is a global animal and food safety company offering a wide portfolio of solutions, including insecticides, diagnostic test kits to detect contamination in animal feed, animal pharmaceuticals, vaccines, and diagnostics for production animals. Neogen currently markets and sells its products through the same distribution channels Elanco uses for StandGuard. In addition, Neogen manufactures and sells liquid insecticides and aerosol products used both on livestock and for in-premise insect control, and it has the capability to manufacture StandGuard in-house.

Each of the divestitures requires Elanco to transfer all supply input and other manufacturing contracts, business information, product approvals (including relevant FDA marketing authorizations), intellectual property, and other related assets to the relevant divestiture buyer. The proposed Consent Agreement also contains provisions to ensure that the divestitures are successful and timely, including provisions that require Elanco to provide the purchasers the opportunity to review product contracts and to designate knowledgeable employees to assist each divestiture buyer in transferring and integrating the relevant divested product into its business.

The Commission will appoint an Interim Monitor to ensure that the parties comply with all of their obligations pursuant to the Consent Agreement and to keep the Commission informed about the status of the transfer of the rights and assets to Dechra, PetIQ, and Neogen. The Commission's goal in evaluating possible purchasers of divested rights and assets is to maintain the competitive environment that existed prior to the Proposed Acquisition.

Analysis to Aid Public Comment

The Commission does not intend this analysis to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

**ABBVIE INC.,
AND
ALLERGAN PLC**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL
TRADE COMMISSION ACT AND SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4713; File No. 191 0169
Complaint, May 5, 2020 – Decision, September 3, 2020*

This consent order addresses the \$63 billion acquisition by AbbVie Inc. of certain assets of Allergan plc. The complaint alleges that the proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in the U.S. markets for (1) prescription drugs for the treatment of exocrine pancreatic insufficiency (“EPI”); (2) Interleukin-23 (“IL-23”) inhibitors for the treatment of moderate-to-severe Crohn’s disease; and (3) IL-23 inhibitors for the treatment of moderate-to-severe ulcerative colitis. The consent order requires Allergan to divest all rights and assets related to its Zenpep and Viokase products to Nestlé S.A. The Order also requires that Allergan return its rights and assets related to brazikumab to AstraZeneca plc.

Participants

For the *Commission*: Catherine M. Sanchez and Kari A. Wallace.

For the *Respondents*: Emily Blackburn and Debbie Feinstein, Arnold & Porter Kaye Scholer LLP; Michael DeRita, Samantha Morelli, and Matthew Reilly, Kirkland & Ellis LLP; Natalie Hayes, Brianne Kucerik, and Ann Malester; Weil, Gotshal & Manges LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent AbbVie Inc. (“AbbVie”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire the equity interests of Respondent Allergan plc (“Allergan”), a public limited company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

I. RESPONDENTS

1. Respondent AbbVie 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 1 North Waukegan Road, North Chicago, Illinois 60064.