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FEDERAL TRADE COMMISSION

[File No. 191 0198]

Elanco Animal Health and Bayer Animal Health; Analysis of Agreement Containing Consent Orders to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement; Request for Comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: "Elanco and Bayer; File No. 191 0198" on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW,

5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Joseph Lipinsky (206-220-4473), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR § 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Website (for July 15, 2020), at this web address: https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. Write "Elanco and Bayer; File No. 191 0198" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Due to the public health emergency in response to the COVID-19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will

be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write "Elanco and Bayer; File No. 191 0198" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov*, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively

sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Website – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at http://www.ftc.gov to read this Notice and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

Analysis of Agreement Containing 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, Osurnia, 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 Osurnia 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, Osurnia, 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.

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 Permectrin). 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 Proposed Consent Agreement

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 Agreement requires Elanco to divest Osurnia 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. Osurnia 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 Osurnia 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.

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

By direction of the Commission, Commissioner Slaughter not participating.

April J. Tabor,

Secretary.

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