Further, the Order requires PSA to notify USFSA and ISI that the Order will prevent PSA from doing on behalf of USFSA or ISI anything that, if done by PSA, would be inconsistent with the Order against PSA. This is necessary because PSA provides various education services on ethics to both USFA and ISI coaches.

Paragraph IV of the Proposed Order requires PSA to design, maintain, and operate an antitrust compliance program. PSA must have an Antitrust Compliance Officer for the duration of the Proposed Order. For a period of five years, PSA must provide guidance to its staff, employees, members, and leaders concerning the antitrust laws and PSA obligations under the Proposed Order. PSA also must implement policies and procedures to enable persons to ask questions about, and report violations of, the Proposed Order and the antitrust laws confidentially and without fear of retaliation, and to discipline its leaders, employees and agents for failure to comply with the Proposed Order.

Paragraphs V–VII of the Proposed Order require certain standard compliance reporting, cooperation, and access.

The Proposed Order will expire in the 20 years.

By direction of the Commission.

Janice Podoll Frankle,

Acting Secretary.

[FR Doc. 2014–30649 Filed 12–30–14; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 141 0142]

Eli Lilly and Company and Novartis AG; Analysis of Proposed Consent Orders To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

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 draft complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 21, 2015.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/elililllyconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Eli Lilly and Company and Novartis A.G.—Consent Agreement; File No. 141–0142'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/elililllyconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, write ''Eli Lilly and Company and Novartis A.G.—Consent Agreement; File No. 141–0142'' 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.

FOR FURTHER INFORMATION CONTACT: Michael Barnett, Bureau of Competition, (202–326–2362), 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 consent orders 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 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 Home Page (for December 22, 2014), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 21, 2015. Write ''Eli Lilly and Company and Novartis A.G.—Consent Agreement; File No. 141–0142'' 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 public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone'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 that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in 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). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/elililllyconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''Eli Lilly and Company and Novartis A.G.—Consent Agreement; File No. 141–0142'' 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

[1] 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), 16 CFR 4.9(c).

possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. 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 January 21, 2015. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm*.

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'') from Eli Lilly and Company (''Eli Lilly''), which is designed to remedy the anticompetitive effects of Eli Lilly's acquisition of the Novartis Animal Health business (''Novartis Animal Health'') from Novartis AG (''Novartis'').

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

Pursuant to a Stock and Asset Purchase Agreement dated April 22, 2014, Eli Lilly proposes to acquire Novartis Animal Health for approximately $5.4 billion (the ''Proposed Acquisition''). Both parties sell canine heartworm parasiticide products in the United States. 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 canine heartworm parasiticides. 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 Consent Agreement, Eli Lilly is required to divest all of the rights and assets related to Sentinel Spectrum and Sentinel Flavor Tabs (''the Sentinel products''). Eli Lilly has proposed Virbac S.A. (''Virbac'') as the buyer of the rights and assets related to the Sentinel products.

II. The Relevant Product and Structure of the Market

The relevant product market in which to analyze the Proposed Acquisition is no broader than all canine heartworm parasiticides. Canine heartworm parasiticides are medications used to treat heartworm disease in dogs. Heartworm disease is a potentially fatal condition caused by parasitic worms living in the arteries of a dog's heart and lungs. Canine heartworm parasiticides primarily target heartworm, but the various products in the category have different attributes. For example, some canine heartworm parasiticides also treat other internal parasites, such as hookworm, roundworm, whipworm and tapeworm, and/or external parasites, like fleas. Canine parasiticides are offered in oral, topical, and injectable formulations, with most customers preferring the oral ones.

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

The market for canine heartworm parasiticides in the United States is highly concentrated. Eli Lilly, which markets Trifexis, is the market leader with a share in excess of 35%. Merial Limited, which sells Heartgard and Heartgard Plus, is the second-leading supplier, with a share of 30%. Heartgard and Heartgard Plus are oral products but do not treat fleas. Novartis's Sentinel product line has an 8% market share. The only other significant supplier is Zoetis Inc., which supplies Revolution and ProHeart 6. Revolution is a combination product that requires topical application. ProHeart 6 is an injectable product that does not impact fleas. Thus, the Acquisition would consolidate the two closest competitors, would substantially increase concentration, and would produce a single firm controlling more than 43% of the relevant market.

III. Entry

Entry into the U.S. market for canine heartworm parasiticides would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. Three major obstacles stand in the way of a prospective canine heartworm parasiticide entrant: Lengthy development timeframes, FDA and other agency approval requirements, and difficulty of establishing a brand name and convincing veterinarians to prescribe new products.

IV. Effects of the Acquisition

Eli Lilly's acquisition of Novartis Animal Health will adversely affect competition in the market for canine heartworm parasiticides by eliminating close head-to-head competition between Trifexis and the Sentinel products. Trifexis and the Sentinel products are each other's closest competitors because, among other reasons, they are the only oral heartworm products that impact fleas. Flea prevention combined with heartworm prevention in one oral treatment is particularly important as it combines the convenience of a single oral treatment while avoiding the mess and smell of topical products. In addition, Trifexis and the Sentinel products are the only oral combination products that treat whipworm. These attributes provide a scope of treatment and ease of use not available with other canine heartworm parasiticides. Absent a remedy, the Proposed Acquisition would likely result in higher prices for consumers due to the ability of Eli Lilly to effect a unilateral price increase.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the canine heartworm parasiticide market by requiring the parties to divest the rights and assets related to the Sentinel products to Virbac. This divestiture will preserve the close competition between the only two oral products on the market indicated for the treatment of heartworm, other internal worms, and fleas in dogs.

Virbac is a multinational pharmaceutical company headquartered in Carros, France with approximately 4,350 employees. In 2013, the company generated $934 million in global revenues. Companion animal products comprise 56% of Virbac sales, making it the sixth-largest veterinary product company in the companion animal products business. Virbac operates in the United States through its subsidiary, Virbac Corp., which focuses on canine, feline, and equine pharmaceutical and hygiene products. Virbac Corp. has 350 employees, and had $130 million in

revenue in 2013. Virbac Corp. is well suited to acquire the Sentinel products because of its current presence in the companion animal health business, and because it already has experience with canine heartworm products. Although Virbac currently sells canine heartworm products, their sales are relatively small and, because they do not contain an active ingredient to treat fleas, their competitive interaction with the Sentinel products is limited.

The Order requires Eli Lilly to divest all of its respective rights and interests in the Sentinel products no later than ten days after the consummation of the Proposed Acquisition or on the date on which the Order becomes final, whichever is earlier. The divestiture includes all regulatory approvals, brand names, marketing materials, and confidential business information, including customer information, related to the Sentinel products, and other assets associated with producing, marketing and selling the Sentinel products. To ensure the divestiture is successful, the Order requires Eli Lilly and Novartis to secure all third-party consents and waivers required to permit Virbac to conduct business with the Sentinel products. The Order also requires Eli Lilly to divest supply chain assets related to the Sentinel products. These assets include certain rights and intellectual property for the active pharmaceutical ingredients in the Sentinel products. Additionally, Eli Lilly and Virbac must complete a technical transfer of manufacturing from Novartis to Virbac. The Order calls for an interim supply agreement of the Sentinel products for up to four years while Eli Lilly and Virbac complete the technical transfer.

The Commission has agreed to appoint an Interim Monitor to ensure that Eli Lilly and Novartis 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 Virbac.

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. If the Commission determines that Virbac is not an acceptable acquirer of the divested rights and assets, or that the manner of the divestitures is not acceptable, the parties must unwind the sale of rights and assets to Virbac and divest them to a Commission-approved acquirer within six months of the date the Order becomes final. In that circumstance, the Commission may appoint a trustee to divest the rights and assets if the parties fail to divest them as required.

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

By direction of the Commission.

Janice Podoll Frankle,

Acting Secretary.

[FR Doc. 2014–30686 Filed 12–30–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2254]

The Drug Supply Chain Security Act Implementation: Product Tracing Requirements—Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''DSCSA Implementation: Product Tracing Requirements—Compliance Policy.'' This guidance announces FDA's intention with regard to enforcement of certain product tracing requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Supply Chain Security Act (DSCSA). FDA does not intend to enforce these requirements against manufacturers, wholesale distributors, and repackagers who do not, prior to May 1, 2015, provide or capture the transaction information, transaction history, and transaction statement required by the FD&C Act (product tracing information) for transaction of certain human, finished prescription drugs that are covered in the statute.

DATES: Effective December 31, 2014. For information about enforcement dates, please see the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: All responses to this notice should be identified with Docket No. FDA–2014–D–2254 and directed to the office listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''DSCSA Implementation: Product Tracing Requirements—Compliance Policy.'' This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance has been implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate. (§ 10.115(g)(2)). This guidance document provides information pertaining to statutory requirements that will take effect on January 1, 2015, regarding the provisions to provide and capture product tracing information under section 582(b)(1), (c)(1), and (e)(1) of the FD&C Act (21 U.S.C. 360eee–1(b)(1), (c)(1), and (e)(1)). It is important that FDA provide this information before that date. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices. (§ 10.115(g)(3)).

On November 27, 2013, the DSCSA (Title II of Pub. L. 113–54) was signed into law. Section 202 of the DSCSA added sections 581 and 582 to the FD&C Act, which set forth new definitions and requirements for the tracing of products through the pharmaceutical distribution supply chain. Starting in 2015, trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) will be required under section 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act, to exchange product tracing information when engaging in transactions involving certain prescription drugs. Manufacturers, wholesale distributors, and repackagers must meet these requirements by January 1, 2015; dispensers must meet these requirements by July 1, 2015.

Although the product tracing requirements under section 582(b), (c), and (e) of the FD&C Act go into effect for manufacturers, wholesale distributors, and repackagers on January 1, 2015, some trading partners have expressed concern that unforeseen complications with the exchange of the required information may result in disruptions in the pharmaceutical supply chain, and ultimately could impact patients' access to needed prescription drugs. FDA recognizes that some manufacturers, wholesale distributors, and repackagers may need time beyond January 1, 2015, to work