[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 141 0141]

GlaxoSmithKline, PLC 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 December 29, 2014.

ADDRESSES: Interested parties may file a comment at https://ftcpublic.commentworks.com/ftc/gsknovartisconsent online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "GlaxoSmithKline, PLC and Novartis AG- Consent Agreement; File No. 141-01414" on your comment and file your comment online at https://ftcpublic.commentworks.com/ftc/gsknovartisconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, write "GlaxoSmithKline, PLC and Novartis AG- Consent Agreement; File No. 141-01414" 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: Mark Silvia, Bureau of Competition, (202-326-3291), 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 November 26, 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 December 29, 2014. Write "GlaxoSmithKline, PLC and Novartis AG- Consent Agreement; File No. 141-01414" 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 Website, 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 Website.

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/gsknovartisconsent 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 website.

If you file your comment on paper, write "GlaxoSmithKline, PLC and Novartis AG"-Consent Agreement; File No. 141-01414" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600

[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).

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.

Visit the Commission Website 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 December 29, 2014. 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 Novartis AG ("Novartis"), which is designed to remedy the anticompetitive effects of Novartis's proposed consumer healthcare joint venture with GlaxoSmithKline, PLC ("GSK").

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 series of agreements dated April 22, 2014, GSK and Novartis intend to combine the GSK consumer healthcare business and most of the Novartis consumer healthcare business (excluding Novartis's nicotine replacement therapy ("NRT") transdermal patch business) into a joint venture in which GSK will hold a 63.5% controlling share and Novartis will hold the remaining 36.5% share (the "Transaction"). Both parties sell over-the-counter ("OTC") NRT transdermal patches in the United States. The Commission alleges in its Complaint that the Transaction, 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 market for the manufacture, marketing, distribution, and sale of NRT transdermal patches. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that would otherwise be eliminated by the Transaction. Specifically, under the terms of the Consent Agreement, Novartis would be required to divest all of its rights and assets related to U.S. NRT transdermal patches, including its branded product, Habitrol. Novartis has proposed Dr. Reddy's Laboratories ("Dr. Reddy's") as the buyer of these assets.

II. The Product and Structure of the Market

The proposed joint venture would likely substantially increase concentration in the market for NRT transdermal patches. Tobacco consumption introduces nicotine into the body, and nicotine addiction is a major contributor to addiction to tobacco. Nicotine replacement therapies work by providing nicotine to the body through sources other than smoking, thereby replacing the nicotine that would have come from tobacco and helping to ease tobacco cravings in those who are attempting to quit. Users of NRT products are therefore more likely to have success in quitting tobacco. NRT transdermal patches work by adhering to the skin, much like an adhesive bandage, and slowly providing a steady amount of nicotine through the skin over the

course of a day. Patches are usually provided in decreasing dosages to help the user step down their nicotine intake over time.

Novartis markets and sells the branded NRT transdermal patch Habitrol. The only other branded patch is GSK's NicoDerm CQ. Both companies also market private label versions of their branded patch. Private label products are competitive with the branded products, but there is only one other manufacturer of private label patches, Aveva Drug Delivery Systems. Therefore, without a remedy, the Transaction will consolidate the only two providers of branded NRT transdermal patches, and two of the three producers of private label NRT transdermal patches.

III. Entry

Entry into the manufacture and sale of NRT transdermal patches would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Transaction. Developing a patch that adheres to the skin and properly delivers nicotine to the body over time is expensive and time consuming, and has a high risk of failure. Even if an entrant is able to successfully develop a new patch, it must then obtain an FDA approval to market the product, which adds several years to the entry process.

IV. Effects

The Transaction is likely to result in significant competitive harm in the market for NRT transdermal patches. Although the Novartis NRT patch business has been excluded from the consumer healthcare joint venture, GSK's patch business will be included. Thus, Novartis's partial interest in the joint venture means it will benefit from any sales lost to GSK NRT patches in the future. With an interest in its most significant competing product, Novartis would have an increased incentive to raise prices for its NRT patches post-transaction. The Transaction, by altering the interactions between Novartis's and GSK's branded and private label NRT

transdermal patches, would likely result in price increases for NRT patches in several ways. First, the Transaction would reduce the competition between the only two branded NRT transdermal patches, and reduce the competition between Novartis's branded Habitrol product and GSK's private label patches, both of which would increase the likelihood that Novartis would increase the prices of Habitrol. Second, the Transaction would reduce the competition between Novartis's private label patches and GSK's NicoDerm CQ and private label patches, which would create incentives for Novartis to increase the price of its private label NRT transdermal patches.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the Transaction's anticompetitive effects in the relevant market. Pursuant to the Consent Agreement, the parties are required to divest Novartis's rights and assets related to its U.S. NRT transdermal patch business to Dr. Reddy's. Further, the proposed Consent Agreement requires Novartis to assign to Dr. Reddy's its contract manufacturing agreements for the divested assets. Finally, Novartis will provide a short term packaging agreement to Dr. Reddy's for secondary packaging of the product while Dr. Reddy's seeks a contract packager. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the Transaction is consummated.

Dr. Reddy's is well positioned to assume Novartis's role in the NRT transdermal patch market. Dr. Reddy's manufactures a wide range of branded and private label OTC products for sale in the United States, including private label versions of popular allergy and gastrointestinal products. Thus, Dr. Reddy's is already a supplier to most major retailers of OTC consumer healthcare products. In addition, because Novartis will be transferring its existing contract manufacturing arrangement for its NRT transdermal patches, the divestiture to Dr. Reddy's will not require a transfer of manufacturing processes or facilities. Dr. Reddy's will therefore be able

to step into Novartis's current position and immediately begin competing in the market for NRT transdermal patches.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Transaction. If the Commission determines that Dr. Reddy's is not an acceptable acquirer of the divested assets, or that the manner of the divestiture is not acceptable, the parties must unwind the sale of rights to Dr. Reddy's, and divest the U.S. NRT transdermal patch assets 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 product if the parties fail to divest the business as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. The Order requires Novartis to take all action necessary to maintain the economic viability, marketability, and competitiveness of the product to be divested until such time that they are transferred to a Commission-approved acquirer. The Order also requires that Novartis transfer all confidential business information, including customer information related to the divestiture product, to Dr. Reddy's.

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.

Donald S. Clark,
Secretary.

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