the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order to Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Order (''Consent Agreement'') from Valeant Pharmaceuticals International, Inc. (''Valeant''), which is designed to remedy the anticompetitive effects of Valeant's acquisition of the Ortho Dermatologics division of Janssen Pharmaceuticals, Inc. (''Janssen''), a wholly owned subsidiary of Johnson & Johnson.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Valeant intends to acquire Ortho Dermatologics from Janssen, a Johnson & Johnson company, in a transaction valued at approximately $345 million. Both parties sell topical pharmaceuticals in the United States. The Commission's Complaint alleges 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 FTC Act, as amended, 15 U.S.C. 45, in the market for tretinoin emollient cream. The proposed Consent Agreement remedies the loss of competition that would result from the merger in this market. Specifically, the Consent Agreement requires that Valeant return the marketing rights to two pharmaceutical products, Refissa, a branded tretinoin emollient cream, and a generic tretinoin emollient cream, to Spear Pharmaceuticals (''Spear''), the company that owns both products.

II. The Products and the Structure of the Market

Valeant's proposed acquisition of Ortho Dermatologics from Johnson & Johnson would create a monopoly in the market for tretinoin emollient cream. Tretinoin emollient cream is a topical retinoid cream used for the treatment of fine line wrinkles (retinoids are chemical compounds derived from Vitamin A, most commonly used in the treatment of acne, but also used to treat fine line wrinkles). This market includes branded and generic tretinoin emollient cream, and is highly concentrated. Pursuant to a co-marketing agreement between Valeant and Spear Pharmaceuticals, Valeant markets branded Refissa tretinoin emollient cream as well as a generic tretinoin emollient cream. Johnson & Johnson's Renova is the only other tretinoin emollient cream product on the market. The proposed acquisition would create a monopoly in the market for tretinoin emollient cream in the United States.

III. Entry

As with most pharmaceutical products, entry into the manufacture and sale of tretinoin emollient cream is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration (''FDA'') approval for the manufacture and sale of topical pharmaceuticals takes at least two years due to substantial regulatory, technological and intellectual property barriers. Moreover, entry is not likely because the relevant market is relatively small, providing limited sales opportunities relative to the cost of entry for any potential entrant.

IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for tretinoin emollient cream by eliminating actual, direct and substantial competition between Valeant and Johnson & Johnson. The evidence indicates that the loss of head to head competition between Renova and the products co-marketed by Valeant (Refissa and generic tretinoin emollient cream) would result in higher prices for tretinoin emollient cream.

V. The Consent Agreement

The proposed Consent Agreement would remedy the competitive concerns raised by the proposed acquisition by requiring that (1) Valeant terminate its agreement with Spear Pharmaceuticals, returning all its marketing rights to Refissa and generic tretinoin emollient cream and allowing Spear to take over its role in the market and (2) Valeant and Johnson & Johnson take steps to ensure that confidential business information relating to Refissa and generic tretinoin emollient cream will not be obtained or used by Valeant.

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 Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2011–32217 Filed 12–15–11; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 111–0215]

Valeant Pharmaceuticals International, Inc.; Analysis of Agreement Containing Consent Order 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 or deceptive acts or practices or 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 order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 12, 2012.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Valeant-Sanofi, File No. 111–0215'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/valeantsanoficonsent,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jacqueline K. Mendel (202) 326–2603), FTC, Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 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 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 12, 2011), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 12, 2012. Write ''Valeant-Sanofi, File No. 111–0215'' 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 obtained from any person and which is privileged or confidential,'' as provided 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/valeantsanoficonsent* 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 ''Valeant-Sanofi, File No. 111–0215'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580. If 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 12, 2012. 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 Order to Aid Public Comment

I. Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Order (''Consent Agreement'') from Valeant Pharmaceuticals International, Inc. (''Valeant''), which is designed to remedy the anticompetitive effects of Valeant's acquisition of certain assets of Sanofi's dermatology unit, Dermik (''Dermik'').

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Valeant proposes to acquire certain assets of Sanofi's dermatology unit, Dermik, in a transaction valued at approximately $425 million (''the Acquisition''). Both parties sell topical pharmaceutical products in the United States. The Commission's Complaint alleges 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 FTC Act, as amended, 15 U.S.C. 45, in the markets for (1) BenzaClin and (2) topical fluorouracil cream (''topical 5FU''). The proposed Consent Agreement remedies the loss of competition in these markets that would result from the Acquisition. Specifically, under the terms of the Consent Agreement, Valeant would be required to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex (''AG Efudex''). Valeant has proposed Mylan Inc. (''Mylan'') as the buyer of generic BenzaClin and AG Efudex assets.

II. The Products and the Structure of the Market

Valeant's proposed acquisition of Dermik from Sanofi would create a monopoly in the BenzaClin market. Dermik manufactures and markets BenzaClin, which is a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. BenzaClin is a combination of clindamycin, an antibiotic, and benzoyl peroxide, an antimicrobial. Valeant owns the only Abbreviated New Drug Application (''ANDA'') for the generic version of BenzaClin, which it licenses to Mylan. Pursuant to that license, Mylan sells the only generic equivalent of BenzaClin in the United States and Valeant receives the vast majority of royalties from those sales. Currently Dermik's BenzaClin sales account for approximately 50 per cent of sales, while sales of Mylan's generic version account for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

In addition, Valeant's proposed acquisition of Dermik is likely to result in anticompetitive effects in the market for topical 5FU products. Topical 5FU

[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).

products are used to treat actinic keratosis (''AK''), which is a pre-cancerous lesion that can result from years of repeated sun exposure. Three branded topical 5FUs are currently on the market, including Valeant's Efudex and Dermik's Carac. There are also two generic versions of Efudex, as well as an ''authorized'' generic, also sold by Valeant. The price of the generic drugs in this market determines the pricing of branded Carac. Post-acquisition, Valeant's market share in the topical 5FU market would be over 50 per cent. Other treatments for AKs are not viable substitutes for topical 5FUs because they are more costly, less efficacious or impracticable.

III. Entry

Entry into the manufacture and sale of both BenzaClin and topical 5FU products is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration approval for the manufacture and sale of topical pharmaceuticals takes over two years due to substantial regulatory, technological and intellectual property barriers. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a new entrant would likely be insufficient to justify the time and investment necessary to enter.

IV. Effects of the Acquisition

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of both BenzaClin and topical 5FU products by eliminating actual, direct and substantial competition between Valeant and Sanofi in those markets. With respect to the BenzaClin market, the transaction would combine BenzaClin and its only generic equivalent, eliminating BenzaClin's closest competitor and creating a monopoly. The impact of eliminating the competition between BenzaClin and its only currently-marketed generic equivalent, is highly likely to result in consumers paying higher prices.

In the topical 5FU market, the transaction would give Valeant control over three linked treatments for AK—Dermik's branded Carac and Valeant's branded and AG Efudex products. The combination of these products at Valeant would eliminate head to head competition between Carac and the Efudex AG and is thus likely to result in higher prices for topical 5FUs.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant markets by requiring Valeant to (1) divest its ANDA for generic BenzaClin to Mylan, and (2) supply an authorized generic of Efudex, pursuant to a license to Mylan. If approved, Mylan will acquire all rights and assets currently held by Valeant, including any existing inventory. The assets to be transferred include all manufacturing and research and development rights in the divested products.

Mylan is a particularly well-suited acquirer of generic BenzaClin because it has been manufacturing and marketing the product, pursuant to an agreement with Valeant, since it was introduced in August 2009. Mylan is the second-largest generic pharmaceutical manufacturer in the United States, and is well-positioned to replicate the competition that would be lost with the proposed Valeant/Dermik acquisition. Headquartered in Pittsburgh, Pennsylvania, Mylan employs more than 18,000 employees and generated approximately $5.45 billion in revenue in 2010. Mylan sells approximately 270 products and has a manufacturing facility where BenzaClin is manufactured. It is in the process of upgrading that facility to handle compounds such as 5FU.

Mylan expects to begin manufacturing generic Efudex at that facility in 2013. Until that time, the proposed Consent Agreement contemplates Mylan's purchase of topical 5FU from Valeant pursuant to a supply agreement. In order to ensure that there is no supply interruption, the proposed Consent Agreement would require that Valeant build up a two-year inventory and establish its own manufacturing as a back-up supply until Mylan is able to manufacture Efudex commercially. Valeant would also be required to assist Mylan with developing its manufacturing capabilities and securing the necessary FDA approvals. With these provisions, Mylan will be able to compete in the 5FU market immediately following the divestiture and establish independent manufacturing as soon as practicable.

The Commission has appointed Francis J. Civille as the Interim Monitor to oversee the asset transfer and to ensure Valeant's compliance with the provisions of the proposed Consent Agreement. Mr. Civille has over 27 years of experience in the pharmaceutical industry. He has extensive experience in areas such as pharmaceutical research and development, regulatory approval, manufacturing and supply, and marketing. Mr. Civille will oversee the transfer of Efudex manufacturing technology to the acquirer and ensure that Valeant is diligent in building up the required inventory of the product and establishing its own back-up supply capabilities. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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.

[FR Doc. 2011–32218 Filed 12–15–11; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day 12–12BZ]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call (404) 639–5960 and send written comments to Daniel Holcomb, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information