FEDERAL TRADE COMMISSION

[File No. 141 0162]

Akorn, Inc.; Analysis 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 September 3, 2014.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/akorninccconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Akorn, Inc.—Consent Agreement; File No. 141 0162'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/akorninccconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, 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: Jasmine Y. Rosner, Bureau of Competition, (202–326–2232), 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 August 4, 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 September 3, 2014. Write ''Akorn, Inc.—Consent Agreement; File No. 141 0162'' 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/akorninccconsent* 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 ''Akorn, Inc.—Consent Agreement; File No. 141 0162'' 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.

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 September 3, 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

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Akorn, Inc. (''Akorn'') that is designed to remedy the anticompetitive effects in the market for generic injectable rifampin (''generic rifampin'') resulting from Akorn's acquisition of VersaPharm Inc. (''VersaPharm''). Under the terms of the proposed Consent Agreement, Akorn is required to divest its Abbreviated New Drug Application (''ANDA'') for generic rifampin to Watson Laboratories, Inc. (''Watson''), a wholly-owned subsidiary of Actavis plc.

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, to make a

[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).

final decision as to whether it should withdraw from the proposed Consent Agreement or make final the Decision and Order (''Order'').

Pursuant to an Agreement and Plan of Merger dated May 9, 2014, Akorn plans to acquire all of VPI Holdings Corp., the parent company of VersaPharm, for approximately $324 million (the ''Proposed Acquisition''). 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 future competition in the sale of generic rifampin. The proposed Consent Agreement will remedy the alleged violations by preserving the future competition that would otherwise be eliminated by the Proposed Acquisition.

The Product and Structure of the Market

The Proposed Acquisition would reduce the number of future suppliers in the market for generic rifampin. Generic rifampin is an antibacterial medication used as a first-line treatment to kill or prevent the growth of tuberculosis. There are currently three generic drug companies with approved ANDAs for rifampin: VersaPharm, Mylan/Agila, and Bedford. Akorn is one of a limited number of firms that have a generic rifampin product in development and an ANDA under review by the U.S. Food and Drug Administration (''FDA''). As a result, the Proposed Acquisition would significantly reduce the number of future suppliers for generic rifampin.

Entry

Entry into the market for generic rifampin would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, is costly and lengthy. In addition, the expertise and facilities required to manufacture injectable products is sufficiently specialized that only a limited number of firms are capable of participating in such markets. The stability and sterility requirements specific to manufacturing injectable pharmaceuticals present a number of problems and costs that discourage new entry or expansion in the market for generic rifampin.

Effects

The Proposed Acquisition would likely cause significant anticompetitive harm to consumers by eliminating the future competition that would otherwise have occurred when Akorn's generic rifampin product entered the market. Market participants consistently characterize generic drug markets as commodity markets in which the number of generic suppliers has a direct impact on pricing. Customers and competitors alike have confirmed that the price of generic pharmaceutical products decreases with new entry even after a number of suppliers has entered the market. Further, customers have confirmed that, in pharmaceutical markets that can experience significant manufacturing problems and shortages, such as the market for generic rifampin, the entry of a fourth, fifth, sixth, or even subsequent generic competitor produces more competitive prices than if fewer suppliers are available to them. The Proposed Acquisition would eliminate significant future competition between Akorn and VersaPharm. The evidence shows that anticompetitive effects are likely to result from the Proposed Acquisition due to a decrease in the number of independent competitors in the market for generic rifampin. Absent the Proposed Acquisition, the presence of Akorn as an additional competitor likely would have allowed customers to negotiate lower prices, as well as secure supply in times of product shortages. Thus, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for generic rifampin, absent a remedy.

The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant product market. Pursuant to the Consent Agreement, Akorn is required to divest its rights related to generic rifampin to Watson. Akorn must accomplish this divestiture no later than ten days after the Proposed Acquisition is consummated.

The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the Proposed Acquisition. If the Commission determines that Watson is not an acceptable acquirer of the divested asset, or that the manner of the divestiture is not acceptable, the parties must unwind the sale of rights to Watson and divest the asset 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 asset if the parties fail to divest it as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. The Order requires Akorn to take all action necessary to maintain the economic viability, marketability, and competitiveness of the asset to be divested. Akorn must assist Watson in securing FDA approval for the pending ANDA. Akorn must also provide transitional services to assist Watson in setting up its generic rifampin manufacturing process, which includes conveying all know-how, data, and other information necessary to transfer its manufacturing capabilities. To allow Watson to enter the market while it validates its manufacturing process, the Order requires Akorn to provide Watson with a supply of product.

The Commission has agreed to appoint F. William Rahe from Quantic Regulatory Services, LLC to act as an interim monitor to assure that Akorn expeditiously complies with all of its obligations and perform all of its responsibilities pursuant to the Consent Agreement. To ensure that the Commission remains informed about the status of the transfer of rights and assets, the Consent Agreement requires Akorn to file reports with the interim monitor who will report in writing to the Commission concerning performance by the parties of their obligations under the Consent Agreement.

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. 2014–18982 Filed 8–11–14; 8:45 am]

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FINANCIAL STABILITY OVERSIGHT COUNCIL

Submission for OMB Review; Comment Requests

ACTION: Notice and request for comments.

SUMMARY: The Financial Stability Oversight Council will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.