

**ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS  
TO AID PUBLIC COMMENT**  
*In the Matter of Akorn, Inc., File No. 141-0162*

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”)

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.