

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.*

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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.

**DATES:** Written comments must be received on or before September 11, 2014 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 11020, Washington, DC 20220, or on-line at <http://www.PRACOMMENT.gov>.

**FOR FURTHER INFORMATION CONTACT:** Copies of the submission(s) may be obtained by calling (202) 927-5331 or emailing at [PRA@treasury.gov](mailto:PRA@treasury.gov), or the entire information collection request may be found at <http://www.reginfo.gov>.

**SUPPLEMENTARY INFORMATION:**

*Title:* Designation of Financial Market Utilities.

*OMB Control Number:* 1505-0239.

*Abstract:* The information collected under 12 CFR 1320.20 from FMUs will be used generally by the Council to determine whether to designate or rescind the designation of an FMU under Title VIII of the Dodd-Frank Act. The collection of information under § 1320.11 provides an opportunity for an FMU to submit written materials to the Council before the Council decides whether to (1) make a proposed designation of the FMU as systemically important; or (2) make a proposed determination to rescind the designation of the FMU as systemically important. Similarly, the collection of information under § 1320.12 provides an opportunity for an FMU to request a hearing before, or submit written materials to, the Council before the Council makes a final designation of the FMU as systemically important or makes a final determination to rescind the designation of the FMU. The collection of information under § 1320.14 provides an opportunity for an FMU to request a hearing before, or submit written materials to, the Council to contest the Council's waiver or modification of any of the notice, hearing, or other requirements in §§ 1320.11 and 1320.12.

*Type of Review:* Extension of a currently approved collection.

*Affected Public:* Businesses or other for-profit and not-for-profit organization.

*Estimated Total Annual Burden Hours for all Collections:* 500 hours.

**David G. Clunie,**

*Executive Secretary.*

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**GENERAL SERVICES ADMINISTRATION**

**[Notice—CECANF-2014-04; Docket No. 2014-0005; Sequence No. 4]**

**Commission To Eliminate Child Abuse and Neglect Fatalities; Announcement of Meeting**

**AGENCY:** Commission to Eliminate Child Abuse and Neglect Fatalities.

**ACTION:** Meeting Notice.

**SUMMARY:** The Commission to Eliminate Child Abuse and Neglect Fatalities (CECANF), a Federal Advisory Committee established by the Protect Our Kids Act of 2012, Public Law 112-275, will hold a meeting open to the public on Thursday, August 28, 2014 in Plymouth, Michigan.

**DATES:** The meeting will be held on Thursday, August 28, 2014, from 8:00 a.m. to 4:30 p.m. Eastern Standard Time.

**ADDRESSES:** CECANF will convene its meeting at The Inn at St. John's, Grande Ballroom, 44045 Five Mile Road, Plymouth, Michigan 48170. This site is accessible to individuals with disabilities. The meeting will also be made available via teleconference.

Submit comments identified by "Notice-CECANF-2014-04", by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for "Notice-CECANF-2014-04". Select the link "Comment Now" that corresponds with "Notice-CECANF-2014-04". Follow the instructions provided at screen. Please include your name, company name (if any), and "Notice-CECANF-2014-04" on your attached document.

- *Mail:* Commission to Eliminate Child Abuse and Neglect Fatalities, c/o General Services Administration, Agency Liaison Division, 1800 F St. NW., Room 7003D, Washington DC 20006.

*Instructions:* Please submit comments only and cite "Notice-CECANF-2014-04" in all correspondence related to this notice. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided.

**FOR FURTHER INFORMATION CONTACT:** Visit the CECANF Web site at <https://eliminatechildabusefatalities.sites.usa.gov/> or contact Ms. Patricia Brincefield, Communications Director, at 202-818-9596, 1800 F St. NW., Room 7003D, Washington, DC 20006.

**SUPPLEMENTARY INFORMATION:**

*Background:* CECANF was established to develop a national strategy and recommendations for reducing fatalities resulting from child abuse and neglect.

*Agenda:* The purpose of the meeting is for Commission members to gather national and state-specific information regarding child abuse and neglect fatalities. The Commission will hear from researchers and issue experts regarding the scope of the problem, strategies for improving national data collection, policy barriers and opportunities to reduce maltreatment fatalities, confidentiality issues, and potential solutions. Experts from such disciplines as child welfare, law enforcement, health, and public health will present strategies for addressing the issue of child abuse and neglect fatalities.

*Attendance at the Meeting:* Individuals interested in attending the meeting in person must register in advance because of limited space. To register to attend in person or by phone, please go to <https://www.surveymonkey.com/s/PFYVWR3> and follow the prompts. Detailed meeting minutes will be posted within 90 days of the meeting. Interested members of the public may listen to the CECANF discussion by calling 1-866-928-2008, and entering pass code 569839. Members of the public will not have the opportunity to ask questions or otherwise participate in the meeting.

However, members of the public wishing to comment should follow the steps detailed under the heading addresses in this publication or contact us via the CECANF Web site at <https://eliminatechildabusefatalities.sites.usa.gov/contact-us/>.

Dated: August 5, 2014.

**Karen White,**

*Executive Assistant.*

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