ANALYSIS OF AGREEMENT CONTAINING CONSENT ORDERS TO AID PUBLIC COMMENT

In the Matter of Mylan N.V., File No. 161-0102

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Mylan N.V. ("Mylan") that is designed to remedy the anticompetitive effects resulting from Mylan's acquisition of Meda AB ("Meda"). Under the terms of the proposed Consent Agreement, Mylan is required to divest all of its rights and assets related to 400 mg and 600 mg generic felbamate tablets to Alvogen Pharma US, Inc. ("Alvogen"), and to return all of its marketing rights and ownership interests in generic carisoprodol tablets to Indicus Pharma LLC ("Indicus") the abbreviated new drug application owner for this product.

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

Pursuant to a public offer to the shareholders of Meda announced on February 10, 2016, Mylan intends to acquire 100% of the issued and outstanding shares of Meda for a total equity value at announcement of approximately $7.2 billion. 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 current competition in the markets for 400 mg and 600 mg generic felbamate tablets and future competition in the market for 250 mg generic carisoprodol tablets in the United States. The proposed Consent Agreement will remedy the alleged violations by preserving the competition that otherwise would be eliminated by the proposed acquisition.

I. The Products and Structure of the Markets

The proposed acquisition would reduce the number of current suppliers in the markets for 400 mg and 600 mg generic felbamate tablets and reduce the number of future suppliers in the market for 250 mg generic carisoprodol tablets.

Generic felbamate tablets treat severe refractory epilepsy and are available in 400mg and 600 mg strengths. Three firms—Mylan, Meda, and Amneal Pharmaceuticals LLC—sell generic felbamate in the United States. A fourth firm, CorePharma LLC, has received U.S. Food and Drug Administration ("FDA") approval for each strength of generic felbamate tablets, but it is not yet on the market

Generic carisoprodol is a muscle relaxer that works by blocking pain sensations between the nerves and the brain. Two firms market generic carisoprodol tablets: Meda and Vensun Pharmaceuticals. Mylan owns the U.S. marketing rights to a generic carisoprodol product that was recently approved by the FDA. Once it begins marketing generic carisoprodol, Mylan likely

would have been the third supplier of generic carisoprodol tablets. Mylan is one of a limited number of suppliers capable of entering the United States market in the near future.

II. Entry

Entry into the three relevant markets 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 approval by the United States Food and Drug Administration ("FDA"), is costly and lengthy.

III. Effects

The proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating competition between Mylan and Meda in the markets for 400 mg and 600 mg generic felbamate tablets. Market participants characterize generic felbamate tablets as commodity products, and prices are inversely correlated with the number of competitors in each market. As the number of suppliers offering a therapeutically equivalent drug increases, the price for that drug generally decreases due to the direct competition between the existing suppliers and each additional supplier. The proposed acquisition would combine two of three companies offering the 400 mg and 600 mg strengths of generic felbamate tablets, likely leading consumers to pay higher prices.

In addition, the proposed acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred in the 250 mg generic carisoprodol market if Mylan and Meda remained independent. The evidence shows that anticompetitive effects are likely to result from the proposed acquisition due to the elimination of an additional independent entrant in the market for 250 mg generic carisoprodol. Customers expect that the price of this pharmaceutical product will decrease with new entry by Mylan. Thus, absent a remedy, the proposed acquisition will likely cause U.S. consumers to pay significantly higher prices for 250 mg generic carisoprodol tablets.

IV. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition in the markets at issue by requiring Mylan to divest all its rights and assets relating to 400 mg and 600 mg generic felbamate tablets to Alvogen. Founded in 2009, Alvogen is an international pharmaceutical company with commercial operations in thirty-four countries. In addition, the proposed Consent Agreement requires Mylan to return its rights to market generic carisoprodol tablets in the United States to Indicus, the abbreviated new drug application owner for this product.

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 Alvogen is not an acceptable acquirer, or that the manner of the divestitures is not acceptable, the proposed Order requires Mylan to unwind the sale of rights to Alvogen and then divest the products to a Commission-approved acquirer within six months of the date the

Order becomes final. The proposed Order further allows the Commission to appoint a trustee in the event the parties fail to divest the products as required.

The proposed Consent Agreement and Order contain several provisions to help ensure that the divestitures are successful. The proposed Order requires that Mylan transfer its manufacturing technology for felbamate to Alvogen and provide transitional services to assist Alvogen in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. The transitional services include technical assistance to manufacture the product in substantially the same manner and quality employed or achieved by Mylan, and advice and training from knowledgeable employees of Mylan. In addition, Mylan must supply Alvogen with 400 mg and 600 mg generic felbamate tablets until Alvogen is able to manufacture generic felbamate successfully in commercial quantities.

To remedy competitive concerns raised by the acquisition in the market for generic 250 mg carisoprodol tablets, the proposed Order requires Mylan to terminate its agreement with Indicus that gives Mylan the exclusive right to market and sell in the United States all strengths of carisoprodol tablets manufactured by Indicus. Indicus has existing relationships with suppliers of generic drugs that it can and expects to use to replace Mylan as its marketing partner for its carisoprodol products.

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.