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# FTC Challenges Mylan's Proposed Acquisition of Merck's Generic Subsidiary

## Companies Required to Sell Assets Related to Five Generic Pharmaceuticals

The Federal Trade Commission today announced its challenge of Mylan Laboratories' (Mylan) proposed $6.6 billion acquisition of Germany's E. Merck oHG (Merck), alleging that the transaction would result in significantly reduced competition for the sale and manufacture of five generic drugs in the U.S. currently produced by both companies. Under a consent order resolving the Commission's complaint, Mylan and Merck will divest all assets related to the five drugs to Amneal Pharmaceuticals LLC (Amneal) within 10 days of completing the deal.

"Mylan's acquisition of Merck's generic drug unit would result in reduced competition and higher prices for U.S. consumers of several important generic pharmaceuticals," said Jeffrey Schmidt, Director of the FTC's Bureau of Competition. "The Commission believes strongly in the benefits of low-priced generic alternatives to branded drugs and strong competition between generic drug manufacturers. The order announced today will ensure that competition is maintained following the completion of this acquisition."

The Relevant Products

Under an agreement and plan of merger executed on May 12 and 13, 2007, Mylan proposes to acquire Merck's generic subsidiary (Merck Generics), and all subsidiaries held either directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries. The transaction is valued at approximately $6.6 billion.

In conducting its investigation of the proposed acquisition, the Commission identified competitive overlaps in the U.S. markets for several generic drugs. They include: 1) acebutolol hydrochloride capsules; 2) flecainide acetate tablets; 3) guanfacine hydrochloride tablets; 4) nicardipine hydrochloride capsules; and 5) sotalol hydrochloride AF tablets.

Generic acebutolol hydrochloride is a beta blocker used to treat hypertension; generic flecainide acetate is an anti-arrhythmia drug used to treat heart problems; generic guanfacine hydrochloride is an alpha blocker used to treat hypertension; generic nicardipine hydrochloride is a calcium blocker used to treat hypertension; and generic sotalol hydrochloride AF is a beta blocker used to treat hypertension. The market shares of the companies selling each drug can be found in the analysis to aid public comment on the FTC's Web site as a link to this press release.

The Commission's Complaint

The FTC's complaint alleges that the transaction as proposed would be anticompetitive and would violate Section 5 of the FTC Act and Section 7 of the Clayton Act, as amended. Specifically, according to the Commission, the proposed acquisition would cause significant anticompetitive harm to consumers in the already concentrated U.S. markets for the manufacture and sale of each of the relevant products identified above. In the market for generic drugs, pricing is heavily influenced by the number of competitors in a given market. In its investigation of this transaction, the Commission found evidence that, given the small number of suppliers of each of the relevant drugs, prices decrease with the entry of each new competitor. Similarly, Mylan's acquisition of Merck could lead to higher price of these drugs, either through unilateral or coordinated actions. Also, according to the complaint, entry by a new competitor would not be timely, likely, nor sufficient to counter the anticompetitive impacts of the acquisition.

Terms of the Consent Order

The Commission's consent order is designed to remedy the alleged anticompetitive effects of Mylan's proposed acquisition of Merck, as proposed. Under its terms, the companies must divest the rights and assets related to each of the relevant products to a Commission-approved buyer no later than 10 days after the acquisition is completed. Specifically, the order requires that Merck divest its product assets to Amneal, a small but growing generic drug manufacturer that is particularly well-positioned to manufacture and market the divested products. If the FTC determines that Amneal is not an acceptable buyer, or that the manner of the divestitures to Amneal is not acceptable, however, the parties must unwind the sale of the assets within six months of the date the order becomes final. If they do not, the Commission can appoint a trustee to divest the assets.

The order contains several provisions to ensure that the product are divested successfully. First, it requires Merck and Mylan to provide transitional services to help Amneal obtain all necessary FDA approvals. Next, it provides for the appointment of R. Owen Richards of Quantic Regulatory Services, LLC to oversee the asset transfer and to ensure the companies' compliance with the order's terms. Finally, the order requires Merck and Mylan to report back to the Commission periodically until the divestitures and transfers are completed.

The Commission vote approving issuance of the complaint and consent order was 5-0. The order will be subject to public comment for 30 days, until October 27, 2007, after which the Commission will decide whether to make it final. Comments should be sent to: FTC, Office of the Secretary, 600 Pennsylvania Ave., N.W., Washington, DC 20580.

**NOTE:** A consent agreement is for settlement purposes only and does not constitute an admission of a law violation. When the Commission issues a consent order on a final basis, it carries the force of law with respect to future actions. Each violation of such an order may result in a civil penalty of $11,000.

The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust@ftc.gov, or write to the Office of Policy and Coordination, Room 394, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave, N.W., Washington, DC 20580. To learn more about the Bureau of Competition, read "Competition Counts" at http://www.ftc.gov/competitioncounts.

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