FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative or Renee Hallman, Contact Representative.

Federal Trade Commission, Premerger Notification Office, Bureau of Competition, Room H–303, Washington, DC 20580, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 07–4969 Filed 10–9–07; 8:45 am]

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FEDERAL TRADE COMMISSION

[File No. 071 0164]

Mylan Laboratories and E. Merck oHG; Analysis of Agreement Containing Consent Orders 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 or deceptive acts or practices or 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 order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before October 27, 2007.

ADDRESSES: Interested parties are invited to submit written comments. Comments should refer to ''Mylan/ Merck, File No. 071 0164,'' to facilitate the organization of comments. A comment filed in paper form should include this reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission/ Office of the Secretary, Room 135-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments containing confidential material must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with Commission Rule 4.9(c). 16 CFR 4.9(c) (2005).[1] The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions. Comments that do not contain any nonpublic information may instead be filed in electronic form as part of or as an attachment to email messages directed to the following e-mail box: *consentagreement@ftc.gov*. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. All timely and responsive public comments, whether filed in paper or electronic form, will be considered by the Commission, and will be available to the public on the FTC Web site, to the extent practicable, at *http://www.ftc.gov*. As a matter of discretion, the FTC makes every effort to remove home contact information for individuals from the public comments it receives before placing those commentson the FTC Web site. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at*http://www.ftc.gov/ftc/privacy.htm*.

FOR FURTHER INFORMATION CONTACT: Kari A. Wallace (202) 326-3085, Bureau of Competition, Room NJ-5108, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order 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 September 27, 2007), on the World Wide Web, at *http://www.ftc.gov/os/2007/09/index.htm*. A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Mylan Laboratories (''Mylan'') and E. Merck oHG (''Merck'') which is designed to remedy the anticompetitive effects of the acquisition of certain assets of Merck by Mylan. Under the terms of the proposed Consent Agreement, the companies would be required to assign and divest the Merck rights and assets necessary to manufacture and market generic: (1) Acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets to Amneal Pharmaceuticals LLC (''Amneal'').

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (''Order'').

Pursuant to 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 directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidies for approximately $6.6 billion. The Commission's Complaint alleges 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 competition in the U.S. markets for the manufacture and sale of the following generic pharmaceutical products: (1) Acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets (the ''Products''). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

Mylan is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical drugs. Headquartered in Pennsylvania, Mylan

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* Commission Rule 4.9(c), 16 CFR 4.9(c).

sells generic pharmaceuticals in the United States and has manufacturing facilities throughout the country. Merck is a German pharmaceutical company that develops and manufactures pharmaceutical products for sale in the United States. Merck sells generic pharmaceutical products directly to customers in the United States through its subsidiary Genpharm L.P., as well as indirectly through distribution agreements with other generic companies, including Par Pharmaceutical Companies, Inc. (''Par'').

The Products and Structure of the Markets

The proposed acquisition of certain assets of Merck by Mylan would strengthen Mylan's worldwide position in generic pharmaceuticals and provide Mylan with a stronger pipeline of generic products. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in five of these markets.

The transaction would reduce the number of competing generic suppliers in the overlap markets. The number of generic suppliers has a direct and substantial effect on generic pricing as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here, the branded versions no longer significantly constrain the generics' pricing.

In the market for generic acebutolol capsules, Mylan and Merck are the only companies manufacturing and selling products in the United States. For the four other generic products, Mylan and Merck currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors.

Generic acebutolol hydrochloride is a beta blocker used to treat hypertension. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Therefore, the proposed transaction would give Mylan a monopoly in this market.

Generic flecainide acetate is an anti-arrhythmia drug used to treat heart problems. Flecainide is produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (''Roxane''), Barr Pharmaceuticals Inc., and Ranbaxy Pharmaceuticals Inc. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. After Mylan's acquisition of Merck Generics, Mylan's market share would increase to approximately 78 percent and the number of suppliers of generic flecainide would decrease from five to four.

Guanfacine hydrochloride, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (''Watson''), Merck/Par, Actavis Group hf. (''Actavis''), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States, although not all six suppliers are capable of supplying all formulations. For instance, Mylan, Merck/Par, Watson and Actavis, are the only suppliers of the 2 mg formulation of guanfacine. Because many customers prefer to purchase the 1 mg and 2 mg formulations of the product from one supplier, the competitive significance of the other four suppliers who do not sell these formulations is limited.

Nicardipine hydrochloride is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (''Teva'') are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed transaction would thus result in an increase in Mylan's market share to approximately 86 percent and reduce the number of suppliers from three to two.

Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is led by Apotex Inc. (''Apotex''). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007. Therefore, the proposed transaction would reduce the number of suppliers from three to two.

Entry

Entry into the markets for the manufacture and sale of the Products would not be timely, likely or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant markets are relatively small and in decline, so the limited sales opportunities available to a new entrant are likely insufficient to warrant the time and investment necessary to enter.

Effects

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic acebutolol hydrochloride capsules, flecainide acetate tablets, guanfacine hydrochloride tablets, nicardipine hydrochloride capsules, and sotalol hydrochloride AF tablets. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. Here, the evidence shows that, given the small number of suppliers, the prices of the generic pharmaceutical products at issue decrease with the entry of each additional competitor. Evidence gathered during our investigation indicates that anticompetitive effects—whether unilateral or coordinated—are likely to result from the proposed transaction due to a decrease in the number of independent competitors in the markets at issue.

The acquisition of Merck by Mylan would create a monopoly in the market for generic acebutolol hydrochloride tablets. The evidence indicates that the presence of more than one competitor allows customers to negotiate lower prices and that the reduction in the number of competitors in this market would allow the merged entity to unilaterally exercise market power with a resulting increase in prices. In the markets for generic flecainide acetate tablets, generic nicardipine hydrochloride capsules, and generic sotalol AF tablets, the proposed acquisition would leave only two significant current competitors: the combined firm and one other company. The evidence indicates that the presence of three or more independent competitors in these markets allows customers to negotiate lower prices, and that a reduction in the number of competitors in these markets would allow the merged entity and other market participants to raise prices. Likewise, in the generic guanfacine hydrochloride tablet market, the reduction in the number of competitors also would likely lead to higher prices.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing. The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Mylan and Merck are required to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Merck divest its assets in the Products to Amneal.

The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not itself present competitive problems.

Amneal, a small but growing generic manufacturer, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Amneal develops, manufacturers, sells, and distributes generic pharmaceuticals within the United States. Moreover, Amneal will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and experience marketing generic products, Amneal is well-positioned to replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that Amneal is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Amneal is not acceptable, the parties must unwind the sale and divest the assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Mylan and Merck to provide transitional services to enable the Commission-approved acquirer to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Merck.

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC (''Quantic'') to oversee the asset transfer and to ensure Mylan and Merck's compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires Mylan and Merck to file reports with the Commission periodically until the divestitures and transfers are accomplished.

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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[BILLING CODE 6750–01–S]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30–Day–08–07AY]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Long-Term Efficacy of a Program to Prevent Beryllium Disease—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Beryllium is a lightweight metal with many applications. Exposed workers may be found in the primary production, nuclear power and weapons, aerospace, scrap metal reclamation, specialty ceramics, and electronics industries, among others. The size of the USA workforce at risk of chronic beryllium disease (CBD), from either current or past work-related exposure to the metal, may be as high as one million. Demand for beryllium is growing worldwide, which means that increasing numbers of workers are likely to be exposed.

Exposure to beryllium can lead to sensitization and cause an immunologic granulomatous lung disease. Sensitization is a cell-mediated allergic-type response that may be detected in the peripheral blood with the beryllium lymphocyte proliferation test (BeLPT), which is used by the industry as a surveillance tool. Workers found to be sensitized may be clinically evaluated for CBD with tests including bronchoalveolar lavage and transbronchial biopsy. Cross-sectional studies in various beryllium workplace populations have identified sensitization in the range of less than 1% to 14% of workers. The proportion of sensitized workers who have beryllium disease at initial clinical evaluation has varied from 10 to 100% in different workplaces. Sensitized workers not initially diagnosed with CBD are often diagnosed with the disease upon follow-up, but whether all sensitized workers will eventually develop beryllium disease is unknown. Industry screening programs have enabled the identification of CBD in persons without apparent symptoms, often early in disease progression (often referred to as ''subclinical disease''). Progression from sensitization to subclinical disease to clinical impairment, while difficult to predict for any one individual, is not uncommon.

Currently, there are no preventive programs that have been demonstrated to have long-term effectiveness in preventing beryllium sensitization and CBD among beryllium-exposed workers. In the United States, recent short-term evidence (i.e., average work tenure 16 months, maximum four years) at one facility suggests that the comprehensive