any ''[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential,'' as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[6] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest. Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/paestudypra*, by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''PAE Reports: Paperwork Comment; Project No. P131203'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex J), 600 Pennsylvania Avenue NW, Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before December 2, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

[6] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2013–24230 Filed 10–2–13; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 131 0112]

Mylan, Inc., Agila Specialties Global Pte. Limited, Agila Specialties Private Limited and Strides Arcolab Limited; 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 28, 2013.

ADDRESSES: Interested parties may file a comment at *https://ftcpublic.commentworks.com/ftc/mylanagilaconsent* online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Mylan, File No. 131 0112'' on your comment and file your comment online at *https://ftcpublic.commentworks.com/ftc/mylanagilaconsent* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Amy Posner (202–326–2614), FTC, Bureau of Competition, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 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 26, 2013), on the World Wide Web, at *http://www.ftc.gov/os/actions.shtm.* 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.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 28, 2013. Write ''Mylan, File No. 131 0112'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential,'' as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[1] Your comment will be kept

[1] In particular, the written request for confidential treatment that accompanies the comment must

confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/mylanagilaconsent* by following the instructions on the web-based form. If this Notice appears at *http://www.regulations.gov/#!home.* you also may file a comment through that Web site.

If you file your comment on paper, write ''Mylan, File No. 131 0112'' on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H–113 (Annex D), 600 Pennsylvania Avenue NW., Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at *http://www.ftc.gov* to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 28, 2013. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at *http://www.ftc.gov/ftc/privacy.htm.*

Analysis of Agreement Containing Consent Order To Aid Public Comment

Introduction

The Federal Trade Commission (''Commission'') has accepted, subject to final approval, an Agreement Containing Consent Orders (''Consent Agreement'') from Mylan Inc. (''Mylan''), Agila Specialties Global Pte. Limited and Agila Specialties Private Limited (collectively, ''Agila''), and Strides Arcolab Limited (''Strides'') that is designed to remedy the anticompetitive effects that otherwise would have resulted in eleven generic injectable pharmaceutical markets from Mylan's proposed acquisition of Agila. Under the terms of the proposed Consent Agreement, Mylan is required to divest either Mylan or Agila/Strides products as follows: (1) To Intas Pharmaceuticals Ltd. (''Intas''), Mylan's fluorouracil injection and methotrexate sodium preservative-free injection; (2) to JHP Pharmaceuticals, LLC (''JHP''), Mylan's etomidate injection, ganciclovir injection, meropenem injection, and mycophenolate mofetil injection and Agila/Strides' amiodarone hydrochloride injection and fomepizole injection; and (3) to Sagent Pharmaceuticals, Inc. (''Sagent''), Agila/Strides' acetylcysteine injection and mesna injection. In addition, Mylan is required to release all of its rights relating to labetalol hydrochloride injection to Gland Pharma Ltd. (''Gland'').

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, in order to make a final decision as to whether it should withdraw from the proposed Consent Agreement, or make final the Decision and Order (''Order'').

Mylan proposes to acquire Agila for approximately $1.85 billion pursuant to a Sale and Purchase Agreement dated February 27, 2013 (''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 current and future competition in eleven generic injectable pharmaceutical product markets in the United States. The eleven product markets are: (1) Amiodarone hydrochloride injection; (2) etomidate injection; (3) fluorouracil injection; (4) labetalol hydrochloride injection; (5) mesna injection; (6) methotrexate sodium preservative-free injection; (7) acetylcysteine injection; (8) fomepizole injection; (9) ganciclovir injection; (10) meropenem injection; and (11) mycophenolate mofetil injection. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the Proposed Acquisition.

The Relevant Products and Structure of the Markets

Mylan's proposed purchase of Agila will lessen current and future competition in each of the eleven generic injectable pharmaceutical product markets, in part, because the Proposed Acquisition will reduce the number of suppliers competing for customers in each market. Injectable drugs are administered intravenously, usually via a syringe or hollow needle. Generic versions of these drugs are usually launched after a branded product's patents expire, or a generic supplier successfully challenges such patents in court or reaches a legal settlement with the branded manufacturer. Once multiple generic suppliers enter a market, the branded drug manufacturer usually ceases to provide any competitive constraint on the prices for generic versions of the drug. Rather, the generic suppliers compete only against each other. Sometimes, however, a branded injectable drug manufacturer may choose to lower its price and compete against generic versions of the drug, in which case it would be a participant in the generic drug market.

The number of suppliers in generic pharmaceutical markets is critical because prices generally decrease as the number of competing generic suppliers increases. In addition, the injectable pharmaceutical industry generally, and the generic products at issue in this investigation in particular, are highly susceptible to supply disruptions caused by the inherent difficulties of producing sterile liquid drugs. Recent manufacturing problems have made it difficult for customers to obtain sufficient quantities of, and contributed to price increases of, several of the generic injectable products impacted by this transaction. By reducing the number of competitors in these markets, the Proposed Acquisition will likely create a direct and substantial anticompetitive effect on prices for each of the relevant products, absent the remedies required by the proposed Consent Agreement.

The Proposed Acquisition will reduce current (or imminent) competition in the markets for each of the following generic injectable products: (1) Amiodarone hydrochloride injection; (2) etomidate injection; (3) fluorouracil injection; (4) labetalol hydrochloride injection; (5) mesna injection; and (6) methotrexate sodium preservative-free injection. The structure of these markets is as follows:

- Amiodarone hydrochloride injection is an anti-arrhythmic cardiac drug of last resort used to treat patients with frequently recurring ventricular fibrillation or unstable ventricular tachycardia. The market for amiodarone hydrochloride injection is highly concentrated with only three current suppliers for the drug—Mylan,

include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Fresenius Kabi AG (''Fresenius''), and Hikma Pharmaceuticals PLC. Mylan has a 60% share of the market. Agila has an approved Abbreviated New Drug Application (''ANDA'') from the U.S. Food and Drug Administration (''FDA'') and is about to enter this market, as is one other firm. Thus, the Proposed Acquisition would reduce the number of suppliers of generic amiodarone hydrochloride injection from five to four.

• Etomidate injection is an anesthetic agent used to induce general anesthesia and sedation for surgical procedures. There are currently four significant suppliers in this highly concentrated market—Mylan, Agila (which distributes its product through Pfizer Inc. and Sagent), Hospira, Inc. (''Hospira''), and American Regent, Inc. Absent a remedy, the Proposed Acquisition would substantially increase concentration in this market, provide the combined firm a market share of 46%, and reduce the number of suppliers of generic etomidate injection from four to three.

• Fluorouracil injection treats colon, rectal, breast, stomach, and pancreatic cancers. In this highly concentrated market, four firms have supplied fluorouracil injection in the recent past—Mylan, Fresenius, Teva Pharmaceutical Industries Ltd. (''Teva''), and Sandoz International GmbH. (''Sandoz''). A number of these suppliers, however, have experienced significant manufacturing issues. Agila is the only other company that currently holds an approved ANDA to sell generic fluorouracil in the United States. The Proposed Acquisition would reduce the number of firms capable of supplying generic fluorouracil injection from five to four.

• Labetalol hydrochloride injection treats severe hypertension. The market for labetalol hydrochloride injection is highly concentrated and only five firms are capable of supplying the drug today—Mylan, Agila, Hospira, Akorn, Inc., and Apotex Inc. Currently, Hospira and Akorn make most of the sales in this market, and Mylan, Agila, and Apotex are the only other firms with approved ANDAs and manufacturing facilities currently capable of producing this product. The Proposed Acquisition would reduce the number of firms capable of supplying generic labetalol hydrochloride injection from five to four.

• Mesna injection is a detoxifying agent used to prevent damage to the urinary tract caused by ifosfamide, a third-line chemotherapy drug used to treat germ cell testicular cancer. There are four current, significant suppliers of generic mesna injection—Mylan, Agila, Fresenius, and Baxter International Inc. The Proposed Acquisition would increase concentration in this market substantially, and reduce the number of current suppliers of generic mesna injection from four to three.

• Methotrexate sodium preservative-free injection treats several types of pediatric cancers, as well as certain autoimmune disorders such as rheumatoid arthritis and multiple sclerosis. Five firms currently supply the market for methotrexate sodium preservative-free injection—Mylan, Agila, Fresenius, Teva, and Hospira. The Proposed Acquisition would reduce the number of current suppliers of this drug from five to four.

In addition, the Proposed Acquisition will significantly reduce future competition in the markets for the following generic injectable products: (1) Acetylcysteine injection; (2) fomepizole injection; (3) ganciclovir injection; and (4) meropenem injection. In each of these markets, either Mylan or Agila, or both, currently do not supply an existing generic product, but will likely do so in the near future, and entry by one or both of the parties will likely increase price competition in that market significantly absent the Proposed Acquisition. The structure of each of these markets is as follows:

• Acetylcysteine injection prevents or minimizes liver damage resulting from acetaminophen overdose. There are two generic acetylcysteine injection products currently on the market, and Mylan and Agila are two of only a limited number of firms that have generic products in development. Therefore, the Proposed Acquisition would significantly reduce the number of likely future suppliers of generic acetylcysteine injection.

• Injectable fomepizole treats accidental poisoning caused by ethylene glycol or methanol ingestion. Three firms currently supply the highly concentrated market for generic fomepizole injection—Mylan, X-Gen Pharmaceuticals, Inc., and Sandoz. Agila is developing its own generic fomepizole injection product and likely would be the next firm to enter the market. As a result, the Proposed Acquisition would significantly reduce the number of suppliers of generic fomepizole injection in the near future.

• Ganciclovir injection is an antiviral medication used to treat patients with weakened immune systems, such as patients with HIV–AIDS and transplant recipients, to slow the growth of cytomegalovirus, a form of herpes virus that can lead to blindness. Currently, Roche Palo Alto, LLC (''Roche'') sells a branded product, Cytovene. Fresenius sells the only generic version of this drug. Mylan and Agila are two of only a limited number of firms that have this drug in development. Therefore, the Proposed Acquisition would result in the reduction of likely future suppliers of generic ganciclovir injection.

• Meropenem injection is an ultra-broad spectrum antibiotic used as a last resort to treat serious bacterial infections in an intensive care setting. There are currently four suppliers of the drug—AstraZeneca PLC, Fresenius, Hospira, and Sandoz. All four of these companies, however, obtain their supplies of meropenem from two manufacturers. Mylan and Agila are two of only a limited number of firms that have a generic meropenem injection product in development. They are also the only likely entrants that will source their meropenem products from alternative manufacturing facilities. As a result, the Proposed Acquisition would significantly reduce the number of marketers, as well as the sources of manufacturing, of generic meropenem injection in the future.

Finally, the Proposed Acquisition will significantly reduce potential competition in one generic market that does not yet exist—the market for mycophenolate mofetil injections. This market would be highly concentrated when Mylan and Agila would likely enter it in the future. Mycophenolate mofetil injection is an immunosuppressant used in transplant medicine to subdue T-cell and B-cell production, reducing the risk of transplant rejection. Today, Roche sells its branded product, CellCept. When generic entry occurs, Mylan and Agila would likely be among a limited number of suppliers. Thus, the Proposed Acquisition would significantly reduce the number of likely future suppliers of this drug to the detriment of consumers.

Entry

Entry into each of these generic injectable product markets will not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the likely anticompetitive effects of the Proposed Acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes well in excess of two years.

Competitive Effects

Absent a remedy, the Proposed Acquisition would likely cause significant anticompetitive harm to consumers in the relevant generic injectable pharmaceutical markets,

either by eliminating significant current or potential competition in concentrated existing markets, or by eliminating significant potential competition among a limited number of likely competitors in a future market. In each of these markets, Mylan and Agila are two of only a limited number of current or likely future suppliers of the drugs in the United States. The evidence shows that prices may continue to decrease even after a number of suppliers have entered a generic injectable drug market. Thus, although Mylan or Agila have not entered some of the markets at issue yet, both companies likely will compete in those markets in the future, and that competition is expected to reduce prices for consumers. The evidence also shows that the removal of an independent generic injectable drug supplier from the relevant markets in which Mylan and Agila currently compete would result in significantly higher prices post-acquisition. Therefore, by eliminating the significant current and future competition between the parties, the Proposed Acquisition will likely cause U.S. consumers to pay significantly higher prices for these generic injectable drugs, absent a remedy.

The Consent Agreement

The Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in each relevant market. Under the Consent Agreement, the parties are required to divest either Mylan's or Agila's rights and assets related to (1) Amiodarone hydrochloride injection, (2) etomidate injection, (3) fluorouracil injection, (4) mesna injection, (5) methotrexate sodium preservative-free injection, (6) acetylcysteine injection, (7) fomepizole injection, (8) ganciclovir injection, (9) meropenem injection, and (10) mycophenolate mofetil injection. In addition, Mylan is required to release all of its rights and assets related to labetalol hydrochloride injection. The parties must accomplish these divestitures and relinquish their rights no later than ten days after the acquisition.

The proposed Consent Agreement requires Mylan to terminate its contract with Gland and to release all rights related to labetalol hydrochloride injection. Gland, a global pharmaceutical company based in India, is Mylan's contract manufacturer for this drug. Given its experience with this drug, Gland is well positioned to replicate the competition that would otherwise have been lost as a result of the Proposed Acquisition. The proposed Consent Agreement also requires Mylan to divest assets related to fluorouracil injection and methotrexate sodium preservative-free injection to Intas and to divest assets related to etomidate injection, ganciclovir injection, meropenem injection, and mycophenolate mofetil injection to JHP. In addition, the proposed Consent Agreement requires Agila and Strides to divest assets related to acetylcysteine injection and mesna injection to Sagent and to divest assets related to amiodarone hydrochloride injection and fomepizole injection to JHP. Intas is a global pharmaceutical company based in India with approximately 79 prescription drugs approved for sale in the United States, as well as an active product development pipeline. JHP is a New Jersey based pharmaceutical company with approximately 22 approved ANDAs and an active product development pipeline. Finally, Sagent, a pharmaceutical company based in Illinois, has approximately 58 approved ANDAs and an active product development pipeline. With their experience in generic markets, Intas, JHP, and Sagent are expected to replicate fully the competition that would otherwise have been lost as a result of the Proposed Acquisition.

The Commission's goal in evaluating possible acquirers of divested assets is to maintain the competitive environment that existed prior to the acquisition. If the Commission determines that Intas, JHP, Sagent, or Gland are not acceptable acquirers, or that the manner of the divestitures or releases is not acceptable, the parties must unwind the sale or release of rights to Intas, JHP, Sagent, or Gland and divest the products 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 products if the parties fail to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Mylan, Agila, and Strides to take all action to maintain the economic viability, marketability, and competitiveness of the products to be divested until such time that they are transferred to a Commission-approved acquirer. Mylan and Agila must transfer their respective manufacturing technologies for generic amiodarone hydrochloride injection, etomidate injection, and fomepizole injection to JHP and must supply JHP with these drugs during the transition period. Further, Agila and Strides must transfer the manufacturing technology for acetylcysteine injection and mesna injection to Sagent and must supply Sagent with the two drugs during the transition period.

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.

[FR Doc. 2013–24144 Filed 10–2–13; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-MK–2013–09; Docket No. 2013–0002; Sequence 31]

The President's Management Advisory Board (PMAB); Notification of Upcoming Public Advisory Meeting

AGENCY: Office of Executive Councils, U.S. General Services Administration (GSA).

ACTION: Meeting Notice.

SUMMARY: The President's Management Advisory Board (PMAB), a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13538, will hold a public teleconference meeting on Monday, October 21, 2013.

DATES: *Meeting date:* The meeting will be held on Monday, October 21, 2013, beginning at 11:00 a.m. eastern time, ending no later than 12:30 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen Brockelman, Designated Federal Officer, President's Management Advisory Board, Office of Executive Councils, General Services Administration, 1800 F Street NW., Washington, DC 20006, at *stephen.brockelman@gsa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The PMAB was established to provide independent advice and recommendations to the President and the President's Management Council on a wide range of issues related to the development of effective strategies for the implementation of best business practices to improve Federal Government management and operation.

Agenda: The main purpose for this meeting is for the PMAB to discuss and define areas of work for the PMAB emerging from the new President's Management Agenda. Focal areas are likely to involve recommendations for