[BILLING CODE: 6750-01S]

FEDERAL TRADE COMMISSION

[File No. 171 0052]

Baxter International Inc., Claris Lifesciences Limited, and Arjun Handa;

Analysis 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 methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders -- embodied in the consent agreement -- that would settle these allegations.

DATES: Comments must be received on or before August 21, 2017.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write: "In the Matter of Baxter International Inc., File No. 171-0052" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ftc/baxterclarisconsent by following the instructions on the web-based form. If you prefer to file your comment on paper, write "In the Matter of Baxter International Inc., File No. 171-0052" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC

20024.

FOR FURTHER INFORMATION CONTACT: Kari Wallace (202-326-3085), 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 July 20, 2017), on the World Wide Web, at https://www.ftc.gov/news-events/commission-actions.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before August 21, 2017. Write "In the Matter of Baxter International Inc., File No. 171-0052" 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 Website, at https://www.ftc.gov/policy/public-comments.

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/baxterclarisconsent 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 website.

If you prefer to file your comment on paper, write "In the Matter of Baxter International Inc., File No. 171-0052" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue, NW, Suite CC-5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex D), Washington, DC. 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC Website at https://www.ftc.gov, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else'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, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential" – as provided by 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) – including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). 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). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC Website – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from the FTC Website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website 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 August 21, 2017. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see https://www.ftc.gov/site-information/privacy-policy.

Analysis of Agreement Containing Consent Orders to Aid Public Comment

I. Introduction

The Federal Trade Commission ("Commission") has accepted, subject to final approval, an Agreement Containing Consent Orders ("Consent Agreement") from Baxter International Inc. ("Baxter") and Claris Lifesciences Limited and Arjun Handa (collectively "Claris") that is designed to remedy the anticompetitive effects resulting from Baxter's acquisition of voting securities of certain entities and related assets from Claris. Under the terms of the proposed Consent Agreement, the parties are required to divest all of Claris's rights and assets related to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to Renaissance Lakewood LLC ("Renaissance").

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 any 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 agreements dated December 15, 2016, Baxter proposes to acquire voting securities of certain entities and related assets from Claris in two related transactions valued at approximately $625 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 current competition in the market for fluconazole in saline intravenous bags and future competition in the market for milrinone in dextrose intravenous bags 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.

II. The Products and Structure of the Markets

The Proposed Acquisition would reduce the current competition in the market for fluconazole in saline intravenous bags, and reduce future competition in the market for milrinone in dextrose intravenous bags.

Fluconazole is an antifungal agent used to treat a variety of fungal and yeast infections. Five companies currently sell generic intravenous fluconazole bags in the United States: Baxter, Claris, Pfizer Inc. ("Pfizer"), Sagent Pharmaceuticals, and Hikma Pharmaceuticals PLC

("Hikma"), but only four of these companies are significant competitors. Baxter and Claris have a combined estimated market share of nearly 60%.

Intravenous milrinone is a vasodilator that dilates the blood vessels, lowering blood pressure and allowing blood to flow more easily through the cardiovascular system. The product is used as a short-term treatment for life-threatening heart failure. Three companies—Baxter, Hikma, and Pfizer—currently sell the product in the United States. Claris is expected to enter this market shortly, once its pending application at the FDA is approved, a development expected to occur in the very near future.

III. Entry

Entry into the two markets at issue 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.

IV. Effects

The Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating current competition between Baxter and Claris in the market for fluconazole in saline intravenous bags. Fluconazole in saline intravenous bags is a commodity product, and prices typically 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 only four significant companies selling the product, likely leading consumers to pay higher prices.

Customers also have indicated that the presence of an independent Claris has allowed them to negotiate lower prices for fluconazole bags.

In addition, the Proposed Acquisition likely would cause significant anticompetitive harm to consumers by eliminating future competition that would otherwise have occurred if Baxter and Claris remained independent in the market for milrinone in dextrose intravenous bags. The evidence shows that the Proposed Acquisition, absent a remedy, would eliminate an additional independent entrant in the currently concentrated market for milrinone in dextrose intravenous bags, which would have enabled customers to negotiate lower prices. Customers and competitors have observed—and pricing data confirms—that the price of these pharmaceutical products decreases with new entry even after several other suppliers have entered the market. Thus, absent a remedy, the Proposed Acquisition likely will cause U.S. consumers to pay significantly higher prices for milrinone in dextrose intravenous bags in the future.

V. The Consent Agreement

The proposed Consent Agreement effectively remedies the competitive concerns raised by the acquisition in both markets at issue by requiring Claris to divest all its rights to fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags to Renaissance. Renaissance is a pharmaceutical corporation that develops, manufacturers, sells, and distributes injectable pharmaceutical products in the United States. The parties must accomplish these divestitures no later than ten days after they consummate the Proposed Acquisition.

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 Renaissance is not an acceptable acquirer, or that the manner of the divestitures

is not acceptable, the proposed Order requires the parties to unwind the sale of rights to Renaissance 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. Baxter will supply Renaissance with fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags for up to five years while the company transfers the manufacturing technology to Renaissance or its contract manufacturing designee. The proposed Order also requires Baxter to provide transitional services to Renaissance to assist it in establishing its manufacturing capabilities and securing all of the necessary FDA approvals. These transitional services include technical assistance to manufacture fluconazole in saline intravenous bags and milrinone in dextrose intravenous bags in substantially the same manner and quality employed or achieved by Claris. It also includes advice and training from knowledgeable employees of the parties. Under the proposed Consent Agreement, the Commission also will appoint an Interim Monitor.

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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