

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

**COMMISSIONERS: Maureen K. Ohlhausen, Acting Chairman
 Terrell McSweeney**

In the Matter of)	
)	
BAXTER INTERNATIONAL INC.,)	
a corporation;)	
)	
CLARIS LIFESCIENCES LIMITED,)	Docket No. C-4620
a corporation;)	
and)	
)	
ARJUN HANDA,)	
an individual.)	

ORDER TO MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Baxter International Inc. (“Baxter”) of the voting securities of certain subsidiaries of Claris Lifesciences Limited (“Claris”), defined herein as “Claris Generic Pharmaceutical Entities,” and related assets from their ultimate parent entity Mr. Arjun Handa (Baxter, Claris and Mr. Handa hereinafter collectively referred to as “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of 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; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of the Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true,

and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Maintain Assets:

1. Respondent Baxter is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its principal executive offices located at One Baxter Parkway, Deerfield, Illinois 60015.
2. Respondent Claris is a corporation organized, existing, and doing business under and by virtue of the laws of the Republic of India with its principal executive offices located at 1 Corporate Towers Nr. Parimal Crossing, Ellisbridge, Ahmedabad, 380006, India, and its United States address for service of process and the Complaint, the Decision and Order, and the Order to Maintain Assets, as follows: Compliance Officer, Company Secretary, Claris Lifesciences Ltd., c/o Claris Life Sciences Inc., 1445 US Highway 130, North Brunswick, New Jersey 08902.
3. Respondent Arjun Handa is an individual with an address of Sharanya, Judges Banglow Road, Bodakdev, Ahmedadbad, Gujarat, India 380054.
4. The Commission has jurisdiction over the subject matter of this proceeding and over the Respondents, and the proceeding is in the public interest.

ORDER

I.

IT IS ORDERED that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Baxter" means: Baxter International Inc.; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Baxter International Inc. (including, without limitation, Baxter Pacific Investments Pte Ltd and Baxter Healthcare (Asia) Pte. Ltd), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Baxter shall include the Claris Generic Pharmaceutical Entities.

- B. “Claris” means: Claris Lifesciences Limited; its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates, in each case controlled by Claris Lifesciences Limited, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Arjun Handa” means: (i) Arjun S. Handa, a natural person; (ii) all employees, agents, representatives, successors, and assigns of Arjun S. Handa; and (iii) all partnerships, joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Arjun S. Handa, and the respective partners, directors, officers, employees, agents, representatives, successors, and assigns of each.
- D. “Commission” means the Federal Trade Commission.
- E. “Respondent(s)” means Baxter, Claris, and Arjun Handa, individually and collectively.
- F. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
 2. Final Decision and Order following its issuance and service by the Commission in this matter.
- G. “Divestiture Product Business(es)” means the Business of Respondent (as that Respondent is specified in the definition of each Divestiture Product) within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products to the extent that such Business is owned, controlled, or managed by the Respondent and the assets related to such Business to the extent such assets are owned by, controlled by, managed by, or licensed to, the Respondent.
- H. “Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- I. “Transition Period” means, for each Divestiture Product that is marketed or sold in the United States before the Closing Date, the period beginning on the date this Order to Maintain Assets is issued and ending on the earlier of the following dates: (i) the date on which the Acquirer directs the Respondent(s) to cease the marketing, distribution, and sale of such Divestiture Product(s); (ii) the date on which the Acquirer commences the marketing, distribution, and sale of such Divestiture Product(s); or (iii) the date four (4) months after the Closing Date for such Divestiture Product(s).

J. "Orders" means the Decision and Order and this Order to Maintain Assets.

II.

IT IS FURTHER ORDERED that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in the Decision and Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the full economic viability, marketability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; High Volume Accounts; end-use customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:
1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans, and promotional activities for such Divestiture Product Business;
 2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by the Respondents, including, but not limited to, all research, Development, manufacturing, distribution, marketing, and sales expenditures;
 3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the

Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Product Assets to an Acquirer;

4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products that were marketed or sold by Respondents prior to the date the Respondents entered the agreement to effect the Acquisition (as such agreement is identified in the definition of Acquisition), at the related High Volume Accounts;
 5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such Divestiture Product Business; and
 6. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such Divestiture Product Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver each of the respective Divestiture Product Assets to an Acquirer, Respondents shall maintain a work force that is (i) at least as large in size (as measured in full time equivalents) as, and (ii) comparable in training, and expertise to, what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Not later than one (1) day after the date this Order to Maintain Assets is issued by the Commission, for each Divestiture Product that has been marketed or sold prior to the Closing Date, Respondents shall provide to the Proposed Acquirer of that Divestiture Product, for each High Volume Account, a list by either SKU or NDC Number containing the current net price per SKU or NDC Number, *i.e.*, the final price per SKU or NDC Number, charged by the relevant Respondent (as that Respondent is identified in the definition of each Divestiture Product) net of all customer-level discounts, rebates, or promotions, for that Divestiture Product, as of five (5) business days or less prior to the date this Order to Maintain Assets is issued.
- E. For each Acquirer of a Divestiture Product that is a Contract Manufacture Product, Respondents shall:
1. for a period of twelve (12) months from the Closing Date, provide that Acquirer or its Manufacturing Designee with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the "Divestiture Product Core Employee Access Period(s);"

2. not later than the earlier of the following dates: (i) ten (10) days after notice by staff of the Commission to the relevant Respondent to provide the Product Employee Information; or (ii) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by that Respondent to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; *provided, however,* that the provision of such information may be conditioned upon the Acquirer's or Proposed Acquirer's written confirmation that it will (i) treat the information as confidential and, (ii) use the information solely in connection with considering whether to provide or providing to Divestiture Product Core Employees the opportunity to enter into employment contracts during a Divestiture Product Core Employee Access Period, and (iii) restrict access to the information to such of the Acquirer's or Proposed Acquirer's employees who need such access in connection with the specified and permitted use;
3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by that Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees related to the Divestiture Products and Divestiture Product Assets acquired by that Acquirer, and remove any impediments within the control of Respondent that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with a Respondent that would affect the ability or incentive of those individuals to be employed by that Acquirer or its Manufacturing Designee. In addition, a Respondent shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph shall not prohibit a Respondent from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with a Respondent prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, manufacture, and/or market the Divestiture Product(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product(s). Such incentives shall

include a continuation of all employee compensation and benefits offered by a Respondent until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law); and

5. for a period of one (1) year from the Closing Date, not: (i) directly or indirectly solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or (ii) hire any Divestiture Product Employee;

provided, however, a Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with that Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided further, however, that this Paragraph does not require nor shall be construed to require a Respondent to terminate the employment of any employee or to prevent a Respondent from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition;

provided further, however, that a Respondent may do the following: (i) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (ii) hire a Divestiture Product Employee who contacts a Respondent on his or her own initiative without any direct or indirect solicitation or encouragement from that Respondent.

- F. During the Transition Period, with respect to each Divestiture Product that is marketed or sold in the United States before the Closing Date for that Divestiture Product, Respondents, in consultation with the Acquirer, for the purposes of ensuring an orderly marketing and distribution transition, shall:
 1. develop and implement a detailed transition plan to ensure that the commencement of the marketing, distribution, and sale of such Divestiture Products by the Acquirer is not delayed or impaired by the Respondents;
 2. designate employees of Respondents knowledgeable about the marketing, distribution, and sale related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer, and the Monitor (if one has been appointed), for the purposes of assisting in the transfer to the Acquirer of the Business related to the Divestiture Products;

3. maintain and manage inventory levels of the Divestiture Products in consideration of the marketing and distribution transition to the Acquirer;
4. continue to market, distribute, and sell the Divestiture Products;
5. allow the Acquirer access at reasonable business hours to all Confidential Business Information related to the Divestiture Products and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Divestiture Products that contain such Confidential Business Information pending the completed delivery of such Confidential Business Information to the Acquirer;
6. to the extent known or available to the specified Respondent, provide the Acquirer with a list of the inventory levels (weeks of supply) in the possession of each customer (*i.e.*, healthcare provider, hospital, group purchasing organization, wholesaler, or distributor) by stock keeping unit or NDA Number on a regular basis and in a timely manner;
7. to the extent known by the specified Respondent, provide the Acquirer with anticipated reorder dates for each customer by stock keeping unit or NDC Number on a regular basis and in a timely manner; and
8. establish projected time lines for accomplishing all tasks necessary to effect the marketing and distribution transition to the Acquirer in an efficient and timely manner.

G. Pending divestiture of the Divestiture Product Assets, Respondents shall:

1. not use, directly or indirectly, any Confidential Business Information related to the Business of the Divestiture Products other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to each respective Acquirer under the terms of any related Remedial Agreement; or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer of the particular Divestiture Assets, (ii) other Persons specifically authorized by that Acquirer or staff of the Commission

- to receive such information (*e.g.*, employees of the Respondents responsible for the Contract Manufacture or continued Development of a Divestiture Product on behalf of an Acquirer), (iii) the Commission, or (iv) the Monitor (if any has been appointed) and *except* to the extent necessary to comply with applicable Law;
3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing, sales or Development of the Divestiture Products to the employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products;
 4. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research and Development of the Development Divestiture Products to any employees associated with the Business related to those Retained Products that are the Therapeutic Equivalent of the Divestiture Products *unless* authorized by the Acquirer of the particular Divestiture Product to do so; and
 5. institute procedures and requirements to ensure that the above-described employees:
 - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- H. Not later than thirty (30) days from the earlier of (i) the Closing Date or (ii) the date this Order to Maintain Assets is issued by the Commission, each Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by that Respondent's personnel to all of its employees who (i) may be in possession of such Confidential Business Information or (ii) may have access to such Confidential Business Information.
- I. Each Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Each Respondent shall provide a copy of the notification to the Acquirer. Each Respondent shall maintain complete records of all such notifications at that Respondent's registered office within the United States and shall provide an officer's certification to the Commission affirming the implementation of, and compliance with, the acknowledgment program. Each Respondent shall provide the Acquirer with copies of all certifications, notifications, and reminders sent to that Respondent's personnel.

- J. Each Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions with respect to Confidential Business Information, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets.
- K. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer; to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory; and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Product Assets except for ordinary wear and tear.

III.

IT IS FURTHER ORDERED that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Monitor, subject to the consent of Respondent Baxter, which consent shall not be unreasonably withheld. If Respondent Baxter has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Baxter of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondent Baxter shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor each Respondent’s compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If a Monitor is appointed, each Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
 - 1. The Monitor shall have the power and authority to monitor each Respondent’s compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission; and
3. The Monitor shall serve until the divestiture of all Divestiture Product Assets has been completed, and the transfer and delivery of the related Product Manufacturing Technology has been completed, in a manner that fully satisfies the requirements of this Order, and, with respect to each Divestiture Product that is a Contract Manufacture Product, until the earliest of:
 - a. the date the Acquirer of that Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture that Divestiture Product and able to manufacture the final finished Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Baxter;
 - b. the date the Acquirer of that Divestiture Product notifies the Commission and Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - c. the date of written notification from staff of the Commission that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product;

provided, however, that, with respect to each Divestiture Product, the Monitor's service shall not extend more than five (5) years after the Order Date *unless* the Commission decides to extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to each Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to that Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Each Respondent shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor that Respondent's compliance with the Orders.
- F. The Monitor shall serve, without bond or other security, at the expense of Respondent Baxter, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Baxter, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

- G. Each Respondent shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor.
- H. Each Respondent shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by a Respondent, and any reports submitted by each Acquirer with respect to the performance of a Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by each Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent Baxter has filed its final report pursuant to Paragraph VII.C. of the Decision and Order, and ninety (90) days thereafter, the Monitor shall report in writing to the Commission concerning progress by each Acquirer or the Acquirer's Manufacturing Designee toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent Baxter.
- I. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- K. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as the Monitor pursuant to the Decision and Order.

- N. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

IV.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets is issued by the Commission, and every sixty (60) days thereafter until Respondents have fully complied with this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with the Orders. Each Respondent shall submit at the same time a copy of its report concerning compliance with the Orders to the Monitor, if any Monitor has been appointed. Each Respondent shall include in its reports, among other things that are required from time to time, a detailed description of its efforts to comply with the relevant paragraphs of the Orders, including:

- A. a detailed description of all substantive contacts, negotiations, or recommendations related to (i) the divestiture and transfer of all relevant assets and rights, (ii) transitional services being provided by the relevant Respondent to the Acquirer, and (iii) the agreement(s) to Contract Manufacture; and
- B. a detailed description of the timing for the completion of such obligations,

provided, however, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission on the same timing as, the reports of compliance required to be submitted by Respondents pursuant to the Decision and Order.

V.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger, or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

VI.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that each Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and
- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

VII.

IT IS FURTHER ORDERED that Respondent Claris's and Respondent Arjun Handa's obligations under this Order to Maintain Assets, shall terminate on the date on which all of the following have occurred:

- A. Respondent Baxter has acquired over fifty (50) percent of the voting securities or equity interests of each of the Claris Generic Pharmaceutical Entities;
- B. the Divestiture Assets are completely owned and controlled either by Respondent Baxter or an Acquirer;
- C. with respect to any Divestiture Product or related Product Intellectual Property or Manufacturing Technology, that is owned or controlled by Respondent Claris prior to the Acquisition, Respondent Claris has:
 - 1. transferred all rights and assets that were owned or controlled by Respondent Claris prior to the Acquisition and necessary to effect the related divestitures to either Respondent Baxter or the Acquirer;
 - 2. transferred or otherwise provided all rights, assets or other resources that were owned or controlled by Respondent Claris prior to the Acquisition and necessary for Respondent Baxter to provide the services and assistance to the Acquirer described in this Order to Respondent Baxter; and
 - 3. secured all consents and waivers from all Third Parties that are necessary to divest the Divestiture Assets to an Acquirer or certified that the Acquirer has executed all such agreements directly with each of the relevant Third Parties;

- D. with respect to any Product Licensed Intellectual Property, Respondent Claris has granted or otherwise provided the rights to use such intellectual property either directly to the Acquirer, or to Respondent Baxter for the purposes of providing such rights to the Acquirer; and
- E. Both Respondent Claris and Respondent Arjun Handa certify to the Commission that all of the above-described acquisitions and transfers have occurred and all of the above-described consents and waivers from Third Parties have been provided to the Acquirer.

VIII.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate as to Respondent Baxter on the later of:

- A. three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. the day after the divestiture of all of the Divestiture Product Assets, as required by and described in the Decision and Order, has been completed;
- C. the day after the Product Manufacturing Technology related to each Divestiture Product that is a Contract Manufacture Product or a Pipeline Product has been provided to the Acquirer in a manner consistent with the Technology Transfer Standards and the Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to the provision of the Product Manufacturing Technology are complete; or
- D. the day the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

April J. Tabor
Acting Secretary

SEAL
ISSUED: July 20, 2017