

## INTERIM MONITOR AGREEMENT

This Interim Monitor Agreement (“Monitor Agreement”) entered into among Quantic Regulatory Services, LLC (“Quantic”) and Baxter International Inc. (“Baxter”) (where “Respondents” as used herein means Baxter and Claris individually and collectively), provides as follows:

WHEREAS, the United States Federal Trade Commission (the “Commission”), in *In the Matter of Baxter International Inc.*, has accepted or will shortly accept for Public Comment an *Agreement Containing Consent Orders*, incorporating a Decision and Order (“Decision and Order”) with Baxter, and an Order to Maintain Assets, with Baxter and Claris Injectables Limited (“Claris”) (collectively, the “Orders”), which, among other things, require Respondents to divest or transfer certain defined assets and maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Interim Monitors to ensure that Respondents comply with their obligations under the Orders;

WHEREAS, the Commission may appoint Quantic as such monitor (the “Interim Monitor”) pursuant to the Orders to monitor Respondents’ compliance with the terms of the Consent Agreement and Orders and with the Remedial Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirer (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and Quantic has consented to such appointment;

WHEREAS, the Orders further provide or will provide that Respondents shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Interim Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement, although executed by the Interim Monitor and Baxter and Claris, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents or the Interim Monitor under the Orders, until it has been approved by the Commission; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term “Divestiture Products” means, individually and collectively, (1) Fluconazole Injections, USP Iso-Osmotic Sodium Chloride Diluent and Fluconazole Injection, USP Iso-osmotic Dextrose Diluent; and (2) Milrinone Injection, USP, in each case, as more fully described on Appendix A hereto
2. The Interim Monitor shall have all of the powers and responsibilities conferred upon the Interim Monitor by the Orders, including but not limited to:

- a. supervising the transfer of the Divestiture Products, including tangible assets, contracts, Product Intellectual Property and Confidential Business Information to Commission-approved Acquirers;
  - b. supervising any redaction of Confidential Business Information retained by Respondents as required by the Orders; and
  - c. supervising the performance of any transition services, including Contract Manufacture, required by the Orders.
3. Respondents hereby agree that, no later than three (3) business days after the Commission approves this Monitor Agreement, Respondents will fully comply with all terms of the Orders requiring them to confer all rights, powers, authority and privileges upon the Interim Monitor, or to impose upon themselves any duties or obligations with respect to the Interim Monitor, to enable the Interim Monitor to perform the duties and responsibilities of the Interim Monitor thereunder.
4. Respondents further agree that:
  - a. they will use their best efforts to ensure that Renaissance Lakewood LLC (“Renaissance”), or any other Commission-approved Acquirer enters into an agreement with the Interim Monitor at or about the Closing Date governing the facilitation of the Interim Monitor’s duties under the Orders and the exchange of information between Renaissance or any other Commission-approved Acquirer and the Interim Monitor;
  - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, they will provide the Interim Monitor with the following, as applicable:
    - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
    - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
    - (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Products relating to the Divestiture Products, and which relate to Respondents' compliance with the Orders, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;

- (4) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products (other than Renaissance or any other entity accepted by the Commission), including copies of all correspondence and written reports of all contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices;
  - (5) a complete inventory of all Patents included in the Divestiture Products related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions; and
  - (6) such other information as reasonably requested by Interim Monitor in order to carry out its duties and responsibilities under the Orders and Consent Agreement.
- c. they will designate a senior individual as a primary contact for the Interim Monitor and provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to the Commission-approved Acquirers, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and will provide the Interim Monitor with written notice of any changes in such personnel occurring thereafter;
- d. they will provide the Interim Monitor with prompt notification of significant meetings involving Renaissance, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Interim Monitor or its representative, at the Interim Monitor's option or at the request of the Commission or staff of the Commission;
- e. they will provide the Interim Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- f. they will provide the Interim Monitor with all correspondence, meeting minutes, telephone summaries, reports, sent to or received from the FDA to the extent specifically relating to the Divestiture Products;
- g. they will provide the Interim Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- h. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, they will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the

Commission for public comment, or as reasonably requested by the Interim Monitor, electronic or hard copy reports to the Interim Monitor reasonably describing Respondents' activities and obligations under the Orders concerning the Divestiture Products including, without limitation to the extent applicable:

- (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
- (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with the Commission-approved Acquirers related to the manufacture, supply, and technology transfer of the Products identified in the Divestiture Products;
- (3) all significant activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer generally as provided in the Decision and Order; and
- (4) on request, Respondents will provide the Interim Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;

*provided, however,* that, at the time the Decision and Order becomes final, the reports described in this paragraph shall be due to the Interim Monitor either as requested by the Interim Monitor or within five (5) business days of the date that Respondents file the Respondents' reports with the Commission as required pursuant to the Decision and Order;

- i. they will comply with the Interim Monitor's reasonable requests for onsite visits and audits of Respondents' facilities (or any contract manufacturer's facility) used to manufacture the Products identified in the Divestiture Products;
- j. they will comply with the Interim Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Interim Monitor pursuant to this Agreement, including, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of the Divestiture Products or any Product comprised therein and, further including, actions necessary to maintain all necessary FDA or other foreign regulatory agency equivalent approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products, and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and will provide the Interim Monitor with access to and hard copies of all other data, records or

other information that the Monitor reasonably believes are necessary to the proper discharge of its responsibilities under the Orders; and

- k. they will provide prompt notice of any meetings or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA to the extent specifically related to the Divestiture Products.
5. Respondents shall promptly notify the Interim Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondents related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of oral communications, summaries), as may be requested by the Interim Monitor, of such communications.
  6. Respondents agree that to the extent authorized by the Orders, the Interim Monitor shall have the authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information; provided that, other than consultants of the Interim Monitor engaged to perform interim monitor Services, prior to any such engagement, the Interim Monitor shall discuss the intended purpose of such third party engagements and will discuss potential options and costs with Respondents prior to finalizing any engagement.
  7. Respondents and the Interim Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Interim Monitor investigate and/or audit Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders, and submit such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders.
  8. The Interim Monitor shall maintain the confidentiality of all information provided to the Interim Monitor by Respondents. Such information shall be used by the Interim Monitor only in connection with the performance of the Interim Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Interim Monitor to any third party other than:
    - a. persons employed by, or working with, the Interim Monitor under this Agreement; or
    - b. persons employed at the Commission and working on this matter.
  9. Upon (i) termination of the Interim Monitor's duties under this Monitor Agreement, and (ii) written request by Respondents, the Interim Monitor shall promptly return to Respondents all material provided to the Interim Monitor by Respondents that is confidential to Respondents and that they are entitled to have returned to them under the Orders, and shall destroy any written material prepared by the Interim Monitor that

contains or reflects any confidential information of Respondents, provided, that, notwithstanding the foregoing, Interim Monitor shall be entitled to keep one copy of such information in its confidential files and all electronic records thereof. Nothing herein shall abrogate the Interim Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of ten (10) years after the termination of this Monitor Agreement;

10. To the extent that the Interim Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Interim Monitor in accordance with the Orders, the Interim Monitor shall ensure that, prior to being retained, such persons agree to confidentiality restrictions consistent with those set forth herein.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Interim Monitor or by any employee, agent, affiliate or consultant of the Interim Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than Respondents, or any director, officer, employee, agent, consultant or affiliate of Respondents, when such source is entitled to make such disclosure to such recipient or such information was independently developed by Interim Monitor as evidenced by written records.

11. Nothing in this Monitor Agreement shall require Respondents to disclose any material or information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.
12. The Interim Monitor shall not have a fiduciary responsibility to the Respondents, but shall have fiduciary duties to the Commission.
13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to Respondents.
14. Respondents will pay the Interim Monitor within four-five (45) days of receipt of an invoice in accordance with the fee schedule attached hereto as Confidential Appendix B for all time spent in the performance of the Interim Monitor's duties including all monitoring activities related to the efforts of the Commission-approved Acquirer of the Divestiture Products (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time, invoiced at 50% of actual hours. Each such invoice will be itemized and show daily entries by personnel detailing relevant activities performed and time spent on such activities.
  - a. In addition, Respondents will pay within thirty days of receipt of an invoice (i) all out-of-pocket expenses incurred by the Interim Monitor in the performance of the Interim Monitor's duties, including any auto, train or air travel in the performance

of the Interim Monitor's duties, international telephone calls, and (ii) all fees and disbursements reasonably incurred by such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties.

- b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.
  - c. The Interim Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.
  - d. To the extent that the Interim Monitor is requested to travel in the performance of the Interim Monitor's duties, the Interim Monitor shall use such travel time, to the extent practicable, to work on the FTC monitor process. The Interim Monitor staff shall travel coach on domestic flights and business class on international flights and shall seek to book all such travel at least 14 days in advance.
15. Respondents hereby confirm their obligation to indemnify the Interim Monitor and hold the Interim Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Interim Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Respondents shall indemnify the Interim Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses arising out of or in connection with, the performance of the Interim Monitor's duties and obligations 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 are finally judicially determined to result from the willful misconduct of the Interim Monitor.

16. The Interim Monitor's maximum liability to the Respondents relating to services rendered pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Interim Monitor by Respondents. **IN NO CIRCUMSTANCES WHATSOEVER SHALL INTERIM MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES.**

17. Respondents agree that the Respondents' obligations to indemnify the Interim Monitor extend to any agreement that is entered between the Interim Monitor and any Commission-approved Acquirer and relates to the Interim Monitor's responsibilities under the Monitor Agreement and/or the Orders.
18. Upon this Monitor Agreement becoming effective, the Interim Monitor shall be permitted, and Respondents shall be required, to notify all current Commission-approved Acquirers and potential future Acquirers with respect to its appointment as Interim Monitor.
19. In the event of a disagreement or dispute between Respondents and the Interim Monitor concerning Respondents' obligations under the Orders and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the case of any disagreement or dispute between Respondents and the Interim Monitor not relating to Respondents' obligations under the Orders, and in the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Orders. Any fees and expenses of the arbitration shall be split between the parties.
20. This Monitor Agreement shall be subject to the substantive law of the State of New Jersey (regardless of any other jurisdiction's choice of law principles).
21. This Monitor Agreement shall terminate when the relevant Commission-approved Acquirer(s) (or the Designee(s) of such Commission-approved Acquirer(s)) is (are) fully validated, qualified, and approved by the FDA, and able to manufacture in commercial quantities each of the relevant Divestiture Products independently of Respondents. The FTC will consult with the Interim Monitor to determine when each such Commission-approved Acquirer has met the criteria set forth in the preceding sentence with respect to each Divestiture Product. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality, indemnity and limitation of liability provisions of this Monitor Agreement shall survive its termination.
22. It is understood that the Interim Monitor will be serving under this Interim Monitor Agreement as an independent contractor and that the relationship of employer and employee shall not exist between Interim Monitor and Baxter or Claris.
23. This Monitor Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.
24. This Monitor Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or



understandings, whether written or oral. Any amendment, waiver, or modification of this Agreement shall not be valid unless in writing and signed by the parties. Purchase Order terms and conditions shall not be applicable.

25. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or email, to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Interim Monitor, to:

Quantic Regulatory Services, LLC  
R. Owen Richards  
President  
5N Regents Street  
Suite 502  
Livingston, NJ 07039  
Email: Orichards@quantic.com

If to Baxter or Claris, to:

Baxter International Inc.  
One Baxter Parkway  
Deerfield, Illinois 60015  
United States  
Attention: General Counsel-Legal  
E-mail: General\_Counsel@baxter.com

If to the Commission:

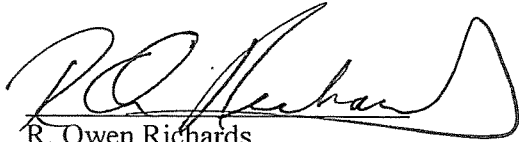
Federal Trade Commission  
601 Pennsylvania Avenue, N.W.  
Washington, DC 20001  
Attn.:  
Telephone:  
Email:

26. This Monitor Agreement shall not become binding until it has been approved by the Commission and the Orders have been accepted for public comment.
27. This Monitor Agreement may be signed in counterparts, each of which shall be deemed an original but when taken together shall constitute one and the same agreement.

**[Remainder of Page Intentionally Left Blank.]**

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 21 of June 2017.

Quantic Regulatory Services, LLC

A handwritten signature in black ink, appearing to read "R. Owen Richards", written over a horizontal line.

R. Owen Richards  
President

Baxter International Inc.

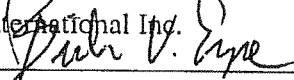
Name: \_\_\_\_\_

Title: \_\_\_\_\_

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the \_\_\_\_\_ of June 2017.

Quantic Regulatory Services, LLC

\_\_\_\_\_  
R. Owen Richards  
President

Baxter International Inc.  
Name:   
Title: Senior Vice President and President,  
Americas, Baxter International Inc.

