

## MONITOR AGREEMENT

This Monitor Agreement (Monitor Agreement) entered into as of this 6<sup>th</sup> day of October, 2021 by and among Denise Smart of SMART CONSULTING GROUP, LLC, 420 W. Miner St., West Chester, PA 19382 (Monitor) and ANI PHARMACEUTICALS, INC., 210 Main Street West Baudette, MN 56623 (Respondent) provides as follows:

WHEREAS, the United States Federal Trade Commission (the Commission) has or shortly will approve a Decision and Order and Order to Maintain Assets (Orders) with Respondent which, among other things, requires Respondent to license or transfer certain defined assets and maintain those assets pending such license or transfer, and provided for the appointment of a Monitor to ensure that Respondent complies with its obligations under the Orders;

WHEREAS, the Commission may appoint Denise Smart as such Monitor (the Monitor) pursuant to the Orders to monitor Respondent's compliance with the terms of the Consent Agreement and Orders and with the Divestiture Agreements referenced in the Orders, and to monitor the efforts of the Acquirer (as defined in the Orders) to obtain all necessary FDA approvals, as applicable, and the Monitor has consented to such appointment;

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

WHEREAS, this Monitor Agreement conforms with the requirements of the Orders and does not contradict the Orders;

WHEREAS, this Monitor Agreement, although subject to Commission approval, is effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents or the Monitor under the Orders, upon execution by the parties; 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.
2. The Monitor shall have the authority to monitor Respondents' compliance with the obligations set forth in the Orders including all of the powers, responsibilities and protections conferred upon the Monitor by the Orders. This authority shall include, but is not limited to:
  - a. supervising the divestiture of the Assets; and
  - b. supervising the performance of any transition services required by the Orders
  - c. acting in consultation with the Commission or its staff

The Orders are hereby attached as Exhibit A to this Monitor Agreement, the terms of which are incorporated herein by reference.

3. Respondent hereby agrees that, upon execution by both parties of the Monitor Agreement, Respondent will fully comply with all terms of the Orders requiring them to confer all rights, powers, authority and privileges upon the Monitor, or to impose upon themselves any duties or obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.
4. Respondent further agrees that:
  - a. it will cooperate with and assist the Monitor in performing the Monitor's duties for the purpose of reviewing Respondents' compliance with their obligations under the Orders, including as requested by the Monitor, (a) providing the Monitor full and complete access to personnel, information and facilities; and (b) making such arrangements with third parties to facilitate access by the Monitor;
  - b. it will not interfere with the ability of the Monitor to perform the Monitor's duties pursuant to the Orders;
  - c. it shall not require the Monitor to disclose to Respondents the substance of the Monitor's communications with the Commission or any other Person or the substance of written reports submitted to the Commission pursuant to the Orders;
  - d. it will use their best efforts to ensure that the Acquirer which is acquiring or licensing assets pursuant to the Orders (or as otherwise specified by the Commission) enters into an appropriate agreement with the Monitor as soon as practicable after the execution of this Monitor Agreement;
  - e. no later than **ten (10)** Business Days after the Commission approves this Monitor Agreement, it will provide the Monitor with:
    - (1) a copy of the Divestiture Agreements (or drafts thereof) relating to the Assets, including any exhibits, schedules and appendices;
    - (2) offering or information memoranda, or similar documents and information, provided to the Acquirer(s) relating to the sale of the Assets;
    - (3) copies of correspondence with, and written reports or minutes of meetings of all substantive contacts and discussions with, any Acquirer(s) relating to the Assets or Divestiture Agreements; and
    - (4) a complete description of the Assets being divested, identifying, in particular, those Assets which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;

- (5) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Assets identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;
  - (6) a complete inventory of all activities or operations that relate to the manufacture of the Products relating to the Assets, and which relate to Respondent's compliance with the Orders, including, to the extent applicable, processes and process validations which are under development, key equipment, test methods, special facilities, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture; and
  - (7) a complete inventory of all Patents included in the Assets, if any, related to the manufacture or sale of the Assets in the United States, identifying actions needed to maintain such Patents and the person(s) responsible for such actions;
- f. it will designate a senior individual as a primary contact for the Monitor and provide a written list of the principal individuals involved in the licensing of the Divestiture Assets to the Acquirer, together with their location, telephone numbers, electronic mail address (if available), and responsibilities, and will provide the Monitor with written notice of any changes in such personnel occurring thereafter;
  - g. it will provide the Monitor with prompt notification of significant meetings, 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 Assets, and such meetings may be attended by the Monitor or its representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
  - h. it will provide the Monitor the minutes 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;
  - i. it will provide the Monitor with all correspondence, meeting minutes, reports, sent to or received from the FDA relating to the Divestiture Assets; and will provide prompt notice of any and all meetings or communications with the FDA relating to or affecting the Divestiture Assets;
  - j. it will provide the 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;
  - k. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, it will provide every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as requested by the Monitor, full and detailed

electronic or hard copy reports to the Monitor as to all of Respondent's activities and obligations under the Orders concerning the Divestiture Assets including, without limitation to the extent applicable:

- (1) all activities involving the research and development, preclinical and clinical studies where appropriate and pursuit and maintenance of FDA clearance or approvals relating to the Divestiture Assets;
- (2) all activities concerned with the licensing, manufacture, supply and technology transfer of the Product that is identified in the Divestiture Assets, including, without limitation, negotiation and operation of supply agreements, actual supply and inventory;
- (3) all minutes and records of meetings, action plans, and follow-ups to actions plans and meetings, with the Acquirers related to the licensing, manufacture, supply, and technology transfer of the Products identified in the Divestiture Assets;
- (4) all activities concerning the assistance, advice and consultation provided to any Acquirer generally as provided in the Decision and Orders; and
- (5) on request, Respondent will provide the Monitor with any and all records that relate to the licensing and manufacture of the Products identified in the Divestiture Assets with the right to use them to achieve the purpose of the Orders;

*provided, however*, that at the time the Orders become final, the reports described in this paragraph together with all other information and documents referred to herein shall be due to the Monitor either as requested by the Monitor or within five (5) Business Days of the date that Respondent files the Respondent's reports with the Commission as required pursuant to the relevant provisions of the Orders;

- l. it will comply with the Monitor's requests for on-site visits and audits of Respondent's facility used to manufacture the Products identified in the Divestiture Assets;
- m. it will comply with the Monitor's requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Agreement or in connection with any matters the Monitor deems reasonably necessary to perform its responsibilities under the Orders, including, without limitation, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale, licensing, and/or divestiture of the Divestiture Assets 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 Assets, to maintain the viability and marketability of the Divestiture Assets, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Assets, and to prevent the destruction,

removal, wasting, deterioration or impairment of the Divestiture Assets, and will provide the Monitor with access to and hard and electronic copies of all other data, records or other information that the Monitor believes are necessary to the proper discharge of its responsibilities under the Orders;

- n. it will provide prompt notice of any meetings, activities or events affecting or likely to affect the maintenance of the Divestiture Assets including, but not limited to, any and all meetings or communications with the FDA; and
  - o. it will provide the Monitor with such other information, documents and the like requested by the Monitor in order to carry out its responsibilities under this Monitoring Agreement.
5. Respondent shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondent 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 Monitor, of such communications.
6. Respondent agrees that, to the extent authorized by the Orders, the Monitor shall have the option and authority to employ, at the expense of the Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information, and Intellectual Property, as defined in the Orders, related to the Divestiture Assets.
7. Respondent and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigate and/or audit the Respondent's compliance with the Respondent's 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 the Respondent's compliance with the Respondent's obligations to maintain or divest assets pursuant to the Orders.

Specifically, but not to limit the foregoing, the Monitor shall issue a written report to the Commission concerning Respondents' compliance with the Orders 30 days after the Order to Maintain Assets is issued, and every 90 days thereafter, and at such other times as may be requested by staff of the Commission.

8. The Monitor shall maintain the confidentiality of all non-public information provided to the Monitor by Respondent. Such information shall be used by the Monitor only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitor to any third party other than:
- a. persons engaged or employed by, or working with, the Monitor under this Monitor Agreement who agree to be bound by the confidentiality stipulations contained herein;

- b. the Acquirer to the extent that the information is of a non-privileged nature and relates to the Divestiture Assets; or
- c. persons employed at or by the Commission and working on this matter.
- d. A recipient who can demonstrate that such information was already known to the recipient at the time of receipt from a source other than the Monitor, Respondent, or any director, officer, employee, agent, consultant or affiliate of the Monitor or Respondent, when such source is entitled to make such disclosure to such recipient.

Notwithstanding anything herein to the contrary, Respondent shall use its best efforts to identify and/or label such information in writing they desire to treat as confidential and not to be disclosed to the Acquirer.

However, it is understood that to the extent that Respondent fails to so identify such confidential to the Monitor (a "Failure to Identify"), the Monitor shall not have liability for disclosure of same to the Acquirer, unless, notwithstanding a Failure to Identify by Respondent, the Monitor knew or should have known that information was privileged or not to be disclosed, and nonetheless discloses such information to the Acquirer.

- 9. The Monitor shall maintain a record and inform the Commission of all persons (other than representatives of the Commission) to whom confidential information related to this Agreement has been disclosed.
- 10. The Monitor shall enter into a non-disclosure or other confidentiality agreement with the Commission related to Commission materials and information received in connection with the performance of the Monitor's duties and require that each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants shall enter into a non-disclosure or other confidentiality agreement with the Commission;
- 11. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor shall, at the Respondent's request and expense, promptly return to Respondent all material provided to the Monitor by Respondent that is confidential to Respondent and shall destroy any material prepared by the Monitor that contains or reflects any confidential information of Respondents provided that the Monitor provides notice to the Commission staff and the Commission staff does not require the Monitor to maintain the materials; provided, however, notwithstanding the foregoing, the Monitor shall be entitled to retain for its records, on a confidential basis, any materials or documents developed by it in furtherance of its responsibilities and obligations under this Monitor Agreement, regardless of whether such materials contain confidential information. Nothing herein shall abrogate the Monitor's duty of confidentiality, including the obligation to keep such information confidential for a period of five (5) years after the termination of this Monitor Agreement. The Monitor shall provide Respondent with a copy of the list of parties to whom the Monitor has divulged Respondent's confidential and privileged information.
- 12. In addition and except as otherwise permitted in Section 10 above, the Monitor shall keep confidential for a period of five (5) years all other aspects of the performance of its duties under this Monitor Agreement and shall not disclose any confidential or proprietary

information relating thereto. To the extent that the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitor shall ensure that such persons execute an appropriate confidentiality agreement.

For the purpose of this Section, 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 Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known or became known to the recipient at the time of receipt from a source other than the Monitor, the Respondent or any director, officer, employee, agent, consultant or affiliate of Respondent when such source is entitled to make such disclosure to such recipient.

13. Nothing in this Monitor Agreement shall require Respondent to disclose any materials or information that is subject to a legally recognized privilege or that Respondent is prohibited from disclosing by reason of law or an agreement with a third party.
14. The Monitor shall serve as an independent third party and not as an employee or agent of the Respondents or of the Commission.
15. 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 Respondent.
16. Respondent will pay the Monitor in accordance with the fee schedule attached hereto as Confidential Appendix A for all time spent in the performance of the Monitor's duties including all monitoring activities related to the efforts of the Acquirer of the Divestiture Assets (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. Every six months such hourly rates should be reviewed and may be adjusted by agreement with Respondent.
  - a. In addition, Respondent will pay (i) all reasonable out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, which conform to the Respondent's expense policies in effect from time to time including any auto, train or air travel in the performance of the 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 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 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.
17. Respondent hereby confirms its obligation and agrees to indemnify the Monitor and hold the Monitor harmless in accordance with and to the extent required by the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Assets).  
  
Without in any way limiting the generality of the foregoing, Respondent shall indemnify the Monitor and any subcontractor and their respective consultants, agents, partners, principles, 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, expenses (including attorneys' fees and out of pocket costs) incurred in connection with the preparations for, or defense of any claim, whether or not resulting in any liability, that may arise out of or is connected with, a claim concerning the performance of the Monitor's duties and obligations under the Orders. except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the gross negligence or willful misconduct of the Monitor. This section shall survive the termination or expiration of this Agreement.
18. The Monitor's maximum liability to the Respondent 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 Monitor by Respondent, not to exceed one hundred fifty thousand dollars (\$150,000). IN NO CIRCUMSTANCES WHATSOEVER SHALL MONITOR BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES. The Monitor is not responsible for evaluating the legal or technical sufficiency of any documents, materials or actions of Respondent or the Acquirer under the Orders. The Monitor shall not incur any liability of any nature for the failure of Respondents, any Acquirer, or the Commission to perform any acts, or not perform any acts. This section shall survive the termination or expiration of this Agreement.
19. Respondent agrees that the Monitor and any subcontractor, consultants, agents, partners, principles, directors, officers, members, managers and employees will serve without bond or other security.
20. Respondent agrees that the Respondents' obligations to indemnify the Monitor and the Indemnified Parties extend to any agreement that is entered between the Monitor and any Acquirer and that relates to the Monitor's responsibilities under the Monitor Agreement or the Orders. This section shall survive the termination or expiration of this Agreement.
21. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondent shall be required, to notify the Acquirer with respect to this appointment as Monitor.

22. In the event that a disagreement or dispute between Respondent and the Monitor 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 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, but only if the individual in charge of the Commission's Compliance division determines within the Commission's reasonable discretion that such a matter is appropriate for submission to the American Arbitration Association. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Orders.
23. This agreement shall be subject to the substantive law of the Commonwealth of Pennsylvania (regardless of any other jurisdictions choice of law principles).
24. This Monitor Agreement shall terminate when the Monitor and Respondent have been notified by the Commission in writing that the Commission staff has determined that Respondents obligations to provide manufacturing and supply of Divestiture Products pursuant to this Order have expired or been terminated and files a final report or (2) at any other such time as determined by the Commission or its staff.. or (2) In all cases, the Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality and indemnity obligations of this Monitor Agreement shall survive its termination.
25. The Monitor shall notify staff of the Commission, in writing, no later than 5 days in advance of entering into any arrangement that creates a conflict of interest, or the appearance of a conflict of interest, including a financial, professional, or personal conflict. If the Monitor becomes aware of a such a conflict only after it has arisen, the Monitor shall notify the Commission as soon as the Monitor becomes aware of the conflict; The Monitor represents that it is aware of no such conflicts as of the Effective Date of this Agreement.
26. This 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.
27. This 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.
28. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by certified mail or electronic mail (with acknowledgement of receipt by the recipient of such electronic mail having been received), to the applicable party at its address below (orto such other address as to which such party shall hereafter notify the other party):

If to the Monitor, to:

Address: Denise Smart, Esq.  
President  
Smart Consulting Group, LLC

P.O. Box 884  
West Chester, PA 19382

Telephone: 610-344-9218  
Mobile Phone: 484-467-0707  
Email: [dsmart@smartconsultinggroup.com](mailto:dsmart@smartconsultinggroup.com)

If to Respondents, to:

Address: Nikhil Lalwani  
Chief Executive Officer and President  
ANI Pharmaceuticals, Inc.  
210 Main Street  
West Baudette, MN 56623

Telephone: 218-634-3500  
Email: [nikhil.lalwani@anipharmaceuticals.com](mailto:nikhil.lalwani@anipharmaceuticals.com)

If to the Commission, to:

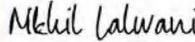
Address: Danielle Sims, Esq.  
Compliance Division  
Federal Trade Commission  
601 New Jersey Avenue, N.W.  
Washington, DC 20580

Telephone: 202-326-3241  
Email: [dsims1@ftc.gov](mailto:dsims1@ftc.gov)

This Monitor Agreement shall become binding upon execution, although it will be subject to approval by the Commission.

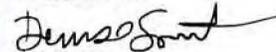
IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the date first above written.

ANI PHARMACEUTICALS, INC.

DocuSigned by:  
  
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Nikhil Lalwani  
Chief Executive Officer and President

SMART CONSULTING GROUP  
MONITOR

DocuSigned by:  
  
EFE07271D9FA43B...

Denise Smart  
President