STATE OF VERMONT
SECRETARY OF STATE
OFFICE OF PROFESSIONAL REGULATION
BOARD OF PHARMACY

IN RE:	)	
PHARMEDIUM SERVICES, LLC	)	**Docket No. 2019-** 135
Application Tracking No. LI-342692	)	

STIPULATION AND CONSENT ORDER

STIPULATION

NOW COME the State of Vermont, by and through State Prosecuting Attorney, Elizabeth A. St. James, and Applicant PharMEDium Services, LLC, who hereby stipulate and agree as follows:

Board Authority

1. The Vermont Board of Pharmacy (the "Board") has authority to deny an applicant's license if it finds that the applicant has engaged in unprofessional conduct in any jurisdiction. 3 V.S.A. § 129(a); 3 V.S.A. §129a; 26 V.S.A. § 2051; the Administrative Rules of the Board of Dental Examiners; and the Rules of the Office of Professional Regulation.

Stipulated Basis for Denial

Basis for Denial One: 3 V.S.A. § 129a(a)(3) Failing to comply with provisions of federal or State statutes or rules governing the practice of the profession, incorporating BOP 20.1(f) Any disciplinary action in any jurisdiction by a licensing authority regulating the practice of a health-related profession.

2. An Application for licensure as a 503B Outsourcer was submitted by PharMEDium Services, LLC of Dayton, New Jersey, Texas (the "Applicant") and was received by the Office of Professional Regulation on July 19, 2019 (the "Application").

3. In the Application, Applicant answered "Yes" to the question "Has Vermont or any other state, federal authority, or other jurisdiction taken any DISCIPLINARY ACTION against (e.g. warned, reprimanded, fined, restricted, suspended, revoked) a license, certificate, or registration that the business entity holds or has held in any profession or occupation?"

4. On May 22nd 2019, Applicant entered into a Consent Decree of Permanent Injunction with the United States Department of Justice, in the United States District Court for the Northern District of Illinois Eastern Division (the "Permanent Injunction"). *See* Attachment A.

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5. The Permanent Injunction is a result of allegations of misbranded and/or adulterated drugs entering interstate commerce.

6. As part of the Permanent Injunction, Applicant is required to hire an independent auditor to inspect Applicant, taking into account the Forms FDA 483 issued by the FDA since 2013. Such audits must commence no less frequently than once every twelve (12) months for a period of four (4) years. Additional conditions are outlined in the Permanent Injunction. *See* Attachment A.

7. Prior to the issuance of the Permanent Injunction, Boards of Pharmacy in South Carolina, Indiana, and Alabama issued discipline to Applicant based on the underlying conduct and concerns which lead to the Permanent Injunction. California issued a Cease and Desist order. Colorado issued a non-disciplinary Interim Cessation of Practice Agreement after the issuance of the Permanent Injunction.

Basis for Denial Two: 3 V.S.A. § 129a(b)(1) Failure to practice competently by reason of any cause on a single occasion or on multiple occasions may constitute unprofessional conduct, whether actual injury to a client, patient, or customer has occurred. Failure to practice competently includes: (1) performance of unsafe or unacceptable patient or client care.

8. The State re-alleges and incorporates Paragraphs 2 through 7 above.

9. Review of the underlying facts of the actions mentioned in Paragraphs 2 through 7 show that Applicant performed unsafe or unacceptable patient or client care.

10. The unprofessional conduct in Paragraphs 2 through 7 above, would constitute unprofessional conduct in Vermont. Pursuant to 3 V.S.A. §129(a)(5), the Board may discipline any licensee or refuse to license any person who has had a license application denied or license revoked, suspended, limited, conditioned or otherwise disciplined by a licensing agency in another jurisdiction for conduct which would constitute unprofessional conduct in this state, or has surrendered a license while under investigation for unprofessional conduct.

Understandings

11. Applicant admits the facts above are true and that the conditions below are necessary to protect the public.

12. Applicant understands that the Board must review and accept the terms of the Consent Order. If the Board rejects any portion, the entire Stipulation and Consent Order shall be null and void.

13. Applicant specifically waives any claims that any disclosures made to the Board during its review of this agreement have prejudiced Applicant's rights to a fair and impartial hearing in future hearings if this agreement is not accepted by the Board.

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14. Applicant has read and reviewed this entire document and agrees that it contains the entire agreement between the parties.

15. Applicant is not under the influence of any drugs or alcohol at the time of signature of this Stipulation and Consent Order.

16. Applicant voluntarily enters into this agreement after the opportunity to consult with legal counsel and is not being coerced by anyone into signing this Stipulation and Consent Order.

17. Applicant voluntarily waives the right to a contested hearing before the Board and waives any right to appeal from this Stipulation and Consent Order.

18. Applicant agrees that the Order set forth below may be entered by the Board.

ORDER

Based on the Stipulation above, it is **ORDERED AND ADJUDGED** as follows:

A. The Applicant's 503B Outsourcer license is hereby **CONDITIONED**, when issued. The conditions shall be as follows:

1. Issuance of License. Upon the commencement of these conditions, Applicant shall be issued a license labeled "conditioned."

2. Length of Time of Conditions Imposed. The conditions shall remain in place until Applicant has completed all conditions ordered. Applicant shall be subject to the conditions for a **MINIMUM OF FOUR (4) YEARS**.

3. Monitoring. The Office of Professional Regulation, through the Enforcement Case Manager, shall be responsible for monitoring Applicant's compliance with these Conditions. All reports or correspondence regarding compliance with these conditions shall be submitted to the Case Manager in accordance with the Conditions listed below.

4. Compliance with applicable laws and regulations. Applicant shall comply with all laws and regulations governing the operation of a 503B Outsourcer in the State of Vermont, to include compliance with federal cGMP regulations and FDA guidance documents as applicable to outsourcing facilities and/or any subsequent regulation that is designated as applying to outsourcing facilities.

5. FDA Form 483 reporting requirements. Applicant shall provide the Board with un-redacted copies of any FDA Form 483 observations within ten (10) days of receipt. Applicant shall further provide any response to such Form 483 observations to the Board within ten (10) days of sending the response to the FDA. Applicant shall further provide the Board with any Warning Letters received from the FDA within (10) days of receipt.

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6. Federal and/or state action reporting requirements. Applicant shall provide the Board with copies of any action taken by a federal or state regulatory agency within ten (10) days of receipt. This reporting requirement applies to any and all actions taken by federal or state regulatory agencies, whether or not said federal or state agency considers the action to be disciplinary in nature.

7. Recalls and/or seizures. Applicant shall report to the Board within five (5) days of any seizure of any product manufactured, produced, stored, maintained, held, distributed by, or otherwise in the possession of Applicant. Applicant shall further report to the Board notice of any recalls of sterile products, both voluntary and/or mandatory, within five (5) days of such recall. Such notice shall include whether any such recalled items were shipped into Vermont.

8. Quality Assurance Reports. Applicant shall submit **QUARTERLY** reports to the Board of its product quality assurance program, including but not limited to any out-of-compliance findings as determined by a relevant state or federal agency, recalls or adverse drug experiences associated or potentially associated with any and all of Applicant's drugs.

9. Notification of Place of Employment/Personal Address/Telephone Number. Within ten (10) days of the date of entry of this Consent Order Applicant shall provide, in writing, notification of Applicant's current contact information, including mailing address, telephone number, email address, and designated contact person for compliance with this Order. Applicant shall provide further notification, in writing, within forty-eight (48) hours of any change in mailing address, telephone number, email address, or designated contact person.

10. Notification to Other States. In the event that Applicant is licensed in any other state(s), Applicant must inform the licensing board of the state(s) in which Applicant is licensed of the conditional status of Applicant's Vermont 503B Outsourcer license within thirty (30) days of the date of entry of this Order.

11. Interview with the Board or its Designee. Applicant shall appear in person for interviews with the Board or its designee upon request.

12. License Renewal. This Order does not automatically extend the license and Applicant must comply with the requirements for license renewal.

13. Costs. Applicant shall bear all costs of complying with this Consent Order.

14. Violation of this Order. If Applicant violates this Order, the Board, after giving Applicant notice and an opportunity to be heard, may rescind or modify this Order and impose additional appropriate disciplinary actions. If a complaint of unprofessional conduct is made against Applicant during the duration of this Order, this Order shall be automatically extended until the unprofessional conduct matter is concluded.

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15. Completion of Conditional License Period. Applicant shall submit a petition to the Docket Clerk to remove any and all conditions on Applicant's license. The State will assent to or oppose Applicant's petition. The Board will conduct a hearing if necessary. Applicant bears the burden and must present proof that Applicant has fully complied with the terms of this Order and the Conditions are no longer necessary to protect the public.

B. Notwithstanding any provision above, the Applicant must continue to meet all requirements for maintaining a license, license renewal and license reinstatement.

C. This Stipulation and Consent Order is a matter of public record and may be reported to other licensing authorities as provided in 3 V.S.A. §129(a).

D. This Stipulation and Consent Order will remain part of Applicant's licensing file and may be used for purposes of determining sanctions in any future disciplinary matter.

AGREED TO:

STATE OF VERMONT
SECRETARY OF STATE

Dated: 8/27/19

By: Elizabeth A. St. James
Elizabeth A. St. James
State Prosecuting Attorney
Elizabeth.st.james@sec.state.vt.us
(802) 828-1218

PHARMEDIUM SERVICES, LLC
APPLICANT

Dated: 8/27/2019

By: _____
Designated Agent
PharMEDium Services, LLC

APPROVED AND SO ORDERED:

Dated: 8/28/'18

By: _____
Board Chair

Date of Entry: 8.29.19

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
v.	)	Civil Action No. 19 C 3382
PHARMEDIUM SERVICES, LLC, a limited liability company, and SCOTT ALADEEN and WARREN HORTON, individuals,	)	
Defendants.	)	

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Defendants, PharMedium Services, LLC ("PharMEDium"), a limited liability company, and Scott Aladeen (who was hired by PharMEDium, and assumed the position of President on January 28, 2019, after the activities alleged in the complaint had occurred) and Warren Horton (who was hired by PharMEDium, and assumed the position of Vice President for Quality and Research & Development on April 15, 2019, after the activities alleged in the complaint had occurred), individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

ATTACHMENT A

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1).

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355, nor exempt from approval.

6. For the purposes of this Decree, the following definitions shall apply:

A. "Additional Facilities" refers to Defendants' Texas and New Jersey Facilities, as defined in paragraph 6.E. Defendants have represented to FDA and now represent to this Court that the Mississippi Facility, as defined in paragraph 6.E., ceased manufacturing drugs on April 17, 2019, and will cease holding and distributing drugs by May 24, 2019. Sixty (60) days before Defendants manufacture, hold, and/or distribute drugs at and/or from the Mississippi Facility or any facility owned or operated by Defendant PharMEDium, other than the facilities included in

the definition of Defendants' Facilities in paragraph 6.E., Defendants shall notify FDA in writing at the physical and electronic addresses specified in paragraph 28 of their intent to manufacture, hold, and/or distribute drugs. If Defendants manufacture, hold, and/or distribute drugs at and/or from the Mississippi Facility, the Mississippi Facility shall thereafter be included in the definition of Additional Facilities and be fully subject to the provisions of the Decree. If FDA inspects any facility owned and/or operated by Defendant PharMEDium and finds a violation of the Act and/or its implementing regulations, FDA may order that such facility or facilities shall thereafter be fully subject to the provisions of this Decree as though the facility or facilities were included in Defendants' Facilities in paragraph 6.E. and included as an Additional Facility in this paragraph when the Decree was entered;

B. "CGMP" shall refer to the current good manufacturing practice requirements for drugs within the meaning of 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211, as described in related guidance, if any, and/or any subsequent regulation that is designated as applying to outsourcing facilities;

C. "Compound" and "compounding" shall include the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug as defined in 21 U.S.C. § 353b(d)(1);

D. "Days" shall refer to calendar days unless otherwise stated;

E. "Defendants' Facilities" shall refer to the facilities located at: (1) Two Conway Park, 150 North Field Drive, Suite 350, Lake Forest, Illinois 60045 ("PharMEDium Corporate Headquarters"); (2) 6100 Global Drive, Memphis, Tennessee 38141 ("Tennessee Facility"); (3) 913 North Davis Avenue, Cleveland, Mississippi 38732 ("Mississippi Facility"); (4) 12620 West

Airport Boulevard, Suite 130, Sugar Land, Texas 77478 ("Texas Facility"); and (5) 36 Stults Road, Dayton, New Jersey 08810 ("New Jersey Facility");

F. "Distribution" and "distributing" shall mean to sell, trade, ship, or deliver and shall include, but not be limited to, delivery or shipment to a healthcare setting for administration and dispensing to a patient or to an agent of a patient;

G. "Drug" shall have the meaning given the term in 21 U.S.C. § 321(g)(1);

H. "Drug product" shall mean a finished dosage form (for example, tablet, capsule, or solution) that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients;

I. "FDA" shall mean the United States Food and Drug Administration;

J. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repacking, holding, and labeling drugs;

K. "New drug" shall have the meaning as set out in 21 U.S.C. § 321(p);

L. "Serious adverse drug experience" shall have the meaning given the term in 21 C.F.R. § 310.305(b); and

M. "Sterile drug" shall have the meaning as set out in 21 U.S.C. § 353b(d)(5).

Tennessee Facility

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly manufacturing,

holding, and/or distributing any drugs manufactured at and/or from the Tennessee Facility, unless and until:

A. Defendants ensure that the facilities, methods, and controls used to manufacture, hold, and/or distribute drugs at or from the Tennessee Facility are established, operated, and administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming: adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B); new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval; and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Defendants ensure that each drug that Defendants intend to manufacture, hold, and/or distribute at or from the Tennessee Facility (except for FDA-approved drug products manufactured by third parties that Defendants receive and hold prior to manipulation) satisfies all of the provisions of 21 U.S.C. § 353b, including but not limited to:

(1) Drug labeling at 21 U.S.C. § 353b(a)(10);

(2) Facility registration at 21 U.S.C. § 353b(b)(1);

(3) Drug reporting at 21 U.S.C. § 353b(b)(2); and

(4) Adverse event reporting at 21 U.S.C. § 353b(b)(5);

C. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert") who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this Decree or a retention agreement to provide CGMP consultant and/or expert services prior to entry of this Decree) to Defendants or their families; and (2) by reason of background, training, education, or experience, is qualified to (i) conduct inspections to determine whether the facilities, methods, and controls at the Tennessee Facility

and PharMEDium Corporate Headquarters are established, operated, and administered in conformity with CGMP and adequate to prevent Defendants from manufacturing, holding, and/or distributing drug products that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), and (ii) recommend and direct the implementation of corrective actions;

D. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within twenty (20) days after retaining the expert;

E. Defendants submit a protocol that identifies the work plan for the CGMP Expert and the methodology that shall be used by the CGMP Expert (the "Work Plan") to: (1) conduct inspections of the Tennessee Facility and PharMEDium Corporate Headquarters as described in paragraph 7.F.; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' procedures for manufacturing, holding, and/or distributing drugs are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). Defendants shall not implement the Work Plan prior to receiving FDA's written approval, and in no circumstances shall FDA's silence be construed as a substitute for written approval. FDA will review and provide a written response regarding the Work Plan as soon as practicable. If FDA disapproves the Work Plan, FDA shall state the reason(s) for such disapproval in writing;

F. The CGMP Expert reviews all observations listed on the Forms FDA 483 issued by FDA since 2013 for the Tennessee Facility and PharMEDium Corporate Headquarters and

performs comprehensive inspections of the facilities, methods, and controls at the Tennessee Facility and PharMEDium Corporate Headquarters to determine whether the facilities, methods, and controls are, at a minimum, operated in conformity with CGMP and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). The CGMP Expert shall evaluate, at the Tennessee Facility and to the extent applicable at PharMEDium Corporate Headquarters, at a minimum, whether:

(1) Defendants have cleaned, sanitized, and satisfactorily maintained the facility, including the equipment and utensils, as necessary to effectively address the risks associated with aseptic processing, at appropriate intervals to ensure the safety, identity, strength, quality, and purity of Defendants' drugs;

(2) Defendants have established and implemented an adequate written cleaning and disinfection program that they have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture drugs;

(3) Defendants have established and implemented an adequate environmental monitoring program to: (a) ensure that all sterile and/or aseptic operations are properly monitored (including surfaces and air quality); (b) include scientifically sound pre-established limits; and (c) ensure that Defendants identify, review, and address any results that exceed the pre-established limits and any adverse trends;

(4) Defendants have established and implemented adequate written procedures designed to prevent microbiological contamination of drug products purporting to be

sterile including, but not limited to, procedures for dynamic smoke studies, media fill simulations, environmental monitoring, and validation of all aseptic and sterilization processes;

(5) Defendants have established adequate control systems necessary to prevent contamination during aseptic processing including, but not limited to, an air supply filtered through high-efficiency particulate air (HEPA) filters under positive pressure;

(6) Defendants have established and implemented adequate written standard operating procedures ("SOPs") for manufacturing, holding, and distributing sterile drugs;

(7) Defendants have established and implemented written procedures to ensure that Defendants' drug products have the strength, purity, and quality they purport to or are represented to possess;

(8) Defendants conform to written procedures for production and process control designed to ensure that Defendants' drug products have the identity, strength, quality, and purity they purport or are represented to possess, and that any deviation from the written procedures are recorded and justified;

(9) Defendants have established and implemented a written program designed to ensure that any automatic, mechanical, or electronic equipment used in the manufacturing or holding of a drug product is routinely calibrated, qualified for intended use, inspected, or checked to ensure proper performance, and that written records of those calibration checks and inspections are maintained;

(10) Defendants have established and implemented an adequate testing program designed to assess sterility, the presence of endotoxin, and the stability characteristics and strength of their drug products;

(11) Defendants have established and implemented written procedures to ensure that they: (a) thoroughly investigate any unexplained discrepancy or the failure of a batch of drug product, whether or not the batch has already been distributed, or any of its components, to meet any of the product's or component's specifications, including the extension of such investigation to other batches of the same product and other products that may have been associated with the specific failure or discrepancy; (b) take required and timely corrective actions for all products that fail to meet specifications; and (c) document in a timely manner investigations and any corrective actions and retain such documentation, as appropriate;

(12) Defendants have established and implemented container closure systems that are clean, and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties (depyrogenation) using a validated method to ensure they are suitable for their intended use;

(13) Defendants ensure that the equipment used in the manufacture and/or holding of their drugs is appropriately designed to facilitate cleaning, sanitization, and maintenance and Defendants have shown through valid scientific evidence that such equipment is adequate for its intended use;

(14) Defendants' employee training and qualification practices are adequate including, but not limited to, employee training and qualification in CGMP, inspection techniques, aseptic techniques, media fill processes, and procedures for responding to product quality deviations;

(15) Defendants ensure that their finished drug products are properly labeled and meet all the requirements of 21 U.S.C. § 353b(a)(10); and

(16) Defendants ensure that their quality control unit has adequate responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, and drug product labeling; review and fully investigate any errors that may occur; and initiate and complete thorough investigations;

G. The CGMP Expert certifies in writing to FDA and Defendants that:

(1) The CGMP Expert has inspected the facilities, methods, and controls at the Tennessee Facility and PharMEDium Corporate Headquarters as described in paragraph 7.F.;

(2) All deviations brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and

(3) The facilities, methods, and controls at the Tennessee Facility and PharMEDium Corporate Headquarters comply with this Decree, the Act, and its implementing regulations, including that the facilities, methods, and controls are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1).

As part of this certification, Defendants shall ensure that the CGMP Expert includes a detailed and complete report of the results of the inspections conducted under paragraph 7.F.;

H. Defendants report to FDA in writing the actions they have taken to:

(1) Correct all insanitary conditions and deviations from CGMP brought to Defendants' attention by FDA, the CGMP Expert, or any other source; and

(2) Ensure that the facilities, methods, and controls at the Tennessee Facility and PharMEDium Corporate Headquarters are established, operated, and administered in conformity with this Decree, the Act, and its implementing regulations;

I. Defendants establish and maintain a system to report to FDA, through the MedWatch reporting system, adverse drug experiences (in the manner described in 21 C.F.R. § 310.305) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after Defendants' initial receipt of reportable adverse event information;

J. Defendants establish and maintain a system to submit to FDA, at the physical and electronic addresses specified in paragraph 28, product quality reports (in the manner and as described in paragraph 20);

K. FDA representatives, without prior notice and when FDA deems necessary, inspect the Tennessee Facility and PharMEDium Corporate Headquarters, which shall include, but not be limited to, observing the preparation for and production of test or validation batches of drug products intended to be sterile (which may not be distributed unless FDA subsequently authorizes distribution in writing) and, without prior notice, take any other action to determine whether the facilities, methods, and controls at the Tennessee Facility and PharMEDium Corporate Headquarters comply with this Decree, the Act, and its implementing regulations, including whether the facilities, methods, and controls are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

L. FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 7.A.–7.J. of this Decree. FDA will notify Defendants as soon as practicable. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. After Defendants have complied with paragraph 7, and received written notification from FDA under paragraph 7.L., Defendants shall retain an independent person who meets the criteria described in paragraph 7.C. and who is qualified to assess Defendants' compliance with paragraph 7 (the "Auditor") to conduct audit inspections of the Tennessee Facility and PharMEDium Corporate Headquarters. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor within twenty (20) days of retaining such Auditor. After Defendants receive written notification from FDA under paragraph 7.L., audit inspections for the Tennessee Facility and PharMEDium Corporate Headquarters shall commence no less frequently than once every six (6) months for a period of one (1) year, and then annually for the next four (4) years. The Auditor may be the same person(s) as the CGMP Expert described in paragraph 7.

A. At the conclusion of each audit inspection described in this paragraph and paragraph 10, the Auditor shall prepare a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The Audit Report shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, the Auditor shall also assess the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, if any, and any Form FDA 483 observations and include this information in the Audit Report. The Audit Report and any supporting

documentation shall be delivered contemporaneously to Defendants and FDA no later than thirty (30) days after the date each audit inspection is completed. In addition, Defendants shall maintain all Audit Reports in a separate file at the associated facility and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any audit report observations, Defendants shall, within thirty (30) days after receipt of the Audit Report, correct those deviations, unless FDA notifies Defendants in writing that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than thirty (30) days, Defendants shall, within fifteen (15) business days after receipt of the Audit Report, propose a schedule for completing corrections. Defendants shall complete all corrections according to the approved correction schedule unless FDA notifies Defendants in writing that a shorter time period is necessary. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule, the Auditor shall initiate review of the actions taken by Defendants to correct the audit report observations. Within fifteen (15) days after beginning that review, Defendants shall ensure that the Auditor reports in writing with supporting documentation to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

9. Within thirty (30) days from the entry of this Decree, Defendants shall, under FDA's supervision, destroy any remaining in-process and finished drug products intended for distribution that were manufactured or held at the Tennessee Facility and are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 19. Defendants shall be responsible for

ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state laws.

Additional Facilities

10. Within thirty (30) days from the date of entry of this Decree, Defendants shall retain, at Defendants' expense, an independent person or persons (the "Additional Facilities Auditor"), which may be the same person or persons retained under paragraphs 7 or 8.

A. The Additional Facilities Auditor: (1) must not have any personal or financial ties (other than a retention agreement to satisfy the requirements of this Decree or a retention agreement to provide CGMP consultant and/or expert service prior to entry of this Decree) to Defendants or their families; and (2) by reason of background, training, education, or experience, must be qualified to (i) conduct audit inspections to determine whether the facilities, methods, and controls at the Additional Facilities are established, operated, and administered in conformity with CGMP and adequate to prevent Defendants from manufacturing, holding, and/or distributing drug products that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), and (ii) recommend and direct the implementation of corrective actions.

B. Defendants shall notify FDA in writing of the identity and qualifications of the Additional Facilities Auditor as soon as they retain such auditor.

C. Within sixty (60) days from the date of entry of this Decree, the Additional Facilities Auditor shall review all observations listed on the Forms FDA 483 issued by FDA since 2013 for the Additional Facilities and commence audit inspections of the facilities, methods, and controls at the Additional Facilities to determine whether the facilities, methods,

and controls are, at a minimum, operated in conformity with CGMP and are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1). The Additional Facilities Auditor shall evaluate, at a minimum, the items listed in paragraphs 7.F.1.–7.F.16.

D. After Defendants commence the audit inspections required under paragraph 10.C., audit inspections of the Additional Facilities shall commence no less frequently than once every twelve (12) months for a period of four (4) years.

E. The requirements in paragraphs 8.A. and 8.B. shall apply to the audit inspections conducted by the Additional Facilities Auditor pursuant to this paragraph.

11. FDA representatives, without prior notice and when FDA deems necessary, may inspect the Additional Facilities, which shall include, but not be limited to, observing the preparation for and production of drug products intended to be sterile, and, without prior notice, take any other action to determine whether the facilities, methods, and controls used to manufacture, hold, and/or distribute drugs comply with this Decree, the Act, and its implementing regulations, including whether the facilities, methods, and controls are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval, and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

12. If FDA determines that any of the Additional Facilities is not operating in compliance with this Decree, the Act, or its implementing regulations, FDA will notify Defendants of the noncompliance and, as it deems necessary, order Defendants to take appropriate corrective action

including, but not limited to, action pursuant to paragraph 16 and/or assessing liquidated damages pursuant to paragraph 25.

13. Within three (3) days from entry of this Decree, Defendants' Additional Facilities shall establish and maintain a system to report to FDA through the MedWatch reporting system adverse drug experiences (in the manner described in 21 C.F.R. § 310.305) associated or potentially associated with any and all of Defendants' drugs as soon as possible, but no later than fifteen (15) days after Defendants' initial receipt of reportable adverse event information.

14. Within three (3) days from entry of this Decree, Defendants' Additional Facilities shall establish and maintain a system to submit to FDA, at the physical and electronic addresses specified in paragraph 28, product quality reports (in the manner and as described in paragraph 20).

General Provisions

15. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them, who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B) and/or misbranded within the meaning

of 21 U.S.C. § 352(f)(1), while such drug is held for sale after shipment of one or more of its components in interstate commerce;

C. Violates 21 U.S.C. § 331(d) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction into interstate commerce, any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval; and/or

D. Any act that results in the failure to implement and continuously maintain the requirements of this Decree.

16. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the CGMP Expert, the Auditor, and/or the Additional Facilities Auditor, or any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act, its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease all manufacturing, holding, and/or distribution of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. Defendants shall initiate the recall(s) within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall bear the costs of such recall(s), including the costs of FDA's supervision at the rates specified in paragraph 19;

C. Destroy, under FDA supervision, specified finished and/or in-process drugs and components that are in Defendants' possession, custody, or control. Defendants shall bear the

costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 19. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law;

D. Submit additional reports or information to FDA;

E. Repeat, revise, modify, or expand any report(s) or plan(s) prepared pursuant to this Decree;

F. Issue a safety alert with respect to a drug manufactured, held, and/or distributed by Defendants; and/or

G. Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act and/or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

17. The following process and procedures shall apply in the event that FDA issues an order under paragraph 16.

A. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the

basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 26.

D. The process and procedures set forth in paragraphs 17.A.–17.C. shall not apply to any order issued pursuant to paragraph 16 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 26.

Any cessation of operations or other action described in paragraph 16 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume

operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. In no circumstance shall FDA's silence be construed as a substitute for written notification. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 16 shall be borne by Defendants at the rates specified in paragraph 19. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

18. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' Facilities, collect samples, and, without prior notice, take any other measures necessary including but not limited to, observing routine production, to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to Defendants' Facilities including, but not limited to, all buildings, equipment, in-process or unfinished and finished materials and products, containers, labeling, and other promotional material therein; to take photographs and make video recordings; to take samples, without charge to FDA, of finished and unfinished materials and products, containers and packaging material therein, labeling, and other promotional material; and to examine and copy all records relating to the receipt, manufacturing, holding, and/or distribution of any and all drugs and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

19. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $97.57 per hour and fraction thereof per representative for inspection work; $132.89 per hour or fraction thereof per representative for analytical or review work; $0.58 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

20. Within three (3) business days after becoming aware of any of the following information pertaining to Defendants' distributed drug products, Defendants shall submit to FDA at the physical and electronic addresses specified in paragraph 28, a product quality report pertaining to any:

A. Product and/or manufacturing defects that could result in serious adverse drug experiences;

B. Incidents that cause a drug product or its labeling to be mistaken for, or applied to, another article;

C. Bacteriological or fungal contamination, or any significant chemical, physical, or other change or deterioration in a distributed drug product, or any failure of one or more distributed batches of a drug product to meet its release specifications.

21. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas at Defendants' Facilities, and publish the Decree on any internal and/or publicly-available website maintained and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted as described herein for not less than twenty-four (24) months.

22. Within fifteen (15) business days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service, personal delivery via electronic mail with acknowledgment of receipt (return receipt email), or certified mail (restricted delivery, return receipt requested), to each and all of their directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (collectively referred to as "Associated Persons"). Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph, and attaching a copy of the return receipts. Thereafter, within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

23. In the event that Defendants become associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants immediately shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Every six (6) months, Defendants shall provide to FDA an affidavit

stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) business days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

24. Defendants shall notify FDA at least fifteen (15) business days before any change in ownership, character, or name of any of Defendants' businesses, including incorporation, reorganization, relocation, bankruptcy, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure, responsibility of any individual defendant, or identity of PharMEDium, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) business days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to any such assignment, change of responsibility of any individual defendant, or change in ownership.

25. If any Defendant fails to comply with any provision of this Decree, the Act, and/or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: fifteen thousand dollars ($15,000) in liquidated damages for each day such violation continues; an additional sum of fifteen thousand dollars ($15,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drug products that have been manufactured and/or distributed in violation of this

Decree, the Act, and/or its implementing regulations. The amount of liquidated damages imposed under this paragraph shall not exceed twenty million dollars ($20,000,000) in any one calendar year. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

26. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time of the decision. No discovery shall be taken by either party.

27. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, court costs, and any other costs or fees incurred by the United States in bringing such an action.

28. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," and shall be addressed to the Director, FDA, ORA/OPQO - Pharm 3 Division of Pharmaceutical Quality Operations, 550 W. Jackson Blvd. #1500, Chicago, IL 60661 and electronically to ORAPHARM3_RESPONSES@fda.hhs.gov, ORAPHARM2_RESPONSES@fda.hhs.gov, and ORAPHARM1_RESPONSES@fda.hhs.gov.

29. If any individual Defendant will no longer be employed by Defendant PharMEDium or otherwise act for Defendant PharMEDium ("Separating Individual Defendant"), then not more

than ten (10) days after the Separating Individual Defendant separates from Defendant PharMEDium, Defendant PharMEDium shall notify FDA in writing at the physical and electronic addresses specified in paragraph 28. The notification to FDA shall include (1) the identity of the Separating Individual Defendant and (2) the identity and nature of employment of an individual of similar position and responsibilities that Defendant PharMEDium will substitute as an individual Defendant ("Substitute Individual Defendant"). Once a Separating Individual Defendant ceases to be employed by Defendant PharMEDium or otherwise act for Defendant PharMEDium, Defendant PharMEDium shall petition the Court to formally remove the Separating Individual Defendant's name from the caption of this Decree and add the Substitute Individual Defendant. The United States will not oppose such a motion, so long as FDA has (1) sufficient evidence or information that the Separating Individual Defendant is no longer directly or indirectly working for or with, or in any way influencing, Defendant PharMEDium and (2) sufficient information about the Substitute Individual Defendant and the position and level of responsibilities he or she holds. Any Substitute Individual Defendants added to this Decree shall be bound by the Decree in the same manner as the individual Defendants originally named in the Decree. A Separating Individual Defendant removed from the caption of this Decree shall not be subject to the terms of this Decree. Notwithstanding this paragraph, a Separating Individual Defendant shall continue to be liable for such individual Defendant's acts and failures to act under this Decree prior to the time such individual ceased to be employed by or act on behalf of Defendant PharMEDium.

30. If any deadline in this Decree falls on a weekend or federal holiday, the deadline is continued to the next business day.

31. No sooner than sixty (60) months after entry of this Decree, Defendants may petition this Court for full relief from this Decree or for specific relief from this Decree with regard to one or more of Defendants' Facilities. If, at the time of the petition, Defendants have satisfied all of their obligations under this Decree with respect to the specific facilities for which Defendants are seeking relief and, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least sixty (60) months, the United States will not oppose the petition, and Defendants may request the Court to grant such relief.

32. Defendants may at any time petition FDA in writing to extend any deadline provided for herein, and FDA may grant such extension without seeking leave of Court. However, any such petitions shall not become effective or stay the imposition of any payments under this Decree unless granted by FDA in writing.

33. This Court retains jurisdiction of this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this 22 day of May, 2019.

UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants:

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Individually and on behalf of PHARMEDIUM SERVICES, LLC

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Individually

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