UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. **Case No: 8:21-cv-2151-MSS-JSS**

PREMIER PHARMACY LABS, INC., a corporation, and VERN A. ALLEN, an individual,

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, Premier Pharmacy Labs, Inc. ("Premier"), a corporation, and Vern A. Allen, an individual (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;

Based solely on the Parties' stipulation, 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.

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. §§ 301–399i ("Act").

3. The Complaint alleges that Defendants violated 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), in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

4. The Complaint alleges that Defendants violated 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)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

5. The Complaint alleges that Defendants violated 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 drugs that are

misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling does not bear adequate directions for use.

6. The Complaint alleges that Defendants violated 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 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while the drugs are held for sale after shipment of one or more of their components in interstate commerce.

7. The Complaint alleges that Defendants violated 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.

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

A. "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;

B. "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;

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

D. "Defendants' facility" shall refer to the facility located at 8265 Commercial Way, Weeki Wachee, Florida 34613, and any other location(s) (including any new locations) at or from which, at any time in the future, any Defendant, directly or indirectly, manufactures, holds, and/or distributes drugs, whether or not any Defendant has an ownership interest in the business, except that "Defendants' facility" shall not refer to any facility at which any Defendant manufactures, holds, and/or distributes drug products provided that the facility manufactures, holds, and/or distributes only drug products for which the facility is specified in an application(s) approved pursuant to 21 U.S.C. § 355, or an approved supplement(s) thereto, as the manufacturer of the drug product;

E. "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;

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

G. "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;

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

I. The terms "manufacture," "manufactured," and "manufacturing" shall include manufacturing, compounding, processing, packing, repackaging, and labeling drugs;

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

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

9. Defendants represent that: (a) they discontinued all operations related to the compounding of drugs at, or distribution of compounded drugs from, the facility located at 8265 Commercial Way, Weeki Wachee, Florida 34613 in or about June 2019; (b) Defendant Premier has not been registered as an outsourcing facility since December 2019; (c) the Defendants do not hold licenses necessary for operating as a pharmacy; and (d) the Defendants are not engaged in any compounding and have no intention to compound drugs in the future.

10. 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 Defendants' facility, unless and until:

A. Defendants ensure that the facility, methods, and controls used to

manufacture, hold, and/or distribute drugs 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);

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Drug Compliance Expert") who: (1) is without any personal or financial ties (other than a retention agreement to satisfy the requirements of this Decree) to Defendants or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are adequate to prevent Defendants from manufacturing, holding, or distributing drug products that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), and to recommend the implementation of corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the Drug Compliance Expert within twenty (20) days after retaining any such Drug Compliance Expert;

C. The Drug Compliance Expert performs comprehensive inspection(s) of Defendants' facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs to determine whether Defendants' facility, equipment, processes, and procedures are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). Pursuant to this paragraph, the Drug Compliance Expert should assess Defendants'

compliance with the Act and its implementing regulations, including, but not limited to, whether:

(i) Defendants have established adequate control systems necessary to prevent contamination during aseptic processing including, but not limited to, adequate air supply and/or airflow in the ISO classified areas for continuous removal or filtering of particles and contaminants from lesser quality air filtered through high-efficiency particulate air (HEPA) filters;

(ii) Defendants have established adequate facility design and operation in a way that prevents the influx of lesser quality air into a higher quality air area;

(iii) Defendants have adequate smoke studies of ISO 5 areas to visualize airflow patterns under operational conditions;

(iv) Defendants establish and follow adequate media fill studies to closely simulate aseptic production operations under the worst-case, most challenging and stressful conditions;

(v) Defendants establish adequate aseptic technique while producing drug products intended to be sterile, including, but not limited to, preventing exposure of sterile drugs and materials to lower than ISO 5 quality air;

(vi) Defendants ensure that aseptic processing is performed only in areas containing smooth and non-porous surfaces that are easily cleanable;

(vii) Defendants ensure that aseptic processing occurs under adequate humidity specifications in classified production areas;

(viii) Defendants properly clean and disinfect rooms, surfaces, and equipment used to produce sterile drug products, including, but not limited to the use of sterile wipes and sporicidal agents at appropriate intervals to prevent contamination of the Defendants' drugs;

(ix) Defendants ensure that aseptic processing areas provide adequate controls to prevent contamination, including, but not limited to, frequent measurement of pressure differentials during operations to demonstrate proper airflow (i.e., airflow from areas of higher quality air to adjacent areas with lower quality air); and,

(x) Defendants adequately contain or segregate highly potent drug operations so as to prevent cross-contamination of drug products.

D. The Drug Compliance Expert certifies in writing to FDA and Defendants that: (1) the Drug Compliance Expert has inspected Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs as described in paragraph 10.C.; and (2) Defendants have undertaken corrective actions to ensure that their facility, equipment, processes, and procedures are adequate to prevent drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). As part of this certification, Defendants shall ensure that the Drug Compliance Expert includes a detailed and complete written report of the results, including any supporting documentation, of the inspection(s) conducted under paragraph 10.C.;

E. Defendants establish and maintain a system to report to FDA all adverse drug experiences (in the manner described in 21 C.F.R. §§ 310.305 and/or

314.80) 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 the information;

F. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 30, Field Alert Reports (in the manner described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days from Defendants' initial receipt of the information triggering the Field Alert Report;

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

(i) Correct all insanitary conditions brought to Defendants' attention by FDA, the Drug Compliance Expert, or any other source; and

(ii) Ensure that Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute Defendants' drugs are established, operated, and administered in conformity with the Act and its implementing regulations;

H. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs comply with this Decree, the Act, and its implementing regulations, including whether Defendants' facility, 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

I. FDA notifies Defendants in writing that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 10.A.–10.H. of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

REQUIREMENTS APPLICABLE IF DEFENDANTS INTEND TO COMPOUND DRUGS AT DEFENDANTS' FACILITY UNDER 21 U.S.C. § 353A

11. 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 compounding any drug unless such drug is compounded in compliance with 21 U.S.C. § 353a and applicable regulations, including, but not limited to, the following:

A. The drug product shall:

(i) Be compounded for an identified individual patient either: (a) based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient; or (b) before the receipt of a valid prescription order for an individual patient, provided that the compounding is performed only in limited quantities and based on a history of receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an

established relationship between Defendant and either (i) the individual patient for whom the prescription order will be provided, or (ii) the physician or other licensed practitioner who will write such prescription order; and

(ii) Not be distributed by Defendants prior to receipt of a valid prescription order for the identified patient;

B. Defendants shall compound the drug product using only approved drug products or bulk drug substances that meet the conditions in 21 U.S.C. §§ 353a(b)(1)(A)(i), (ii), and (iii), and/or other ingredients that meet the conditions in 21 U.S.C. § 353a(b)(1)(B);

C. Defendants shall not compound regularly or in inordinate amounts any drug product that is essentially a copy of a commercially available drug product, as defined in 21 U.S.C. § 353a(b)(2);

D. Defendants shall not compound a drug product that appears on any existing or future list published by FDA in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective;

E. Defendants shall not compound any drug product that is identified by FDA by current existing or future regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of the drug product;

F. Defendants shall compound drug products in conformance with 21 U.S.C. § 353a(b)(3)(B), after FDA finalizes a memorandum of understanding and

makes it available to the states for their consideration and signature and after the time period FDA allows for states to consider whether to sign the memorandum of understanding; and

G. Defendants shall compound drug products in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding, including but not limited to USP <797>, USP <795>, and any other current or future chapters of the USP that are applicable to compounding drugs. Nothing in this paragraph modifies or relieves Defendants from any obligation to comply with any state statute or regulation.

REQUIREMENTS APPLICABLE IF DEFENDANTS INTEND TO COMPOUND DRUGS AT DEFENDANTS' FACILITY UNDER 21 U.S.C. § 353B

12. Notwithstanding paragraph 11, at any time following receipt of the notification pursuant to paragraph 10.I, Defendants may elect to register Defendants' facility as an outsourcing facility under 21 U.S.C. § 353b, and compound drugs for human use that are made in compliance with all of the requirements in 21 U.S.C. § 353b. Prior to compounding any drug for human use in an outsourcing facility:

A. Defendants shall notify FDA in writing of their intent to register and operate Defendants' facility as an outsourcing facility;

B. Defendants shall ensure that each and every drug that Defendants intend to manufacture, hold, and/or distribute at or from their facility satisfies all of the provisions of 21 U.S.C. § 353b, including but not limited to:

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

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

(iii) Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

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

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

C. Defendants shall ensure that the facilities, methods, and controls used to manufacture, process, pack, and/or hold Defendants' drug products are established, operated, and administered in conformity with CGMP;

D. Defendants shall 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 provision) to Defendants or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are established, operated, and administered in conformity with CGMP, and to recommend corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within twenty (20) days after retaining any such CGMP Expert;

E. Defendants shall 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 inspection(s) of Defendants' facility as described in paragraph 12.F.; (2) ensure that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacturing, processing, packing, and/or holding of drugs will be continuously administered in conformity with CGMP.

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;

F. The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants since 2014 and performs a comprehensive inspection(s) of Defendants' facility and the methods and controls used to manufacture, process, pack, and/or hold drugs to determine whether Defendants' facility, methods, and controls are in conformity with CGMP. The CGMP Expert shall evaluate, at a minimum, whether:

(i) Defendants have conducted adequate investigations into discrepancies that may impact the safety, identity, strength, quality, and purity of Defendants' drug products;

(ii) Defendants have ensured that their Quality Control Unit conducts adequate oversight and fulfills its responsibilities under 21 C.F.R. § 211.22(d), including, but not limited to, approval of each batch of drug product before it is released, the establishment and implementation of an adequate supplier qualification program, the establishment and implementation of adequate specifications for air velocity in the clean areas, and review of certification reports and/or studies pertaining to ISO5 classified areas;

(iii) Defendants have established and implemented procedures and specifications for adequate finished product testing of sterile products, including, but not limited to, sterility testing, endotoxin testing, and visual checks for particles;

(iv) Defendants ensure that aseptic processing areas provide adequate conditions to prevent contamination, including by establishing a system for monitoring environmental conditions that includes continuous monitoring of differential pressures between classified rooms or between classified and unclassified areas, and adequate monitoring of non-viable particle counts in ISO 7 cleanrooms;

(v) Defendants establish, implement, and follow adequate laboratory controls including, but not limited to, the size of samples used for testing;

(vi) Defendants complete stability studies for all the sterile drug products to support the beyond use dates and discontinue the practice of re-processing drug products to maintain acceptable potency levels throughout the drug's beyond use date;

(vii) Defendants establish and implement adequate production and process controls to assure drug products have the identity, strength, quality, and purity that they purport or are represented to possess, including but not limited to, product-specific process validation for drug products;

(viii) Defendants establish adequate control systems necessary to prevent contamination during aseptic processing, including a system for cleaning and disinfecting the room, equipment, and utensils to produce aseptic conditions;

(ix) Defendants establish adequate control systems necessary to prevent contamination during aseptic processing including, but not limited to, an air supply filtered through HEPA filters; and

(x) Defendants establish and follow appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile;

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

(i) The CGMP Expert has inspected Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs;

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

(iii) Defendants' facility, methods, and controls comply with CGMP. As part of this certification, the CGMP Expert shall include a detailed and complete report of the results of the CGMP Expert's inspection(s) conducted under this paragraph;

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

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

(ii) Ensure that Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute Defendants' drugs are established, operated, and administered in conformity with CGMP;

I. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants' facility,

methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP; and

J. Defendants receive written notice from FDA that they appear to be in compliance with all of the requirements set forth in paragraphs 12.A-12.H of this Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification.

13. Paragraphs 11 and 12 do not prohibit Defendants from manufacturing any drug product for which they are the manufacturer specified in an application approved pursuant to 21 U.S.C. § 355, provided that Defendants comply with all statutory and regulatory requirements applicable to manufacturing such drugs, including but not limited to CGMP.

14. Paragraphs 11 and 12 do not apply to drugs that Defendants manufacture, hold, and/or distribute for animal use. Defendants shall ensure that any drugs they manufacture, hold, and distribute for animal use are compounded in compliance with USP chapters on pharmacy compounding, including but not limited to USP <797>, USP <795>, and any other current or future chapters of the USP that are applicable to compounding drugs. Nothing in this Decree modifies or relieves Defendants from any obligation to comply with the Act or any other federal or state statute or regulation. Nothing in this Decree shall affect the authority of the United States to bring an action against Defendants for a violation of the Act and/or applicable regulations.

ADDITIONAL REQUIREMENTS

15. After Defendants have complied with paragraph 10, and received written notification from FDA under paragraph 10.I., Defendants shall retain an independent person who meets the criteria described in paragraph 10.B. and who is qualified to assess Defendants' compliance with paragraph 10, and paragraphs 11 and 12 (as applicable) (the "Auditor") to conduct audit inspections of Defendants' facility. 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 10.I., audit inspections under this paragraph shall commence no less frequently than once every four (4) months for a period of one (1) year, and once every six (6) months thereafter. The Auditor may be the same person(s) as the CGMP Expert described in paragraph 12.

A. At the conclusion of each audit inspection described in this paragraph, Defendants shall ensure that the Auditor prepares 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, Defendants shall ensure that the Auditor assesses the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, and include this information in the Audit Report. Defendants shall ensure that the Audit Report is 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 Defendants' facility to which the report pertains 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 ten (10) business days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. 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 approved by FDA, Defendants shall ensure that the Auditor reviews the actions taken by Defendants to correct the audit report observations. Within fifteen (15) business days after beginning that review, Defendants shall ensure that the Auditor reports in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

16. Upon receipt of written notification from FDA under paragraph 10.I., 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) or 351(a)(2)(B), 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) or 351(a)(2)(B), 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.

17. 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 Drug Compliance Expert, the CGMP Expert, and/or the Auditor, or

any other information, that Defendants have failed to comply with the provisions of this Decree, violated the Act and/or its implementing regulations with regard to any drug manufactured, held, and/or distributed at or from Defendants' facility, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act and/or its implementing regulations with regard to any drug manufactured, held, and/or distributed at or from Defendants' facility, 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, processing, packing, labeling, 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, under FDA's supervision, destroy all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control, for which a recall was initiated. Defendants shall bear the costs of such recall(s), including the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 20. 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;

C. Submit additional reports or information to FDA;

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

E. Issue a safety alert with respect to a drug manufactured, processed, packed, labeled, held, and/or distributed by Defendants; and/or

F. 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.

18. Any cessation of operations or other action described in paragraph 17 shall be implemented immediately by Defendants and 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 such 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 17 shall be borne by Defendants at the rates specified in paragraph 20. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

19. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility, 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' facility 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.

20. 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: $102.39 per hour and fraction thereof per representative for inspection

work; $122.71 per hour or fraction thereof per representative for analytical or review work; $0.56 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.

21. Within three (3) business days after becoming aware of any of the following information about any drugs manufactured, held, and/or distributed at or from Defendants' facility, Defendants shall submit to FDA at the address specified in paragraph 30, a product quality report describing all information pertaining to any:

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

B. Mislabeling or mix-ups, including incident(s) that causes any drug or its labeling to be mistaken for, or applied to, another article; and/or

C. Contamination, including any bacteriological, fungal, or environmental contamination, or any significant chemical, physical, or other change or deterioration, or lack of stability or incorrect potency, in any drug.

22. 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' facility, and publish the Decree on any internal website maintained

and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted as described herein for as long as the Decree remains in effect.

23. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service 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 executed certified mail return receipts. Within seven (7) 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. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Such meeting(s) may be conducted in-person or by videoconferece. Within fifteen (15) 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 a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

25. 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). Within thirty (30) days after each time Defendants become associated with any such additional Associated Person(s), 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 seven (7) 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.

26. 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, the creation of any additional entities that engage in manufacturing, holding, packing, and/or distributing drugs, or any other change in the corporate structure, or identity of Premier, including a change in Premier's registration status pursuant to 21 U.S.C. § 353b, 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) 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 or change in ownership.

27. 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: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drug products that have been manufactured, held, 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 one million dollars ($1,000,000) 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.

28. 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.

29. 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.

30. 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 submitted electronically to the Program Division Director, Office of Pharmaceutical Quality Operations, Division II, at ORAPHARM2_RESPONSES@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the Program Division Director, FDA, ORA/OPQO/DPQO2, One Main Place, 1201 Main Street, STE 7200, Dallas, TX 75202.

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

32. Except as provided in the foregoing provisions of this Decree, the parties shall bear their own costs and attorneys' fees in this action.

33. If Defendants have continuously complied with the terms of this Decree, the Act, and all applicable laws and regulations for a period of five (5) years after entry of this Decree, Defendants may petition this Court for relief from this Decree. If, at the

time of the petition, in FDA's judgment Defendants have met the foregoing criteria, Plaintiff will not oppose such petition.

34. 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.

35. This Court retains jurisdiction of this action and the parties thereto **FOR THE LIMITED PURPOSE OF ENFORCEMENT OF THIS CONSENT DECREE** on motion of either party. The **CLERK** is **DIRECTED** to **CLOSE THIS CASE**.

DONE and **ORDERED** in Tampa, Florida, this 17th day of September 2021.

MARY S. SCRIVEN
UNITED STATES DISTRICT JUDGE