IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA, Plaintiff, v. MEDISTAT RX, LLC, a corporation, and MARK D. ACKER, TIMOTHY L. FICKLING, and V. ELAINE WALLER, individuals, Defendants.	)	Civil Action No. 17-CV-236-C **CONSENT DECREE OF PERMANENT INJUNCTION**

The United States of America, plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against Defendants, Medistat Rx, LLC ("Medistat"), a limited liability corporation, and Mark D. Acker, Timothy L. Fickling, and V. Elaine Waller, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest 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.

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. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and 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 rendered injurious to health.

4. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and 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, the manufacture, processing, packing, or holding of drugs 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. Defendants violated the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug 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. 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. Defendants violated the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, and delivering and 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. "Bulk drug substance" shall mean any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances;

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. If Defendant elects to register Defendants' facility as an outsourcing facility under 21 U.S.C. § 353b, as provided in paragraph 12 of this Consent Decree, then in determining whether Defendants are compounding drugs at an outsourcing facility in compliance with CGMP, Defendants, their expert consultants, and FDA may consider any regulations and/or guidance that FDA has issued with respect to CGMP for 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;

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

E. "Defendants' facility" shall refer to the facility located at 110 East Azalea Avenue, Foley, Alabama, and any other location(s) (including any new locations) at which Defendant(s), manufacture, hold, and/or distribute drugs on their own behalf or on the behalf of any business association(s) in which they have a legal interest and/or have any supervisory or management responsibilities;

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, and labeling drugs;

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

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

9. Defendants represent that: (a) as of September 1, 2015 they have discontinued all operations related to the manufacturing, holding, or distribution of drugs at Defendants' facility; and (b) Medistat RX, LLC located at 110 East Azalea Avenue, Foley, Alabama dissolved as a legal entity on November 10, 2016 and has not re-formed.

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 concern 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 manufacturing, holding and/or distributing any drugs manufactured at or from Defendants' facility, unless and until:

A. Defendants' facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs are established, maintained, 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(s) (the "Drug Compliance Expert"), who: (i) is without any personal or financial ties (other than a retention agreement with Defendants) to Defendants or their families; and (ii) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, equipment, processes, and procedures are 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 misbranded within the meaning of 21 U.S.C. § 352(f)(1), and to recommend corrective actions. Defendants shall notify FDA in writing of the identity and qualifications of the Drug Compliance Expert within ten (10) days of retaining any such 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), including, but not limited to, whether:

(i) Defendants' facility is adequately designed for the manufacture of aseptically processed and/or sterile drugs with adequate separation, defined functional areas, and/or such control systems necessary to prevent contamination or mix-ups;

(ii) Defendants have thoroughly and adequately cleaned and sanitized (and sterilized, as appropriate) the manufacturing areas of their facility, including, but not limited to, equipment and utensils used in the manufacture and/or holding of their drugs;

(iii) Defendants have established and implemented a 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;

(iv) Defendants ensure that their facility is suitably designed with respect to the flow of personnel, in-process materials, and finished drugs; the need for room segregation and process separation; and the impact from heating ventilation and air conditioning (HVAC), air pressurization, and unidirectional airflow, to prevent contamination and other hazards to aseptically processed and/or sterile drugs;

(v) Defendants have ensured that the equipment used in the manufacture and/or holding of Defendants' drugs is appropriately designed to facilitate operations for the equipment's intended use, cleaning, and maintenance, and Defendants have shown through valid scientific evidence that such equipment is adequate for its intended uses;

(vi) Defendants have established and implemented adequate written standard operating procedures ("SOPs") to ensure proper maintenance of aseptic processing areas and equipment used therein;

(vii) Defendants have established and implemented adequate written procedures for sterile and aseptically manufacturing, holding, and distributing drugs that are aseptically processed and/or sterile and properly labeled;

(viii) Defendants have established and implemented adequate procedures designed to prevent microbiological contamination of drugs purporting to be sterile,

including, but not limited to, operational procedures, procedures for dynamic smoke studies, sterilization processes, and procedures for conducting appropriate media fill simulations;

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

(x) Defendants have established and implemented written SOPs for manufacturing personnel practices adequate to protect drug products from contamination.

D. The Drug Compliance Expert certifies in writing to FDA and Defendants that: (1) he/she has inspected Defendants' facility, equipment, processes, and procedures; 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, the Drug Compliance Expert shall include a detailed and complete report of the results of the inspection(s) he or she conducted under paragraph 10.C;

E. Defendants establish and maintain a system to report to FDA through the Medwatch reporting system 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 28, 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 the deviations brought to Defendants' attention by FDA, the Drug Compliance Expert, or any other source; and

(ii) Ensure that Defendants' facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs will be continuously administered and operated 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);

H. FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility to determine whether Defendants are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and whether Defendants' facility, equipment, processes, and procedures are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A); and

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

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 (collectively referred to as "Associated Persons"), 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 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.

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, Defendants shall:

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

B. Ensure that each and every drug that Defendants intend to compound, hold, and/or distribute at or from Defendants' facility satisfies all of the conditions set forth in 21 U.S.C. § 353b, including but not limited to the requirements regarding:

(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. Ensure that the facilities, methods, and controls used to compound, hold, and/or distribute Defendants' drugs are established, operated, and administered in conformity with CGMP;

D. Defendants retain, at Defendants' expense, an independent person(s) (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 ten (10) days after retaining any such CGMP 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 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, holding, and distribution of drugs will be continuously administered in conformity with CGMP. Defendants shall not implement the Work Plan prior to receiving FDA's written approval of the Work Plan, 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 the Forms FDA-483 issued to Defendants since September 2014, and performs comprehensive inspection(s) of Defendants' facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether such facilities, methods, and controls are in conformity with CGMP. The CGMP Expert shall evaluate, at a minimum, whether:

(i) Defendants have cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized equipment and utensils at appropriate intervals to prevent malfunctions or contamination;

(ii) Defendants have established and implemented an adequate system for monitoring environmental conditions that would alter the safety, identity, strength, quality or purity of the sterile drug product beyond the official or other established requirements;

(iii) Defendants have established and implemented appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including the validation of all aseptic and sterilization processes;

(iv) Defendants ensure that personnel engaged in the manufacture, processing, packing, or holding of drug products wear clean clothing appropriate for the duties

they perform, and that protective apparel, such as head, face, hand, and arm coverings, are worn as necessary to protect drug products from contamination;

(v) Defendants have established and implemented an adequate written testing program designed to assess the stability characteristics of their drug products;

(vi) Defendants have, for each batch of drug product purporting to be sterile and/or pyrogen-free, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product;

(vii) Defendants thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed;

(viii) Defendants obtain and retain, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient prior to release;

(ix) Defendants conform to written procedures for production and process control designed to assure that the drug products manufactured have the identity, strength, quality, and purity they purport or are represented to possess;

(x) Defendants have established and implemented written SOPs to ensure that they: (a) thoroughly investigate any unexplained discrepancy or the failure of a batch of drug product 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 and components that fail to meet

specifications; and (c) document in a timely manner these investigations and any corrective actions, and retain these documents as appropriate;

(xi) Defendants have established and implemented written SOPs to ensure that they thoroughly investigate and document in a timely manner any drug complaints, returns, or adverse events, and any associated trends in these product quality deviations and/or problems, and take any needed corrective actions in a timely manner; and

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

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 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. Defendants establish and maintain a system to report to FDA all adverse drug experiences associated with or potentially associated with any of Defendants' drugs as soon as possible through the MedWatch reporting system (in the manner described in 21 C.F.R. §§ 310.305 and/or 314.80), but no later than fifteen (15) days after their initial receipt of the information;

J. Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 28, Field Alert Reports (in the manner and as described in 21 C.F.R. § 314.81(b)(1)) for all of Defendants' distributed drugs within three (3) working days after their initial receipt of the information triggering the Field Alert Report;

K. 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

L. 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.J of this Decree. In no circumstances shall FDA's silence be construed as a substitute for written notification.

13. 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 violations of the Act and/or applicable regulations.

14. After Defendants have complied with paragraph 10 and received written notification from FDA under paragraph 10.I, Defendant shall retain an independent person who meets the criteria described in paragraph 10.B and is qualified to assess Defendant's compliance

with paragraph 11 (the "Auditor") to conduct audit inspections of Defendants' facility. If Defendants elect to operate Defendants' facility as an outsourcing facility under 21 U.S.C. § 353b, for all audit inspections conducted after such election, Defendants shall retain as the Auditor an independent person who meets the criteria described in paragraph 12.D and who is qualified to assess Defendants' compliance with paragraph 12. Defendants shall notify FDA in writing as to the identity and qualifications of the Auditor as soon as they retain 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 for an additional four (4) year period.

A. At the conclusion of each audit inspection described in this paragraph, 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, and include this information in the Audit Report. The Audit Report shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service no later than fifteen (15) 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, the Auditor shall review the actions taken by Defendants to correct the audit report observations. Within five (5) 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.

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 and causing to be introduced, and delivering and 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 and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery 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 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, 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 distributing of any and all drug(s);

B. Recall specified drugs manufactured, held, and/or distributed by Defendants. The recalls(s) shall be initiated 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 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;

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, held, and/or distributed by Defendants;

F. Pay liquidated damages as provided in paragraph 25; 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. Any cessation of operations or other action described in paragraph 16 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 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' facility, collect samples, and, without prior notice, take any other measures necessary 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 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, 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: $93.26 per hour and fraction thereof per representative for inspection work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 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) 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 28, 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. 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 or fungal contamination, or any significant chemical, physical, or other change or deterioration in any drug.

21. Within seven (7) days after initiating or resuming operations at Defendants' facility, Defendants shall post a copy of this Decree on a bulletin board in the employee common areas, and shall ensure that the Decree remains posted at Defendants' facility for as long as the Decree remains in effect.

22. Within seven (7) 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. Within thirty (30) days of the date of 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.

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). 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.

24. Defendants shall notify FDA at least fifteen (15) 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 or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Medistat, 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) days prior to any such assignment or change in ownership.

25. If Defendants fail to comply with any provision of this Decree, the Act and/or its implementing regulations with respect to any of Defendants' drugs and/or Defendants' facility, including any time frame imposed by this Decree, then, upon receipt of an order issued under paragraph 15, 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, held, or distributed in violation of this Decree, the Act, and/or its implementing regulations. 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, if contested, 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 pay all attorneys' fees and costs, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs incurred by Plaintiff 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 marked "Consent Decree Correspondence," and shall be addressed to the Director, FDA New Orleans District Office, 404 BNA Drive, Building 200, Suite 500, Nashville, Tennessee 37217.

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

30. 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.

31. No sooner than five (5) years after entry of this Decree, Defendant(s) may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendant(s) have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations, for at least five (5) years after entry of this Decree, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

IT IS SO ORDERED, this 5th day of July, 2017.

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
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as its Owner

TIMOTHY L. FICKLING
Individually and on behalf of
MEDISTAT RX, LLC,
as its Owner

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Individually

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