Attachment A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, Plaintiff,	)	
v.	)	Civil Action No. _____
DOWNING LABS, LLC, ASHLEY MICHELLE DOWNING, CHRISTOPHER VAN DOWNING, and ROGER E. MANSFIELD, Defendants.	)	**CONSENT DECREE OF PERMANENT INJUNCTION**

The United States of America, Plaintiff, by its undersigned attorneys, having filed its complaint for injunctive relief against Defendants, Downing Labs, LLC, a limited liability company ("Downing Labs"), and Ashley Michelle Downing, Christopher Van Downing, and Roger E. Mansfield, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree"), without contest, without admitting the allegations referenced herein, 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 over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint for Permanent Injunction ("Complaint") states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f (the "Act").

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

4. The Complaint alleges that Defendants violate 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. 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),while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

6. 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 set forth in 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211, interpreted in a manner consistent with FDA's expectations regarding compliance with current good manufacturing requirements for facilities that compound human drugs. 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' facilities" shall refer to the facility located at 4001 McEwen Road, Suite 110, Dallas, Texas ("McEwen Road Facility"), and any other location(s) (including any new locations) at which one or more Defendants manufacture, hold, and/or distribute drugs;

F. "Distribution" and "distributing" shall mean selling, trading, shipping, or delivering and shall include, but not be limited to, dispensing to a patient or to an agent of a patient and delivery or shipment to a healthcare setting for administration;

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 bulk 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;

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

L. "Sterile drug" shall include a drug that is labeled as sterile or otherwise purports to be sterile and any drug that, by nature of its intended use or method or administration is expected to be sterile.

7. On June 23, 2015, the McEwen Road Facility was registered with FDA as an outsourcing facility pursuant to 21 U.S.C. § 353b.

REQUIREMENTS TO RESUME OPERATIONS AT THE MCEWEN ROAD FACILITY AS AN OUTSOURCING FACILITY

8. 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 or from the McEwen Road Facility, unless and until:

A. The McEwen Road 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) and 351(a)(2)(B);

B. Defendants ensure that each and every drug that Defendants intend to compound, hold, and/or distribute at or from the McEwen Road Facility 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) Use of bulk drug substances at 21 U.S.C. § 353b(a)(2);

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

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

C. Defendants 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 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, or retention agreements entered into prior to the entry of this Decree) to Defendants, their officers or directors, or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether the McEwen Road 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 the McEwen Road Facility as described in paragraph 8.D; (2) ensure

that Defendants implement all recommended corrective actions; and (3) ensure that Defendants' manufacture, holding, and distribution of drugs will be continuously administered in conformity with CGMP. Defendants shall first obtain FDA's written approval of the Work Plan prior to commencement of the CGMP Expert's inspection. FDA shall review and respond to the Work Plan on an expedited basis;

F. The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants in April 2013 (when the McEwen Road Facility operated under the name NuVision Pharmacy), July 2014, and October 2015, and performs a comprehensive inspection(s) of the McEwen Road Facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether such facilities, methods, and controls are, at a minimum, in conformity with CGMP. The CGMP Expert shall, at a minimum, evaluate whether:

(1) Defendants have cleaned, sanitized, and maintained the entire facility, including the equipment and utensils, as appropriate for the risks associated with aseptic processing, at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product;

(2) Defendants have established an adequate system for review, identification, investigation, and monitoring of environmental conditions, including adequate personnel monitoring;

(3) Defendants have established and implemented appropriate written procedures designed to prevent microbiological contamination of drug products purporting to be sterile and/or pyrogen-free, including the validation of all aseptic and sterilization processes, facility and equipment;

(4) 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;

(5) Defendants have implemented proper personnel monitoring processes, and/or certifications to ensure proper contamination control as they enter into aseptic areas;

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

(7) 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;

(8) Defendants thoroughly review and document 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;

(9) Defendants have performed an appropriate and complete risk assessment for all facility equipment, processes, components, drug products, environmental and personnel monitoring, and sanitation techniques;

(10) 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;

(11) 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;

(12) Defendants have established and implemented written standard operating procedures ("SOPs") to ensure that Defendants: (i) thoroughly investigate, document in a timely manner, and retain such documents, 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; and (ii) take required and timely corrective actions for all products that fail to meet specifications;

(13) Defendants have established and implemented written SOPs to ensure that the Defendants 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;

(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; and

(15) Defendants' controls are adequate to ensure that data generated from the manufacturing operations, including laboratory testing, cannot be deleted or altered; and such controls record changes to existing data, such as the individuals making changes, the date, and the reason for changes;

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

(1) The CGMP Expert has inspected the McEwen Road Facility, methods, and controls used to manufacture, hold, and/or distribute drugs;

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

(3) The McEwen Road 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:

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

(2) Ensure that the McEwen Road Facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP;

I. Defendants establish and maintain a system to: (1) 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 21 C.F.R. § 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 initial receipt of the information; (2) submit to FDA, at the address specified in paragraph 26, 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 initial receipt of the information triggering the Field Alert Report; and (3) submit product quality reports to FDA, in the manner and as described in paragraph 18.

J. FDA representatives, without prior notice and when FDA deems necessary, inspect the McEwen Road Facility to determine whether the McEwen Road Facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with CGMP. FDA will initiate an inspection of the McEwen Road Facility no later than forty-five (45) days after receiving written notice from Defendants that the requirements of paragraph 8 have been completed; and

K. Following inspection(s) by FDA, Defendants receive written notice from FDA that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 8.A -8.I. FDA shall provide written notice to Defendants regarding the results of its inspection on an expedited basis. In no circumstances shall FDA's silence be construed as a substitute for written notification.

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

9. If, before receiving notice from FDA under paragraph 8.K, Defendants' McEwen Road facility is deregistered as an outsourcing facility under 21 U.S.C. § 353b, or the registration as an outsourcing facility is not renewed, and Defendants intend to compound drugs at the McEwen Road Facility under 21 U.S.C. § 353a, then the requirements of paragraph 8 do not apply and 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 or from Defendants' McEwen Road Facility, unless and until:

A. Defendants comply with requirements set forth in 21 U.S.C. § 353a, including the following:

(1) Drug products compounded by Defendants shall: (a) be compounded for an identified individual patient either: (i) 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 (ii) 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 Defendants 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 (b) not be distributed by Defendants prior to receipt of a valid prescription order for the identified patient;

(2) 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), & (iii), and/or other ingredients that meet the conditions in 21 U.S.C. § 353a(b)(1)(B);

(3) 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);

(4) Defendants shall not compound a drug product that appears on a 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;

(5) Defendants shall not compound any drug product that is identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding;

(6) 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

(7) Defendants shall compound the drug product 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.

B. Defendants' McEwen Road 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);

C. 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 provision, or retention agreements entered into prior to the entry of this Decree) to Defendants, their officers or directors, or their families; and (2) by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether the McEwen Road Facility, equipment, processes, and procedures are adequate to prevent Defendants from manufacturing, holding, and/or distributing drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A),

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 after retaining any such Drug Compliance Expert;

D. The Drug Compliance Expert performs a comprehensive inspection(s) of the McEwen Road Facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs to determine whether the McEwen Road 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), including, but not limited to, whether:

(1) Defendants have thoroughly and adequately cleaned and sanitized (and sterilized, as appropriate) the manufacturing areas of the McEwen Road Facility, including, but not limited to, equipment and utensils used in the manufacture and/or holding of Defendants' drug products;

(2) Defendants have established and implemented a cleaning and disinfection program that Defendants have shown through valid scientific evidence is effective for cleaning and disinfecting equipment and facilities used to manufacture sterile and non-sterile drug products;

(3) Defendants' equipment used in manufacturing and/or holding 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;

(4) The McEwen Road Facility is adequately designed for the manufacture of aseptically processed drug products with adequate separation, defined functional areas, and/or other such control systems necessary to prevent contamination or mix-ups;

(5) Defendants have established and implemented adequate written SOPs to ensure proper maintenance of aseptic processing areas and equipment used therein;

(6) Defendants ensure that the McEwen Road Facility is suitably designed with respect to the flow of personnel, in-process materials, and finished drug products; 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 sterile drug products;

(7) Defendants have established and implemented adequate procedures designed to prevent microbiological contamination of drug products purporting to be sterile, including but not limited to operational procedures, procedures to ensure proper airflow in laminar flow hoods and biologic safety cabinets under dynamic conditions, sterilization processes, and procedures for conducting appropriate media fill simulations;

(8) Defendants have established and implemented adequate written SOPs for aseptically manufacturing, holding, and distributing drug products that are sterile and properly labeled;

(9) Defendants have established and implemented written SOPs for personnel practices adequate to protect drugs from contamination, including, but not limited to, ensuring appropriate use of sterile gowning components; and

(10) Defendants have established and implemented an adequate environmental monitoring program to (a) ensure that all aseptic operations are properly monitored (including manufacturing operations, personnel, 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;

(11) Defendants' have established adequate controls to ensure that data generated from the manufacturing operations, including laboratory testing, cannot be deleted or altered; and such controls record changes to existing data, such as the individuals making changes, the date, and the reason for changes.

E. The Drug Compliance Expert certifies in writing to FDA and Defendants that: (1) he/she has inspected the McEwen Road Facility, equipment, processes, and procedures; and (2) Defendants have undertaken corrective actions to ensure that the McEwen Road 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). 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 9.D;

F. Defendants establish and maintain a system to: (1) 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 21 C.F.R. § 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 initial receipt of the information; (2) submit to FDA, at the address specified in paragraph 26, 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 initial receipt of the information triggering the Field Alert Report; and (3) submit product quality reports to FDA, in the manner and as described in paragraph 18.

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

(1) Correct all deviations brought to Defendants' attention by FDA, the Drug Compliance Expert, and any other source; and

(2) Ensure that the McEwen Road 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 as and when FDA deems necessary, inspect the McEwen Road Facility to determine whether Defendants are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and whether the McEwen Road Facility, equipment, processes, and procedures are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). FDA will initiate an inspection of the McEwen Road Facility no later than forty-five (45) days after receiving written notice from Defendants that the requirements of paragraph 9 have been completed; and

I. Following inspection(s) by FDA, Defendants receive written notice from FDA that Defendants appear to be in compliance with all of the requirements set forth in paragraphs 9.A-9.G. FDA shall provide written notice to Defendants regarding the results of its inspection on an expedited basis. In no circumstances shall FDA's silence be construed as a substitute for written notification.

ADDITIONAL REQUIREMENTS

10. Nothing in this Decree will prohibit Defendants, after receiving written notice from FDA pursuant to paragraph 8.K or 9.I, from operating Defendants' facilities under § 353a or as outsourcing facilities under § 353b , provided that Defendants comply with all applicable provisions of the Act and this Decree relating to operation in such a manner. Defendants must

conduct all human drug compounding at Defendants' facilities in accordance with the provisions of either 21 U.S.C. § 353a or 21 U.S.C. § 353b and this Decree.

11. Paragraphs 8-10 do not prohibit Defendants from manufacturing any drug for which they are the sponsor of an application approved pursuant to 21 U.S.C. § 355, provided that Defendants (a) have received notification from FDA pursuant to paragraphs 8.K or 9.I, and (b) comply with all statutory and regulatory requirements applicable to manufacturing such drugs, including, but not limited to, CGMP.Paragraphs 8-10 do not apply to drugs that Defendants manufacture, hold, and/or distribute for animal use. 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.

12. After Defendants have received written notification from FDA under paragraphs 8.K or 9.I, Defendants shall retain an independent person (the "Auditor") to conduct audit inspections of the McEwen Road Facility. If Defendants elect to operate the McEwen Road 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 8.D and who is qualified to assess Defendants' compliance with paragraph 8. If Defendants elect to operate the McEwen Road Facility under 21 U.S.C. § 353a, for all audit inspections conducted after such election, Defendants shall retain as the Auditor an independent person who meets the criteria described in paragraph 9.C and who is qualified to assess Defendants' compliance with paragraph 9. 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 paragraphs 8.K or 9.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(s) 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(s). The Audit Reports 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 the Audit Reports in a separate file at the McEwen Road 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, the Auditor shall report in writing to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

13. 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 at or from Defendants' facilities that:

A. Violates 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/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);

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) while such drug is held for sale after shipment of one or more of its components in interstate commerce; and/or

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

14. 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 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 17. 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 23; 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.

15. The following process and procedures shall apply when FDA issues an order under paragraph 14, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall 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 complete basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames 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 shall 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 if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 24 of this Decree.

D. The process and procedures set forth in paragraph 15.A-15.C shall not apply to any order issued under paragraph 14 if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall, upon receipt of such an 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. The costs of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in this paragraph and paragraph 14 shall be borne by Defendants at the rates specified in paragraph 17.

16. 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 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 Defendants' 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.

17. 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: $89.35 per hour and fraction thereof per representative for inspection work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 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. The costs set forth in this paragraph are separate from, and in addition to, any costs that may be applicable pursuant to 21 U.S.C. § 379j-62.

18. Within three (3) days after becoming aware of any of the following information about any of Defendants' drugs, Defendants shall submit to FDA at the address specified in paragraph 26, a product quality report describing all information pertaining to any:

A. Product and/or manufacturing defects that could result in serious adverse drug experiences as defined in 21 C.F.R. § 310.305;

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.

19. Within seven (7) 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 consent decree on any internal and/or publically-available website maintained and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted and/or published for as long as the Decree remains in effect.

20. Within seven (7) days after entry of this Decree, Defendants shall provide a copy of this Decree, by email and 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.

21. In the event that any of Defendants becomes 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 email and by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within thirty (30) days after each time any of Defendants becomes 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. 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.

22. Defendants shall notify FDA at least fifteen (15) days before any change in ownership, character, or name of their businesses, including incorporation, reorganization, bankruptcy, assignment, or sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure, responsibility of any individual defendant, or identity of Downing Labs, 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 such assignment, change of responsibility of individual defendant, or change in ownership.

23. If Defendants fail to comply with any of the Act, its implementing regulations, and/or the provisions of this Decree with respect to any of Defendants' products and/or Defendants' facilities, including any time frame imposed by this Decree, then, upon receipt of an order issued under paragraph 14, Defendants shall pay to the United States of America: ten thousand dollars ($10,000) in liquidated damages for each day such violation continues; an additional sum of ten thousand dollars ($10,000) in liquidated damages for each violation; and

further additional sum equal to the retail value of drugs that have been manufactured, held, or distributed in violation of the Act, its implementing regulations, and/or this Decree. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

24. 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.

25. 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.

26. 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 District Director, FDA Dallas District Office, 4040 North Central Expressway, Suite 300, Dallas, TX 75204.

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

28. If Defendants have maintained to FDA's satisfaction a state of continuous compliance with all applicable laws and regulations and this Decree for at least sixty (60) months

after satisfying all of their obligations under this Decree, Defendants may petition this Court for relief from this Decree, and the United States will not oppose such petition.

29. 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 _____ day of _____, 2015.

_____
UNITED STATES DISTRICT JUDGE

WE HEREBY AGREE THE ENTRY OF THE CONSENT DECREE OF PERMANENT INJUNCTION:

FOR THE DEFENDANTS:

Dated: 12/19/15

_____
ASHLEY MICHELLE DOWNING
Individually and on behalf of
DOWNING LABS, LLC,
as its Co-Owner/Vice-
President/Director/Secretary/and Treasurer

Dated: 12/19/15

_____
CHRISTOPHER VAN DOWNING
Individually and on behalf of
DOWNING LABS, LLC,
as its Co-Owner and President

Dated: 12/19/15

_____
ROGER E. MANSFIELD
Individually, as Pharmacist-in-Charge,
DOWNING LABS, LLC

Dated: 12.21.15

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Dated: 12/23/15

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FOR THE PLAINTIFF:

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Dated: _____

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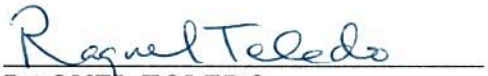
Dated: _____



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