UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

UNITED STATES OF AMERICA, Plaintiff, v. EDGE PHARMA LLC, a limited liability company, and WILLIAM MARC CHATOFF and KURT RADKE, individuals, Defendants.	)	Civil Action No. 5:22-CV-109 **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Edge Pharma LLC ("Edge Pharma"), a limited liability company, and William Marc Chatoff and Kurt Radke, individuals (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

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

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

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.* ("Act").

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

§ 351(a)(2)(A) in that the drugs have been prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, current good manufacturing practice to assure that such drugs meet the requirements of the Act as to safety and have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

5. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling does not bear adequate directions for use.

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

7. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(d), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction,

into interstate commerce new drugs as defined by 21 U.S.C. § 321(p) that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval.

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

a) "Associated Persons" shall refer collectively to each and all of Defendants' directors, officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them who are involved in the manufacture and/or distribution of articles of drug, as these terms are defined herein;

b) "Bulk drug substance" shall have the meaning given to the term in 21 C.F.R. § 207.3 or any successor regulation;

c) "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. In determining whether Defendants are manufacturing 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;

d) "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;

e) "Days" shall refer to calendar days;

f) "Defendants' facility" shall refer to the facilities located at 856 Hercules Drive, Colchester, Vermont 05446, and 948 Hercules Drive, Colchester, Vermont 05446, and any other location(s) (including any new locations) at or from which, at any time in the future,

any Defendant, directly or indirectly, manufactures, holds, and/or distributes drugs, whether or not any Defendant has an ownership interest in the business;

g) "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;

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

i) "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;

j) "FDA" shall mean the United States Food and Drug Administration;

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

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

m) "Sterile drug" shall have the meaning given to the term in 21 U.S.C. § 353b(d)(5).

9. Defendants and all 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, holding, and/or distributing any drug at and/or from Defendants' facility unless such drug is manufactured and distributed in compliance with the Act, its implementing regulations, and, as applicable, paragraph 10 and paragraph 11.

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

10. Defendants and all 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, holding, and/or distributing any drug at and/or from Defendants' facility under 21 U.S.C. § 353b unless and until:

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

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

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

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

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

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

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

c) Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert") who: *(i)* 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 *(ii)* 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 and direct the implementation of 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;

d) 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: *(i)* conduct inspection(s) of Defendants' facility as described in paragraph 10(e); *(ii)* ensure that Defendants implement all recommended corrective actions; and *(iii)* ensure that Defendants' procedures for manufacturing, holding and/or distributing drugs will be continuously administered in conformity with CGMP and are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B). Defendants shall not implement the Work Plan prior to receiving FDA's written approval, and in no circumstances, shall FDA's silence be construed as a substitute for written approval;

e) The CGMP Expert reviews all observations listed on Forms FDA-483 issued to Defendants since 2014 and performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, hold, and/or distribute drugs to determine whether Defendants' facility, methods, and controls are in conformity with CGMP and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B). Defendants shall ensure that the CGMP Expert evaluates, at a minimum, whether:

(i) Defendants employ an adequate quality control unit, capable of detecting and correcting all CGMP deficiencies, that conducts appropriate oversight and fulfills its responsibilities including, but not limited to, establishing and implementing an adequate supplier qualification program; approving or rejecting all components and in-process materials; reviewing production records to assure that no errors have occurred or if errors have occurred that they have been fully investigated; approving each batch of drug product before it is released for distribution and ensuring that non-conforming drug products are rejected; approving or rejecting drug products manufactured or held under contract by another company; and approving or rejecting all procedures and specifications that have an impact on the identity, strength, quality, and purity of drug products;

(ii) Defendants have established adequate control systems to prevent contamination during aseptic processing including, but not limited to, an air supply filtered through high-efficiency particulate air ("HEPA") filters under positive pressure; a system for monitoring environmental conditions; a system for cleaning and disinfecting the room, surfaces, equipment, and utensils used to produce drug products intended to be sterile including, but not limited to, establishing and implementing appropriate dwell times for sporicidal agents in classified areas; and a system for maintaining equipment used to control the aseptic conditions;

(iii) Defendants ensure that all environments where drugs are processed and/or held are adequately protected against mold contamination by, among other things, determining and remediating the root cause(s) of mold growth at Defendants' facility, and resolving all roof leaks, water damage, and condensation in heating, ventilation, and air conditioning ductwork that may affect areas used for drug processing and/or holding;

(iv) Defendants have established and implemented adequate written procedures to ensure that buildings used in the manufacture, holding, and/or distribution of drugs are free of vermin and are maintained in good repair and in a clean and sanitary condition;

(v) Defendants have established and implemented appropriate written procedures, including validation of all aseptic and sterilization processes, designed to prevent microbiological contamination of drug products intended to be sterile including, but not limited to, procedures for smoke studies to visualize airflow patterns under operational conditions, media fill simulations in each aseptic processing area, environmental and personnel monitoring, and frequent measurement of air-pressure differentials during operations to demonstrate proper airflow (i.e., airflow from areas of higher-quality air to adjacent areas with lower-quality air);

(vi) Defendants ensure that all drug product production and control records are reviewed and approved by their quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed; that any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications is thoroughly investigated, whether or not the batch has already been distributed; that investigations extend to other batches of the same drug product and other drug products that may be associated with the specific failure or discrepancy; that written records of investigations are made and include conclusions and follow-up; and that appropriate steps to correct and prevent recurrence of the specific failure or discrepancy are taken;

(vii) Defendants ensure that laboratory records (electronic and paper-based) include complete data derived from all tests necessary to ensure compliance with established specifications and standards;

(viii) Defendants implement adequate written procedures to conduct investigations of environmental monitoring excursions and media fill failures to identify the

probable root cause(s) for microbial contamination, to assess product impact, and to take appropriate corrective action;

(ix) Defendants establish and follow appropriate written procedures for handling all written and oral complaints regarding a drug product, including review by their quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications and a determination as to the need for an investigation and whether the complaint represents a serious and unexpected adverse drug experience that is required to be reported to FDA;

(x) Defendants ensure that each person engaged in the manufacture, holding, and/or distribution of drug products is trained to enable such persons to perform their assigned functions and that each person responsible for supervising the manufacture, holding, and/or distribution of drug products has the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug products have the safety, identity, strength, quality, and purity that they purport or are represented to possess; and, in conjunction with the requirements of this paragraph, Defendants develop and implement an adequate ongoing training program on CGMP requirements to be provided at appropriate intervals, and no less frequently than once every twelve (12) months, and retain records of the CGMP training provided in accordance with the training program established under this paragraph;

(xi) Defendants establish and maintain written quality requirements that must be met by contractors engaged in the analytical testing and/or manufacture, holding, and/or distribution of drug products for Defendants; document in writing that contractors engaged in the analytical testing and/or manufacture, holding, and/or distribution of drug

products for Defendants meet the quality requirements established under this paragraph, and retain records of such documentation; and conduct periodic evaluations of contractors engaged in the analytical testing and/or manufacture, holding, and/or distribution of drug products for Defendants to ensure that the contractors continuously meet the quality requirements established under this paragraph, and retain records of such evaluations; and

(xii) Defendants ensure that their finished drug products are properly labeled and are not otherwise unapproved new drugs;

f) 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 and are adequate to prevent drugs from becoming adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) and 351(a)(2)(B).

Defendants shall ensure that, as part of this certification, the CGMP Expert includes a detailed and complete written report of the results, including any supporting documentation, of the inspection(s) conducted under paragraph 10(e);

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

h) Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 29, 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 after initial receipt of information triggering the Field Alert Report;

i) Defendants report to FDA in writing the actions they have taken to:

(i) Correct all deviations 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 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); new drugs that are neither approved under 21 U.S.C. § 355 nor exempt from approval; and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

j) FDA representatives, without prior notice and when FDA deems necessary, conduct inspection(s) at Defendants' facility, which shall include, if FDA deems necessary, observing the preparation for and production of test or validation batches of drug products intended to be sterile (which shall not be distributed unless FDA subsequently authorizes distribution in writing), 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 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).

Defendants shall bear the costs of FDA's inspection under this paragraph at the rates specified in paragraph 19; and

k) Defendants receive written notice from FDA that they appear to be in compliance with all the requirements set forth in paragraphs 10(a)–10(i) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification. If, pursuant to paragraph 10(f), the CGMP Expert has provided a certification and written report that is limited to designated categories of Defendants' drugs, then FDA, as it deems appropriate, may issue a notification under this paragraph to authorize resumption of manufacturing, holding, and/or distribution that is limited to designated categories of drugs.

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

11. If Defendants intend to compound drugs at Defendants' facility under 21 U.S.C. § 353a, then Defendants and all 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, holding, and/or distributing any drug at and/or from Defendants' facility under 21 U.S.C. § 353a unless and until:

a) Defendants notify FDA in writing of their intent to operate Defendants' facility under 21 U.S.C. § 353a;

b) Defendants comply with the requirements set forth in 21 U.S.C. § 353a including, but not limited to, the following:

(i) The drug product shall: (A) be compounded for an identified individual patient either: (1) 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 (2) 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 (B) not be distributed by Defendants prior to receipt of a valid prescription order for the identified patient;

(ii) 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);

(iii) 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;

(iv) 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; and

(v) 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;

c) Defendants ensure that Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs are established, operated, and administered in conformity with this Decree, the Act, and its implementing regulations, and are adequate to prevent Defendants' drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A);

d) Defendants retain, at Defendants' expense, an independent person or persons (the "Drug Compliance Expert") who: *(i)* 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 *(ii)* by reason of background, training, education, or experience, is qualified to conduct inspections to determine whether Defendants' facility, methods, and controls are adequate to prevent Defendants from manufacturing, holding, and/or distributing drug products that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), and to recommend and direct the implementation of 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;

e) The Drug Compliance Expert performs a comprehensive inspection of Defendants' facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs to determine whether Defendants' facility, methods, and controls are adequate to prevent Defendants' drug products from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). Defendants shall ensure that the Drug Compliance Expert evaluates, at a minimum, whether:

(i) Defendants ensure that all buildings used in the manufacture, holding, and/or distribution of drugs are free of vermin infestation and are in a good state of repair;

(ii) Defendants ensure that all environments where drugs are processed and/or held are adequately protected against mold contamination by, among other things, determining and remediating the root cause(s) of mold growth at Defendants' facility, and resolving all roof leaks, water damage, and condensation in heating, ventilation, and air conditioning ductwork that may affect areas used for drug processing and/or holding;

(iii) Defendants ensure that facility design and control systems are suitable to prevent the reflux of lower-quality air into areas designated to have higher-quality air including, but not limited to, ISO 5 classified aseptic processing areas;

(iv) Defendants adequately clean, sanitize, and disinfect rooms, surfaces, equipment, and utensils used to produce drug products intended to be sterile to prevent contamination;

(v) Defendants implement adequate written procedures designed to prevent contamination of drug products intended to be sterile including, but not limited to, procedures for smoke studies to visualize airflow patterns under operational conditions, media fill simulations in each aseptic processing area, environmental and personnel monitoring, and frequent measurement of air-pressure differentials during operations to demonstrate proper airflow (i.e., airflow from areas of higher-quality air to adjacent areas with lower-quality air);

(vi) Defendants implement adequate written procedures to conduct investigations of environmental monitoring excursions and media fill failures to identify the probable root cause(s) for microbial contamination, to assess product impact, and to take appropriate corrective action; and

(vii) Defendants implement adequate control systems to prevent distribution of non-conforming product including, but not limited to, drug products intended to be sterile that fail sterility and/or endotoxin testing;

f) The Drug Compliance Expert certifies in writing to FDA and Defendants that:

(i) The Drug Compliance Expert has inspected Defendants' facility, equipment, processes, and procedures used to manufacture, hold, and/or distribute drugs as described in paragraph 11(e); and

(ii) Defendants have undertaken corrective actions to ensure that Defendants' facility, methods, and controls are adequate to prevent drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A).

Defendants shall ensure that, as part of this certification, the Drug Compliance Expert includes a detailed and complete written report of the results, including any supporting documentation, of the inspection(s) conducted under paragraph 11(e);

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

h) Defendants establish and maintain a system to submit to FDA, at the address specified in paragraph 29, 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 after initial receipt of information triggering the Field Alert Report;

i) Defendants report to FDA in writing the actions they have taken to:

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

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

j) FDA representatives, without prior notice and when FDA deems necessary, inspect Defendants' facility, which shall include, if FDA deems necessary, observing the preparation for and production of test or validation batches of drug products intended to be sterile (which shall not be distributed unless FDA subsequently authorizes distribution in writing), to determine whether Defendants' facility, methods, and controls used to manufacture, hold, and/or distribute drugs comply with this Decree, the Act, and its implementing regulations, including whether Defendants' facility, methods, and controls are adequate to prevent their drugs from becoming adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). Defendants shall bear the costs of FDA's inspection under this paragraph at the rates specified in paragraph 19; and

k) FDA notifies Defendants in writing that Defendants appear to be in compliance with all the requirements set forth in paragraphs 11(a)–11(i) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

12. The following conduct is not enjoined under paragraphs 10 or 11:

a) Defendants' manufacturing drugs for the sole purpose of performing validation studies, provided, however, that the drugs shall not be commercially distributed.

Defendants shall maintain in a separate file at Defendants' facility a written log of all lot numbers of drugs manufactured under this provision and shall promptly make the written log available to FDA upon request; and

b) Defendants' manufacturing limited quantities of drugs solely for distribution of those drugs to a contract testing laboratory for the sole purpose of demonstrating compliance with the requirements of paragraphs 10 and/or 11.

ADDITIONAL REQUIREMENTS

13. Within sixty (60) days after entry of this Decree, Defendants shall destroy, under FDA's supervision, all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control. The parties may mutually agree in writing to modify this sixty-day time frame, which modification may be granted without seeking leave of Court. Defendants shall bear the costs of recall and destruction, including 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.

14. After Defendants have received written notification from FDA under paragraph 10(k), Defendant shall retain an independent person (the "Auditor") who meets the criteria described in paragraph 10(c) and who is qualified to assess Defendants' compliance with paragraph 10 to conduct audit inspections of Defendants' facility. If Defendants elect to operate Defendants' 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 11(d) and who is qualified to assess Defendants' compliance with paragraph 11. 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(k) or paragraph 11(k), 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.

a) At the conclusion of each audit inspection described in this paragraph, Defendants shall ensure that the Auditor prepares a written audit report ("Audit Report") analyzing whether Defendants comply with the requirements of this Decree, the Act, and its implementing regulations. The Audit Report shall identify all deviations from this Decree, the Act, and its implementing regulations ("audit report observations"). Beginning with the second Audit Report, Defendants shall ensure that the Auditor assesses the adequacy of any corrective actions taken by Defendants to correct all previous audit report observations, if any, and any Form FDA-483 observations, and include this information in the Audit Report. Defendants shall ensure that the Audit Report is delivered contemporaneously to Defendants and FDA in accordance with the terms of paragraph 29 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) days after receipt of the audit report, propose a schedule for completing corrections. FDA shall, as it deems appropriate, review and approve the

proposed schedule in writing prior to implementation. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved correction schedule. Within thirty (30) days after Defendants' receipt of an Audit Report, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, Defendants shall ensure that the Auditor reviews the actions taken by Defendants to correct the audit report observations. Within seven (7) days after beginning that review, Defendants shall ensure that the Auditor reports in writing with supporting documentation to FDA whether each of the audit report observations has been fully corrected and, if not, which audit report observations remain uncorrected.

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

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

b) Violates 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. §§ 351(a)(2)(A) or 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352(f)(1) while such drug is held for sale after shipment of one or more of its components in interstate commerce;

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

d) Results in the failure to implement and continuously maintain the requirements of this Decree.

16. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analyses of samples, a report or data prepared or submitted by Defendants, the CGMP Expert, the Drug Compliance 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 distribution of any and all drug(s);

b) Recall specified drugs manufactured, held, and/or distributed by Defendants. Defendants shall initiate the recall(s) within twenty-four (24) hours after receiving notice from FDA that a recall is necessary. Defendants shall destroy, under FDA's supervision, 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) Destroy, under FDA supervision, all finished and/or in-process drugs and components that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 19. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law Submit additional reports or information to FDA;

d) Submit additional reports or information to FDA;

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

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

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

Any cessation of operations or other action described in paragraph 16 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in 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. 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. If FDA issues a directive pursuant to paragraph 16, the following process and procedures shall apply:

a) Unless a different time frame is specified by FDA in its directive, within ten days after receiving such directive, Defendants shall notify FDA in writing either that: (*i*) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (*ii*) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement and, in doing so, may provide specific alternative actions and time frames for achieving FDA's objectives. After receipt of Defendants' notification and explanation, FDA will review Defendants' notification and explanation and, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's affirmed or modified directive, immediately implement it, and may, if Defendants so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to implement and fully comply with FDA's directive, unless

and until the Court stays, reverses, or modifies FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 27; and

b) The process and procedures in paragraph 17(a) shall not apply to any directive issued pursuant to paragraph 16 if such directive states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such directive, immediately and fully comply with the terms of that directive, and the directive shall constitute final agency action. Should Defendants seek to challenge any such directive, they may petition the Court for relief while they implement FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 27.

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

19. Defendants Edge Pharma LLC and William Marc Chatoff shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including the travel incurred by specialized investigatory and expert personnel, at the standard rates prevailing at the time the costs are incurred. As of the date that this Decree is signed by the parties, these rates are: $105.46 per hour and fraction thereof per representative for inspection work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 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 29, a product quality report describing all information pertaining to any:

a) Product and/or manufacturing defects that could result in serious adverse drug experiences;

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

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

21. 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' facility, and publish the Decree on any internal or publicly-available website maintained and/or controlled by Defendants. Defendants shall ensure that the Decree remains posted as described herein for as long as the Decree remains in effect.

22. Within seven (7) days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service, certified mail (restricted delivery, return receipt requested), or electronic mail to all Associated Persons. Within thirty (30) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts or emails acknowledging receipt. Within ten (10) 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. Within ten (10) days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings, in person or by video-conferencing or combination thereof, for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

24. In the event that 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 personal service, certified mail (restricted delivery, return receipt requested), or electronic mail 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 or emails acknowledging receipt. Within ten (10) 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.

25. 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 corporation, the creation or dissolution of subsidiaries, the creation of any additional entities that engage in manufacturing, holding, and/or distributing drugs, or any other change in the corporate structure, responsibility of any individual defendant, or identity of Edge Pharma, including a change in Edge Pharma's registration status pursuant to 21 U.S.C. § 353b, or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assign at least fifteen (15) days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) days prior to any such assignment or change in ownership.

26. If any Defendant fails to comply with any provision of this Decree, the Act and/or its implementing regulations, including any time frame imposed by this Decree, then Defendants Edge Pharma LLC and William Marc Chatoff 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, and/or distributed in violation of this Decree, the Act, and/or its implementing regulations. The total amount of such liquidated damages shall not exceed fifteen million dollars ($15,000,000) annually. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

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

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

29. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked

"Consent Decree Correspondence," and shall be submitted electronically to the Program Division Director, Office of Pharmaceutical Quality Operations, Division I, at ORAPHARM1_RESPONSES@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of the Program Division Director, FDA, ORA/OPQO/Division 1, 10 Waterview Blvd. 3rd Floor Parsippany, NJ 07054.

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

31. Defendants may petition FDA in writing to extend any deadline in this Decree, and FDA may grant such extension without seeking leave of Court. Any such grant of extension shall become effective upon Defendants' receipt of written notification from FDA.

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

33. No sooner than sixty (60) months after resuming production of drug products intended to be sterile, after receipt of written notification from FDA under paragraph 10(k) or paragraph 11(k), Defendants may provide written notice to FDA that they seek relief from this Decree. If, at the time of such notice, in FDA's judgment Defendants have maintained a state of continuous compliance with the terms of this Decree, the Act, and all applicable laws and regulations for at least sixty months after resuming production after receipt of written notification from FDA under paragraph 10(k) or paragraph 11(k), Defendants may petition the Court to grant such relief and the United States will not oppose Defendants' petition.

34. 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 10th day of June, 2022.

UNITED STATES DISTRICT JUDGE

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

For Defendants

WILLIAM MARC CHATOFF,
Individually and on behalf of
EDGE PHARMA LLC

KURT RADKE,
Individually
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Office of the Chief Counsel
Food and Drug Administration

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

For Defendants

WILLIAM MARC CHATOFF,
Individually and on behalf of
EDGE PHARMA LLC

KURT RADKE,
Individually

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

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KURT RADKE,
Individually

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