UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. MED-PHARMEX, INC., a corporation, GERALD P. MACEDO and VINAY M. RANGNEKAR, PH.D., individuals, Defendants.	No. 2:20-cv-09844-JAK-AFM **CONSENT DECREE OF PERMANENT INJUNCTION** **JS-6**

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), having filed a First Amended Complaint for Permanent Injunction ("Complaint") against Med-Pharmex, Inc. ("MPX" or "the company"), a corporation, Gerald P. Macedo and Vinay M. Rangnekar, Ph.D., individuals, and Defendants MPX and Gerald P. Macedo (collectively, "Defendants") having appeared and consented to entry of this Decree without contest, without admitting the allegations in the Complaint, before any testimony has been taken, and the United States of America having consented to this Decree;

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

1. This Court has jurisdiction over the subject matter of this action under 21 U.S.C. § 332 and has personal jurisdiction over all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c).

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

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce animal drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they are manufactured, processed, packed, and held in violation of the current good manufacturing practice ("cGMP") regulations for drugs set forth in 21 C.F.R. Part 211.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of animal drug that they hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

5. The term "MPX's Facilities" includes the facility at 2727 Thompson Creek Road, Pomona, California 91767 and any other facility where MPX now or in the future directly or indirectly manufactures, processes, packs, holds, or distributes any articles of drug. The term "MPX's Facilities" does not include the Cephazone Pharma, LLC facility at 250 East Bonita Avenue, Pomona, California 91767.

6. The terms "sterile drug" or "articles of sterile drug" means a drug that purports to be sterile and is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law. 21 U.S.C. § 353b(d)(5). "Sterile drug" or "articles of sterile drug" does not include euthanasia products and natural and synthetic steroid hormonal ear implants intended for use in bovine and ovine species.

7. Defendants represent that: (a) MPX discontinued all sterile drug manufacturing at MPX's Facilities in or about July 2020; and (b) at the time of entry of this Decree, Defendants are not engaged in sterile manufacturing at MPX's Facilities, and have no intention to engage in sterile manufacturing in the future at MPX's Facilities. If Defendants later intend to resume sterile drug manufacturing at MPX's Facilities, they must comply with Paragraph 8 of this Decree. Defendants shall not resume sterile drug manufacturing until FDA has inspected MPX's Facilities pursuant to Paragraph 8.F, Defendants have paid the costs of such inspection(s) pursuant to Paragraph 8.G, and Defendants have received written notification from FDA that Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendants may resume sterile drug manufacturing at MPX's Facilities.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who receive notice of this Decree by personal service or otherwise (collectively, "Associated Person(s)"), 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, processing, packing, holding, and distributing any articles of sterile drug manufactured at MPX's Facilities, unless and until:

A. Defendants ensure that the methods, facilities, and controls used to manufacture, process, pack, hold, and distribute sterile drugs at or from MPX's Facilities are established, operated, and administered in conformity with cGMP. *See* 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Part 211;

B. Defendants select and retain, at their expense, an independent person or persons (the "Expert"), to conduct inspections of MPX's operations and to review

MPX's procedures and methods for manufacturing, processing, packing, holding, and distributing articles of sterile drug, to determine whether the methods, facilities, and controls are operated and administered in conformity with this Decree, the FDCA, and its implementing regulations. The Expert shall be qualified by education, training, and experience to conduct such inspections, have specific expertise in evaluating compliance with the cGMP requirements for sterile drugs as set forth in 21 C.F.R. Part 211, have expertise in aseptic processing and microbiology as it relates to sterile drug manufacturing, and be without personal or financial ties (other than a retention agreement or contract between the parties, covering the Expert's activities under the Decree) to Defendants' officers or employees or their families;

C. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within ten (10) business days of retaining such Expert, or, if such Expert has already been retained upon entry of this Decree, within ten (10) business days after entry of this Decree;

D. The Expert shall perform a comprehensive inspection of MPX's Facilities and the methods and controls used to manufacture, process, pack, hold, and distribute sterile drugs. The Expert shall determine whether MPX's Facilities and the methods and controls used to manufacture, process, pack, hold, and distribute sterile drugs are in compliance with cGMP for sterile drugs, the FDCA and its implementing regulations, and this Decree. The Expert's report of the inspection of MPX's Facilities shall be submitted to FDA and shall include, but not be limited to, the following:

i. An evaluation of MPX's current state of compliance with respect to the violations set forth on FDA's Lists of Inspectional Observations issued to MPX since February 2016;

ii. A determination of whether Defendants have established and implemented at MPX's Facilities adequate procedures, processes, equipment, and facilities designed to prevent microbiological contamination of each component and

batch of sterile drug product to ensure that they are free of objectionable organisms;

iii. A determination of whether the accuracy, sensitivity, specificity, and reproducibility for all test methods used at MPX's Facilities have been established and documented;

iv. A determination of whether Defendants have established and are following at MPX's Facilities laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, sterile drug product containers, closures, in-process materials, labeling, and sterile drug products conform to appropriate standards of identity, strength, quality and purity;

v. A determination of whether Defendants have established and are following at MPX's Facilities written procedures for equipment cleaning and maintenance, including utensils, used in the manufacturing, processing, packing, labeling, and distributing of sterile drug products;

vi. An evaluation of whether MPX's Quality Assurance Unit reviews and approves all sterile drug product production and control records to determine compliance with all established, written procedures before a batch is released or distributed, as required by 21 C.F.R.§ 211.192;

vii. A determination of whether Defendants have corrected all violations set forth in FDA's Inspectional Observations ("Forms FDA-483") from all prior FDA inspections of MPX's Facilities since February 2016;

viii. A determination of whether, based upon this comprehensive inspection, Defendants' sterile drug manufacturing operations at MPX's Facilities are operated in conformity with this Decree, the FDCA, and its implementing regulations. The Expert shall submit his/her report(s) to FDA at the address specified in Paragraph 21; and

ix. A written report to FDA with the actions that Defendants have

taken to (a) correct all violations brought to Defendants' attention by the Expert and/or set forth in FDA's Forms FDA-483 from all prior FDA inspections of MPX's Facilities since February 2016; and (b) ensure that the methods used in, and the facilities and controls used for manufacturing, processing, packing, holding, and distributing articles of sterile drug at or from MPX's Facilities are designed, operated, and administered, and will be continuously operated and administered, in conformity with this Decree, the FDCA, and its implementing regulations. Defendants shall include with their report a copy of a written certification from the Expert that Defendants are in compliance with this Decree, the FDCA, and its implementing regulations;

E. Within twenty (20) business days after submission of the Expert report to FDA, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy all articles of sterile drug in their possession, custody, or control that were manufactured at MPX's Facilities. Defendants' notice shall specify the proposed time, place, and method of destruction ("Destruction Plan"). Defendants shall neither commence nor permit any other person to commence destruction until they have received written authorization from FDA to commence the destruction. At or after the time FDA evaluates the Expert report as discussed in Paragraph 8.H.i, FDA will decide if and when to authorize destruction;

F. FDA, as and when it deems necessary, inspects MPX's Facilities to determine whether the requirements of this Decree have been met, and whether Defendants' sterile drug manufacturing operations at MPX's Facilities are otherwise operated in conformity with cGMP, the FDCA, and its implementing regulations;

G. Defendants pay all costs of expenses incurred under Paragraph 8 for FDA inspections, investigations, supervision, reviews, examinations, evaluations, and analyses, at the rates set forth in Paragraph 15 of this Decree; and

H. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraph 8.A – 8.G and that Defendants

may resume directly or indirectly manufacturing articles of sterile drug at or from MPX's Facilities. In no circumstance shall FDA's silence be construed as a substitute for written notification.

i. Within forty-five (45) business days after FDA's receipt of the Expert's report discussed above in Paragraph 8.D and 8.D, subparagraphs i. – ix., FDA will notify Defendants in writing whether the Expert report demonstrates that Defendants appear to be in compliance with the requirements set forth in Paragraph 8.A – 8.G. If FDA notifies Defendants that the Expert's report does not demonstrate that Defendants appear to be in compliance with the requirements set forth in Paragraph 8.A – 8.G, FDA shall identify in writing any deficiencies in the report. If FDA determines that an inspection under Paragraph 8.F is necessary to determine whether Defendants appear to be in compliance with Paragraph 8.A – 8.G, FDA shall begin an inspection as soon as is practicable, taking into account then-existing public health circumstances, including the COVID-19 pandemic.

I. Nothing in Paragraph 8 of this Decree shall preclude Defendants from holding sterile drugs that are maintained solely as stability and retention samples. No drugs held under this subparagraph may be commercially distributed.

9. Upon entry of this Decree, Defendants and each and all of their Associated Person(s) who receive notice of this Decree by personal service or otherwise are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that:

A. Violates the FDCA, 21 U.S.C. § 331(a), and results in the introduction or delivery for introduction into interstate commerce of articles of drug that are adulterated; or

B. Violates the FDCA, 21 U.S.C. § 331(k), and results in an article of drug becoming adulterated while held for sale after shipment of one or more of its components in interstate commerce.

10. Within ten (10) business days after entry of this Decree, Defendants shall select and retain an independent person or persons (the "Auditor"), at Defendants' expense, to conduct audit inspections of Defendants' drug manufacturing operations at MPX's Facilities, not less than once every four (4) months for a period of two (2) years and not less than once every twelve (12) months for a period of three (3) years thereafter, for a total of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a retention agreement or contract entered into by the parties covering the Auditor's activities under this Decree) to Defendants' officers or employees or their families. The Auditor may be the same person or persons described as the Expert in Paragraph 8.B. Additionally:

A. At the conclusion of each audit inspection of MPX's Facilities, Defendants shall ensure that the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' operations are operated and administered in compliance with cGMP, the FDCA, its implementing regulations, and this Decree, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, Defendants shall ensure that the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. Defendants shall ensure that the Audit Reports shall be delivered contemporaneously to Defendants and FDA no later fifteen (15) business days after the date the audit inspections are completed. If any Audit Report identifies any deviations from the FDCA, its implementing regulations, and/or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended for two (2) years. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at MPX's Facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request; and

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) business days after receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. For any adverse Audit Report Observations that are not corrected within thirty (30) business days after receipt of the Audit Report, Defendants shall propose a schedule for completing such corrections, including Defendants' justification for additional time (the "Corrections Schedule"). FDA may approve, modify, or reject the proposed Correction Schedule in writing. In no circumstance shall FDA's silence be construed as a substitute for written approval of the proposed Correction Schedule.

C. Within thirty (30) business days after Defendants' receipt of an Audit Report, 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 adverse Audit Report Observation(s). Within fifteen (15) business days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

11. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection of MPX's Facilities, the analysis of a sample, a report, a review, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the FDCA or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the FDCA, 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 manufacturing, processing, packing, holding, and/or distributing any or all articles of drugs at or from MPX's Facilities;

B. Recall, at Defendants' sole expense, any specific articles of drug manufactured, held, and/or distributed at or from MPX's Facilities that are adulterated or otherwise in violation of this Decree, the FDCA, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA;

E. Issue a press release about a safety issue or recall; and

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the FDCA, and its implementing regulations.

The provisions of Paragraph 11 shall be apart from, and in addition to, all other remedies available to FDA.

12. The following process and procedures shall apply in the event that FDA issues an order under Paragraph 11.

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

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

modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose, bring the matter before the Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies the order. Any judicial review of FDA's order under this paragraph shall be made pursuant to Paragraph 20.

D. The process and procedures set forth in Paragraphs 12.A-12.C shall not apply to any order issued pursuant to Paragraph 11 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 order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to Paragraph 20.

13. Any cessation of operations or other action described in Paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the FDCA, and its implementing regulations, and that Defendant may, therefore, resume operations. Defendants may submit to FDA a written request to resume operations. Within forty-five (45) business days after FDA's receipt of a written request to resume operations, FDA will determine whether Defendants appear to be in compliance with this Decree, the FDCA, and its implementing regulations and notify Defendants whether they may resume operations.

14. FDA shall be permitted, without prior notice and as FDA deems necessary, to inspect MPX's Facilities and without prior notice take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the FDCA, and its implementing regulations. During inspections of MPX's Facilities, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process

materials, finished products, containers, packing material, labeling, and other material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material; and examine and copy all records relating to manufacturing, processing, packing, holding, and distributing any and all articles of drug and their respective components. The inspection 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 FDCA, 21 U.S.C. § 374.

15. Defendants shall reimburse FDA for the costs of all inspections, investigations, supervision, reviews, examinations, evaluations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree. The costs shall be borne by Defendants at the prevailing rates in effect at the time the costs are incurred. As of the date this Decree is signed by the parties, the rates are $102.39 per hour or fraction thereof per representative for inspection work; $122.71 per hour or fraction thereof per representative for analytical work; and $0.56 per mile (plus tolls) for travel expenses 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 generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

16. Within fifteen (15) business days after entry of this Decree, Defendants shall post a copy of this Decree in common areas at MPX's Facilities and at any other location at which the MPX conducts business, including any at which it contracts to manufacture, store, or distribute drugs, and shall ensure that the Decree remains posted for as long as it remains in effect. Defendants shall ensure that the decree remains posted

as described for not less than twenty-four (24) months.

17. Within fifteen (15) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service, personal delivery via electronic mail with acknowledgment of receipt (return receipt email) or certified mail (restricted delivery, return receipt requested) to each Associated Person(s). Within thirty (30) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

18. In the event that Defendants become associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Every six (6) months, Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

19. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Med-Pharmex, Inc., or 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 assignee at least fifteen (15) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than

fifteen (15) business days prior to such assignment or change in ownership.

20. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No further discovery shall be taken by either party.

21. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to the Director, Division of Pharmaceutical Quality Operations IV, FDA Los Angeles District Office, 19701 Fairchild, Irvine, CA 92612, and ORAPHARM4_Responses@FDA.HHS.GOV, and shall reference the case name and civil action number.

22. The parties may, at any time, petition each other in writing to extend any deadline provided herein, and the parties may grant such an extension without seeking leave of the Court. Any such petitions shall not become effective unless and until granted in writing.

23. Should Defendants fail to comply with any provision of this Decree, the FDCA, or its implementing regulations, the Defendants shall pay to the United States of America the sum of Five Thousand Dollars ($5,000.00) in liquidated damages for each day such violation continues; an additional sum of Five Thousand Dollars ($5,000.00) in liquidated damages for each violation of this Decree, the Act, or its implementing regulations; and an additional sum equal to five (5) times the retail value of each shipment of an adulterated drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States of America to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated

damages. The amount of liquidated damages imposed under this paragraph shall not exceed Two Hundred and Fifty Thousand Dollars ($250,000.00) in any one calendar year.

24. Should Plaintiff bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other costs or fees relating to such proceedings.

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

26. Sixty (60) months after entry of this Decree, Defendants may petition this Court for full relief from this Decree or for specific relief from this Decree with regard to one or more of MPX's Facilities. If, at the time of the petition, Defendants have satisfied all of their obligations under this Decree with respect to the specific facilities for which Defendants are seeking relief and, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least sixty (60) months, the United States shall not oppose the petition, and Defendants may request the Court to grant such relief.

27. Nothing in this Decree shall prevent FDA from accepting for filing, reviewing, and approving any supplemental new animal drug application (NADA) or supplemental abbreviated new animal drug application (ANADA) submitted by MPX and listing MPX's Facilities as a manufacturing facility. Further, FDA shall not withhold approval of any such supplemental NADA or supplemental ANADA for a non-sterile drug solely on the basis of MPX's Facilities' inspectional classification prior to FDA performing an inspection at MPX's Facilities after entry of this Decree.

28. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may

be necessary or appropriate.

IT IS SO ORDERED.

Dated this 19 day of November, 2021.

John A. Kronstadt
United States District Judge