UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. PHARMASOL CORPORATION, a Delaware corporation, and MARC L. BADIA, an individual, Defendants.	23 CV 12801 AK **CONSENT DECREE**

Plaintiff, the United States of America, by and through its undersigned counsel, having filed a Complaint for Permanent Injunction against Pharmasol Corporation ("Pharmasol"), a Delaware corporation, and Marc L. Badia, an individual (collectively, "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint and disclaiming any liability in connection therewith, having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

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

1. This Court has jurisdiction over the subject matter and all parties to this action.

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

3. The Complaint alleges that Defendants violated 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that they have been manufactured, processed, packed, labeled, held and/or distributed in violation of current good manufacturing

practice for drugs. *See* 21 C.F.R. Parts 210-211. The complaint also alleges Defendants violated 21 U.S.C. § 331(k) by causing the adulteration of drugs while they are held for sale after shipment of one or more of their components in interstate commerce.

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

A. "Drug(s)" refers to any product that meets the definition in 21 U.S.C. § 321(g), including, but not limited to, finished drugs, drug components, and active pharmaceutical ingredients ("API").

B. "Defendants' Facilities" means Pharmasol's principal place of business, 1 Norfolk Avenue, South Easton, Massachusetts, 02375; and its warehouse, located at 146 Campanelli Parkway, Stoughton, Massachusetts 02072; and any facility at or from which one or more Defendants, now or in the future, manufacture, process, pack, repack, label, hold, and/or distribute any drug.

C. "CGMP" means current good manufacturing practice requirements for drugs. *See* 21 U.S.C. § 351(a)(2)(B); 21 C.F.R. Parts 210 and 211.

5. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise (collectively, "Associated Persons") are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

6. Upon entry of this Decree, Defendants, and each and all of their Associated

Persons, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any drug at or from Defendants' Facilities, unless and until:

A. Defendants retain, at Defendants' expense, an independent person or persons (the "CGMP Expert"), who is without any personal or financial ties (including, but not limited to, prior employment by Defendants), other than the retention agreement, to Defendants and their families, and who, by reason of background, training, education, or experience (*see* 21 C.F.R. § 211.34), is qualified to inspect Defendants' drug manufacturing operations to determine whether the methods, facilities, and controls are operated and administered in conformity with CGMP. Defendants shall follow the CGMP Expert's guidance for remediation. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert as soon as they retain such expert;

B. The CGMP Expert shall perform a comprehensive inspection of Defendants' Facilities and the methods and controls used to manufacture, process, pack, label, and hold drugs, and certify in writing to FDA that (1) he or she has inspected Defendants' Facilities, methods, processes, and controls; and (2) whether Defendants' operations are, in the CGMP Expert's opinion, in compliance with 21 U.S.C. § 351(a)(2)(B), 21 C.F.R. Parts 210-211, and this Decree. The CGMP Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, the following:

i. An evaluation of whether Defendants, in a timely manner, thoroughly investigated discrepancies and failures thoroughly and accurately, including, but not limited to, those involving complaints and equipment cleaning failures, as required by 21 C.F.R. § 211.192;

ii. A determination of whether Defendants have established written responsibilities and procedures applicable to the quality control unit and are following the written procedures as required by 21 C.F.R. § 211.22 (a) and (d);

iii. An evaluation of whether Defendants enacted procedures to describe the handling of written and oral complaints regarding a drug product, including reviewing complaints in a timely manner, providing adequate justification for complaints that remain open, and closing complaints classified as "critical" and "major" in a timely manner, as required by 21 C.F.R. § 211.198(a); and

iv. A determination of whether Defendants adequately clean and maintain equipment to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product(s) beyond the official or other established requirements, as required by 21 C.F.R. § 211.67(a).

C. The CGMP Expert will evaluate Defendants' CGMP operations and will conduct and/or approve a CGMP training program and requirements.

D. Defendants shall recall from their customers, and further advise their customers to recall to the retail level, all adulterated prescription drugs that: are within expiration date; and Defendants have manufactured, processed, held, or distributed on or after February 10, 2022. Defendants will destroy the drugs recalled from Defendants' customers in accordance with the procedures provided in paragraph 7. The requirements in this paragraph shall not apply to: (1) unopened API from a third party or parties; and (2) any finished drug products that are in compliance with the Act and that Defendants acquired from a third party or parties.

E. Defendants shall complete a written report and submit it to FDA that details the actions they have taken to:

i. correct the CGMP deviations violations brought to Defendants' attention by FDA, the CGMP Expert, and any other source; and

ii. ensure that the methods used in, and the facilities and controls used for, manufacturing, processing, packing, labeling, holding, and distributing drugs are operated and will be continuously administered in conformity with CGMP.

F. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 6(A)-(E) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

G. Within forty-five (45) calendar days of receiving the CGMP Expert's report, FDA shall provide notification to Defendants either acknowledging concurrence with the report or explaining the basis for FDA's decision not to concur with any part of the report. Upon receiving FDA's notification, Defendants shall address FDA's concerns and submit a revised report to FDA. Within thirty (30) calendar days of receiving the revised report, FDA shall provide notification to Defendants either concurring with the report or explaining the basis for FDA's decision not to concur with any part of the report. This process shall be repeated until Defendants receive written notification of concurrence from FDA.

7. Within thirty (30) calendar days after the entry of this Decree, Defendants, under FDA's supervision, shall destroy all prescription drugs that are in Defendants' possession, custody, or control at Defendants' Facilities. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any drugs in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the drugs are disposed. The requirements in this paragraph shall not apply to: (1) unopened API from a third party or parties; and (2) any finished drug products

that are in compliance with the Act and that Defendants acquired from a third party or parties.

8. Nothing in this Decree shall preclude Defendants from receiving, holding, and distributing in the United States any finished drug products or any API that are in compliance with the Act and that Defendants purchase from a third party or parties, so long as:

A. Defendants do not manufacture or process such finished drug products and act only as a distributor of such products;

B. The third party or parties who manufacture or supply the finished drug products to Defendants are not owned, controlled by, or affiliated in any way with Defendants, and have no connection to Defendants, Defendants' families, or Associated Persons;

C. Prior to Defendants' receipt of finished drug products from any third parties, Defendants' CGMP expert certifies in writing that Defendant's Facilities that receive, hold, and distribute finished drug products have adequate controls for temperature, humidity, and light, and such other control systems as are necessary to prevent contamination, mix-ups, or other CGMP violations. Defendants' Facilities must maintain these control systems while holding drug products, or FDA may, in its discretion, invoke any actions set forth in paragraph 10; and

D. If any CGMP violations are found that FDA deems significant during an inspection of any third-party provider of finished drug products or API, or through Defendants' monitoring of third parties, then FDA may, in its discretion, invoke any of the actions set forth in paragraph 10.

9. After Defendants have complied with paragraphs 6(A)-(E) and received FDA's written notification pursuant to paragraph 6(F), Defendants shall retain an independent person or persons (hereinafter, the "Auditor") who shall meet the criteria described in paragraph 6(B) to

conduct an audit of Defendants' Facilities no less frequently than once every six (6) months for a period of no less than five (5) years, unless FDA in its discretion deems less frequent audits are warranted. The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to paragraph 6(F). If Defendants choose, the Auditor may be the same person or persons retained as the CGMP Expert described in paragraph 6(A).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants' operations are in compliance with CGMP and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by electronic mail, courier service, or overnight delivery service, no later than fifteen (15) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facilities and shall promptly make the Audit Reports available to FDA upon request.

B. If an Audit Report contains any observations indicating that Defendants' drugs are not in compliance with CGMP, Defendants shall, within fifteen (15) calendar days of receipt of the Audit Report, submit a written response to each Audit Report Observation contemporaneously to the Auditor and FDA. If an Audit Report contains any observations indicating that Defendants' drugs are not in compliance with CGMP, Defendants shall further correct all Audit Report Observations within fifteen (15) calendar days of receipt of the Audit Report, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer

than fifteen (15) calendar days, Defendants shall, within ten (10) calendar days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor and to FDA. Within thirty (30) calendar days of the Auditor's receipt of Defendants' documentation of corrections, 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 of beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

C. Defendants' retention agreement with the Auditor must permit the Auditor to communicate and/or meet directly with FDA, either upon the initiative of the Auditor or upon the Agency's request, and with Defendants' actual knowledge to discuss his or her review of Defendants' Facilities. This should not be construed as prohibiting or otherwise limiting the Auditor's ability to inform or disclose to Defendants that it met with or plans to meet with FDA.

10. If at any time after entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, a report, or data prepared or submitted by Defendants, the CGMP Expert, the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act, or its implementing regulations, or that

additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations at Defendants' Facilities, 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 at Defendants' Facilities:

A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drug that in FDA's judgment is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Destroy, at Defendants' expense, any drug in their possession, custody, or control, that in FDA's judgment is adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations;

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

E. Submit additional reports or information to FDA as requested;

F. Assess liquidated damages, as provided by paragraph 19 of this Decree;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, 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.

The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to

implement the remedies set forth in paragraph 10 shall be borne by Defendants at the rates specified in paragraph 13.

11. The following process and procedures shall apply in the event that FDA issues an order under paragraph 10, except as provided in paragraph 11(D) below:

A. Unless a different timeframe is specified by FDA in its order, within ten (10) business days after receiving such order under paragraph 10, 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 order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in detail and writing their basis for their disagreement; in doing so, Defendants may also 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 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 may, if they choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless and until the Court stays, reverses, 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 21.

D. The process and procedures set forth in paragraphs 11(A) through 11(C) shall not apply to any order issued pursuant to paragraph 10, if such order states that, in FDA's judgment, the matter raises a significant public health concern or concerns. In such case, Defendants shall immediately and fully comply with the terms of the order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any cessation of operations under this paragraph shall continue until Defendants receive written notice from FDA that Defendants appear to be in compliance with the Act, its implementing regulations, and this Decree.

12. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' places of business, and without prior notice, and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During inspections, FDA representatives shall be permitted to: have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the manufacture, processing, packing, labeling, 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 make inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to

evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment to FDA within twenty (20) business days after receiving an electronic invoice for payment, which shall be sent to mbadia@pharmasol.com. Defendants shall make payment through the Pay.gov electronic billing system, subject to all interest, fees, and penalties applicable to delinquent payments, in accordance with 31 U.S.C. § 3717 and 45 C.F.R. § 30. As of the date of entry of this Decree, these rates are: $110.59 per hour or fraction thereof per representative for inspection and investigative work; $132.56 per hour or fraction thereof per representative for analytical or review work; $0.655 per mile (plus tolls) for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate 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. Defendants shall notify FDA within fifteen (15) business days of any change to the email address at which Defendants receive electronic invoices.

14. Within ten (10) calendar days of the entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' Facilities and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

15. Within ten (10) calendar days of the date of entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, attorneys, employees, successors and assigns, and any and all persons or entities in active concert or participation with any of them. Within thirty (30) calendar days of the date of entry of this Decree, 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 persons who have received a copy of this Decree.

16. In the event that any of the Defendants becomes 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, electronic mail (with read-receipts), or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Within ten (10) calendar days of each time any of the 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 ten (10) calendar days of 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.

17. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their 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 the corporate Defendants, 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 prospective successor or assign at least thirty (30) calendar days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) calendar days prior to such assignment or change in ownership.

18. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the Director of FDA's Office of Pharmaceutical Quality Operations Division I, at ORAPHARM1_RESPONSES@fda.hhs.gov.

19. If Defendants fail to comply with any provision of the Act, its implementing regulations, and/or this Decree with respect to any of Defendants' products and/or Defendants' Facilities, including any time frame imposed by this Decree, then, on written notice of FDA in this proceeding, Defendants shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation; and further additional sum equal to the retail value of drugs that have been received, manufactured, processed, packed, repacked, labeled, held, and/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.

20. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

21. 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 the decision was made. No discovery shall be taken by either party.

22. If Defendant Badia ceases to be affiliated in any capacity (*e.g.*, as owner, director, officer, employee, or consultant), directly or indirectly with Pharmasol Corporation or any of its affiliates (including but not limited to franchises, "doing business as" entities, subsidiaries, successors, or assigns), then he may provide FDA an affidavit setting forth the facts and manner of his employment along with supporting documentation. If Defendant Badia has submitted evidence satisfactory to the United States that he is no longer affiliated with Pharmasol Corporation or any of its affiliates, he will have no liability under this Decree for any acts or omissions by Pharmasol Corporation or any of its affiliates after the date Defendant Badia's affiliation ends.

23. Defendant Badia shall notify FDA within twenty (20) calendar days after he ceases to be affiliated in any capacity, directly or indirectly, with Pharmasol Corporation or any of its affiliates. Within thirty (30) calendar days after Defendant Badia ceases to be affiliated with Pharmasol Corporation or any of its affiliates, Pharmasol Corporation shall designate an individual of similar position and responsibilities to be named as an individual Defendant and notify FDA in writing of the identity and nature of employment of such individual. Pharmasol Corporation shall petition the Court to add this individual to the Decree, and the United States will not oppose such a motion so long as FDA has sufficient evidence or information regarding this individual's position and responsibilities. This new individually-named Defendant shall be bound by the Decree in the same manner as the originally named individual Defendant.

24. This Court retains jurisdiction over 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.

SO ORDERED, this 13th day of December, 2023.

/s/ Angel Kelley
UNITED STATES DISTRICT JUDGE

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