IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SHAMROCK MEDICAL SOLUTIONS GROUP, LLC, a limited liability company, and JOHN P. REICHARD, ROBERT E. TROOP, DAVID L. BYSTROM, and REBECCA H. MULLIS, individuals, Defendants.	)	Civil No. 2:13–cv–590 JUDGE MARBLEY MAGISTRATE JUDGE PRESTON DEAVERS

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Preliminary Injunction ("Complaint") against Shamrock Medical Solutions Group, a limited liability company ("Shamrock Medical"), and John P. Reichard, Robert E. Troop, David L. Bystrom and Rebecca H. Mullis, the "Individuals" (hereinafter Shamrock Medical and the Individuals are, 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 of this action and has personal jurisdiction over 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 *et seq.* (the "Act").

3. The complaint alleges Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), 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 distributed in violation of the current good manufacturing practice ("cGMP") requirements for drugs, see 21 C.F.R. Parts 210 and 211.

4. The complaint alleges Defendants violate the Act, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug after shipment in interstate commerce.

5. The complaint alleges Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. §§ 352(a) and (j).

6. The complaint alleges Defendants violate the Act, 21 U.S.C. § 331(k), by causing the misbranding, within the meaning of 21 U.S.C. §§ 352(a) and (j), of articles of drug after shipment in interstate commerce.

7. Upon entry of this Decree, Defendants represent to the Court that Defendants are not directly or indirectly engaged in manufacturing, processing, packing, labeling, holding, or distributing any article of drug. If Defendants later intend to resume manufacturing, processing, packing, labeling, holding, or distributing any article of drug at 741 Radio Drive, Lewis Center, Ohio, or to have ownership or control over any company, facility, or other entity engaged in the manufacturing, processing, packing, labeling, holding, or distributing any article of drug at or from any other location, Defendants must first notify FDA in writing at least ninety (90) calendar

days in advance of resuming such operations and Defendants shall comply with paragraphs 9(A) – (E) of this Decree. This notice shall include what type(s) of operations Defendants intend to resume and the facility in which Defendants intend to resume operations. Defendants shall not resume operations until FDA has inspected any such facility and operations pursuant to paragraph 9(F), Defendants have paid the cost of such inspection(s) pursuant to paragraph 17, and Defendants have received written notice from FDA, as required by paragraph 9(G), and then shall resume operations only to the extent authorized in FDA's written notice. Nothing in this paragraph prevents the Individual Defendants from obtaining employment involving the manufacturing, processing, packing, labeling, holding, or distribution of any article of drug while complying with the terms of this Decree, including but not limited to, paragraph 12.

8. Within 5 days after entry of this Decree, Defendants shall send a notification to each customer to whom Defendants distributed any drugs since May 2011. The notification shall include a list of all products Defendants distributed to each customer in that time period and request that the customer confirm the accuracy of the labels and/or destroy the drugs. Defendants shall simultaneously send copies of all such letters to FDA. Prior notification to customers by Shamrock Medical in March and April 2013 pursuant to Shamrock Medical's Action Plan shall be deemed to satisfy the requirements of this paragraph.

9. Upon entry of this Decree, Defendants, and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any articles of drug, or causing any of the foregoing, at or from any facility over which Defendants have ownership or control of the

operations, including but not limited to the facility located at 741 Radio Drive, Lewis Center, Ohio, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with cGMP. 21 U.S.C. § 351(a)(2)(B) and 21 C.F.R. Parts 210 and 211;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "cGMP expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' facilities to determine whether the methods, facilities, and controls are operated and administered in conformity with applicable laws and regulations, the Act, and this Decree, including but not limited to cGMP requirements related to packing and labeling. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the cGMP expert as soon as they retain such expert;

C. The cGMP expert performs a comprehensive inspection of Defendants' facilities and the methods and controls used to manufacture, process, pack, label, hold, and distribute drugs to determine whether they are in compliance with applicable laws and regulations, the Act, and this Decree. This inspection shall include, at a minimum:

(1) An evaluation as to whether Defendants have established a comprehensive written quality assurance (QA) and quality control (QC) program (QA/QC program) that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The expert shall determine whether the QA/QC program, at a minimum:

(a) Addresses all facets of compliance monitoring and trend analyses, and internal audit procedures, and confirms that Defendants' Quality Unit is adequately trained and staffed to evaluate cGMP compliance and prevent and correct future deviations from cGMP;

(b) Includes written procedures to ensure that Defendants, in a timely manner, thoroughly investigate (i) product deviations, (ii) reports of complaints about Defendants' products, and (iii) any unexplained discrepancy or failure of a batch of drug to meet any of the product's specifications, including the extension of such investigation to other batches of the same drug product and other drug products that may have been associated with the specific discrepancy or failure, and to take required and timely corrective actions for all products that fail to meet their specifications;

(c) Establishes mechanisms to ensure that written procedures are periodically evaluated to ensure they reflect acceptable cGMP compliant practices, and that these procedures provide for all facets of cGMP compliance to be reviewed and controlled by an independent QA unit;

(d) Includes written procedures to ensure that (i) Defendants' QA personnel are promptly notified in writing of all deviations and/or problems that could affect the safety, identity, strength, quality, and purity of any drug, (ii) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations and/or problems, and (iii) there are systems to ensure that such written procedures are continuously followed; and

(e) Includes written procedures that specify the responsibilities and procedures applicable to QA and QC personnel, and establishes systems to ensure that such procedures are followed; and

(2) An evaluation as to the adequacy of Defendants' (i) systems for issuance of labels and control of operations, (ii) written repackaging procedures and documentation of repackaging operations, (iii) systems for establishing and assigning expiration dates to drug products, (iv) procedures for creating and maintaining master batch and control records, and (v) systems and procedures for authorizing release of products for distribution;

D. The cGMP expert certifies in writing to FDA that: (1) he or she has inspected Defendants' facilities, methods, and controls; (2) all cGMP deviations brought to Defendants' attention since 2007 by FDA, the cGMP expert, or any other source, including but not limited to any experts hired prior to the entry of this Decree, have been corrected; and (3) Defendants' facilities, methods, and controls are in compliance with the requirements of applicable laws and regulations, the Act, and this Decree. As part of this certification, the cGMP expert shall include a detailed written report which addresses, at a minimum, each of the matters discussed in paragraph 9(C) above;

E. Defendants report to FDA in writing the actions they have taken to: (1)correct the cGMP deviations brought to Defendants' attention by FDA, the cGMP expert, and any other source, including but not limited to any experts hired prior to the entry of this Decree; and (2) 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 applicable laws and regulations, the Act, and this Decree;

F. FDA representatives inspect Defendants' facilities to determine whether the requirements of this Decree have been met, and whether Defendants' facilities are operating in compliance with the requirements of applicable laws and regulations, the Act, and this Decree.

FDA will commence such an inspection within forty-five (45) business days after receiving Defendants' paragraph 9(E) notification. FDA will notify Defendants within forty-five (45) business days of completing its inspection whether the facility appears to be in compliance, and if in compliance, issue to Defendants written notification pursuant to paragraph 9(G); and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in Paragraph 9(A)-(E). In no circumstance will FDA's silence be construed as a substitute for written notification.

10. Notwithstanding the injunction provisions in Paragraph 9 of this Decree:

A. Defendants may return to any of Shamrock Medical's customers or the customer's wholesaler on behalf of the customer, any bulk drug product the customer sent to Shamrock Medical, if the bulk product has not been repackaged pursuant to Shamrock Medical's unit dose repackaging operations;

B. Defendants may destroy retained samples of drugs in the possession of Shamrock Medical, including but not limited to controlled substances, in accordance with all applicable laws and regulations.

11. After Defendants have complied with Paragraph 9(A)-(E) and FDA has notified them pursuant to Paragraph 9(G), and if Defendants have ownership or control over manufacturing, processing, packing, labeling, holding, or distributing any article of drug at or from any location, Defendants shall retain an independent person or persons (the "auditor") who shall meet the criteria described in Paragraph 9(B) to conduct audit inspections of Defendants' facilities no less frequently than once every six (6) months for a period of no less than five (5) years. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to Paragraph 9(G). If Defendants choose, the auditor may be the same

person or persons retained as the cGMP expert in Paragraph 9(B). Defendants shall notify FDA in writing of the identity and qualifications of the auditor within five (5) calendar days after retention.

A. At the conclusion of each audit inspection, the auditor shall prepare a detailed written audit report ("audit report") analyzing whether Defendants are in compliance with applicable laws and regulations, the Act, and this Decree and identifying any deviations from applicable laws and regulations, the Act, and this Decree ("audit report observations"). As a part of every audit report, except the first audit report, the auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous audit report observations. The auditor shall deliver each audit report contemporaneously to Defendants and FDA no later than fifteen (15) calendar days after the date the audit inspection is completed. In addition, Defendants shall maintain the audit reports in separate files at their facilities and shall promptly make the audit reports available to FDA upon request.

B. If an audit report contains any observations indicating that Defendants are not in compliance with applicable laws and regulations, the Act, and this Decree, Defendants shall, within twenty (20) calendar days of receipt of the audit report, correct those observations, 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 twenty (20) 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 ("correction schedule") and provide justification describing why the additional time is necessary. The correction schedule must be reviewed and approved in writing by FDA. 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.

C. Within twenty (20) calendar days of Defendants' receipt of an audit report, unless FDA has notified 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 any audit report observations. Within five (5) calendar days of completing 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.

12. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and all persons in active concert or participation with any of them who receive notice of this Decree, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly:

A. Introducing or delivering for introduction into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

B. Causing any drug to be adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) while such drug is held for sale after shipment in interstate commerce;

C. Introducing or delivering for introduction into interstate commerce any drug that is misbranded within the meaning of 21 U.S.C. §§ 352(a) or 352(j); or

D. Causing any drug to be misbranded within the meaning of 21 U.S.C. §§ 352(a) or 352(j) while such drug is held for sale after shipment in interstate commerce;

13. 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 or the auditor, or any other information, that Defendants have failed to comply

with any applicable law and regulations, the Act, and/or this Decree, or that additional corrective actions are necessary to achieve such compliance, 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, processing, packing, labeling, holding, and/or distributing any or all drugs;

B. Recall, at Defendants' expense, any drugs that are adulterated, misbranded, or otherwise in violation of this Decree, the Act, 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. Assess liquidated damages, as provided by Paragraph 21 of this Decree; and

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

14. The following process and procedures shall apply when FDA issues an order under paragraph 13, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, within ten (10) days after receiving such an order, Defendants shall notify FDA in writing either that:

1. Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or

2. Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants also may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it 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 this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement FDA's order, unless 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 23 of this Decree.

D. The process and procedures set forth above in paragraphs 14(A)-(C) shall not apply to any order issued pursuant to paragraph 13 if such an order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition the Court for relief while they implement the order.

15. Any cessation of operations or other corrective action described in Paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in

compliance with applicable laws and regulations, the Act, and this Decree, and that Defendants may resume operations.

16. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted ready access to Defendants' facilities including, but not limited to, all buildings, equipment, drug products, containers, packaging, labeling, other promotional materials, and other documents and things therein; to take photographs and make video recordings; to take samples of Defendants' drug products, containers, packaging, and labeling; and to examine and copy all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' drug products. The costs of all such inspections, record reviews, and sample analysis shall be borne by Defendants at the rates specified in paragraph 17. 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.

17. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, reviews, examinations, and analyses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57 per hour and fraction thereof per representative for inspection work; $104.96 per hour and fraction thereof per representative for analytical or review work; $0.565 per mile for travel expenses by automobile, government rate or the equivalent for travel by air; 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.

18. Defendants shall provide notice of this Decree in the following manner:

A. Within five (5) calendar days of the entry of this Decree, Defendants shall provide a copy of the Decree, by personal service or by certified mail (return receipt requested), to each of Shamrock Medical's directors, officers, agents, employees, representatives, attorneys, successors, assigns, and all persons in active concert or participation with any of them. Within fifteen (15) calendar days of the 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 received a copy of this Decree pursuant to this paragraph;

B. Within five (5) calendar days of entry of this Decree, Defendants post a copy of this Decree on a bulletin board in a common area at Shamrock Medical's facility located at 741 Radio Drive, Lewis Center, Ohio, or at any other address and at any other facility that any of the Defendants own or control which is subject to or under the jurisdiction of the Act or the Public Health Service Act, and shall ensure that the Decree remains posted at each location for as long as the Decree remains in effect or Defendants' facilities remain open, whichever is shorter; and

C. If, after entry of this Decree, any of the Defendants becomes associated with any additional officers, agents, employees, attorneys, successors, assigns, or persons in active concert or participation with any of them at any facility that any of the Defendants own or control which is subject to or under the jurisdiction of the Act or the Public Health Service Act, that Defendant shall immediately provide a copy of this Decree, by personal service or by certified mail (return

receipt requested), to each such additional person. Within ten (10) calendar days of each time that any Defendant becomes associated with any additional 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 the additional person(s) who received a copy of this Decree pursuant to this paragraph.

19. Defendants shall notify FDA in writing, at least fifteen (15) calendar days before any change in ownership, name, or character of Shamrock Medical or any other operation that Defendants own or control involving the manufacturing, processing, packing, labeling, holding, or distributing any article of drug that occurs after entry of this Decree, including relocation, incorporation, reorganization, creation of a subsidiary, dissolution, bankruptcy, assignment, sale or any other change in the structure or identity of Shamrock Medical, 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 assignee of Shamrock Medical at least ten (10) 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.

20. All communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the Director, Cincinnati District Office, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237, and shall reference this civil action by case name and civil action number.

21. If Defendants fail to comply with the Act, its implementing regulations, and/or any provision of this Decree, including any time frame imposed by this Decree, Defendants shall pay liquidated damages to the United States of America as follows: (a) ten thousand dollars

($10,000) for each violation of the Act, its implementing regulations, and/or this Decree; (b) an additional five thousand dollars ($5,000) in liquidated damages for each day on which Defendants violate the Act, its implementing regulations, and/or this Decree; and (c) an additional sum equal to twice the retail value of any distributed drugs that are adulterated, misbranded, or otherwise 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.

22. 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, expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to the contempt proceeding.

23. 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.

24. This Court retains jurisdiction over this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

25. The parties may, at any time, petition each other in writing to extend any deadline provided herein, and the parties may grant such extension without seeking leave of Court.

SO ORDERED, this 17 day of September, 2013.

UNITED STATES DISTRICT JUDGE

Entry consented to:
For Defendants

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