JS-6

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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, vs. 577 CARTONS, MORE OR LESS, EACH CARTON CONTAINING 21 KILOGRAMS OF AN ARTICLE OF DRUG, LABELED IN PART: (CARTON) "*** DRIED HERBAL LEAF *** MITRAGYNA SPECIOSA *** MADE IN INDONESIA *** NOT FOR HUMAN CONSUMTION *** BATCH	NO. CV 14-6729 PA (MRWx) CONSENT DECREE OF CONDEMNATION, DESTRUCTION, AND PERMANENT INJUNCTION

cc. USMS, Fiscal

NO.: *** WEIGHT: *** 21 KGS ***"

AND

ALL OTHER QUANTITIES OF THE ABOVE ARTICLE OF DRUG, IN ANY SIZE AND TYPE OF CONTAINER, THAT ARE LOCATED ANYWHERE ON THE PREMISES OF ROSEFIELD MANAGEMENT, INC., 7660 GLORIA AVENUE, VAN NUYS, CALIFORNIA AND WHICH ARE LABELED OR OTHERWISE DETERMINED TO HAVE ORIGINATED OUTSIDE OF THE STATE OF CALIFORNIA,

Defendants.

ROSEFIELD MANAGEMENT, INC.,

Claimant.

On August 27, 2014, the United States filed a Verified Complaint for Forfeiture *In Rem* ("Verified Complaint") against the above-described articles "Articles").

The Verified Complaint alleges that the Articles are a drug within the meaning of 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and that they are a new drug within the meaning of 21 U.S.C. § 321(p), because they are not generally recognized by qualified experts as safe and effective under conditions of use recommended or suggested in their labeling. The Verified Complaint alleges that such Articles may not, under 21 U.S.C. § 355(a), be introduced or delivered for introduction into interstate commerce, because they are new drugs within the meaning of 21 U.S.C. § 321(p) and no approvals of applications filed

pursuant to 21 U.S.C. § 355(b) or exemptions from such requirements pursuant to 21 U.S.C. § 355(i) are in effect for such drugs. The Verified Complaint also alleges that such Articles are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use, and they are not exempt from such requirement under 21 C.F.R. § 201.115. The Verified Complaint requests that the above-described Articles be condemned and disposed of by order of the Court.

Pursuant to a Warrant of Arrest *In Rem* issued by the Court, the United States Marshal for this District seized the Articles on September 25, 2014, at a warehouse located at 7660 Gloria Avenue, Van Nuys, California, within the Central District of California (the "Warehouse"). Thereafter, the United States caused notice of the Verified Complaint and seizure to be published in accordance with the applicable rules of this Court and Rule G of the Supplemental Rules for Admiralty or Maritime and Asset Forfeiture Claims of the Federal Rules of Civil Procedure ("Supplemental Rules").

On October 28, 2014, Rosefield Management, Inc. ("Claimant"), through its attorney, intervened and filed a Verified Claim with respect to the seized Articles in accordance with the Supplemental Rules. Claimant is a California incorporated firm located at 7660 Gloria Ave., Van Nuys, California (the "Facility"). Claimant claims a bona fide possessory interest in the defendant Articles as bailee. No other party has filed a claim to the Articles, and the time for filing claims has expired.

Claimant affirms that it will hold the United States harmless should any party or parties hereafter file or seek to file a claim to intervene in this action, or seek to defend or to obtain any part of the Articles subject to this Decree, or assert any claim against the United States arising from the seizure, condemnation, and destruction of the seized Articles. Claimant hereby releases the United States from any claims it may have against the United States arising from the seizure, condemnation, and destruction of the seized Articles.

WHEREAS Claimant having appeared and consented, without contest, to entry of this Decree after filing a Verified Answer and before any testimony has been taken, and waiving the filing and service of an amended complaint seeking injunctive relief, and the United States having consented to the entry of this Decree, pursuant to the request of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. §§ 332 and 334, and personal jurisdiction over all parties to this action. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1395.

2. The Articles are a drug within the meaning of 21 U.S.C. § 321(g)(1)(B), in that they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man.

3. The Articles are a "new drug" within the meaning of 21 U.S.C. § 321(p), because no approvals of applications filed under 21 U.S.C. § 355(b) or exemptions from such requirements under 21 U.S.C. § 355(i) are in effect for such drug and, therefore, the Articles may not be introduced or delivered for introduction into interstate commerce under 21 U.S.C. § 355(a).

4. The Articles are misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(1), in that their labeling fails to bear adequate directions for use and they are not exempt from such requirement under 21 C.F.R. § 201.115 because the Articles are an unapproved new drug.

5. The seized Articles, therefore, are condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

6. Claimant shall pay to the United States all court costs and fees, storage, and other proper expenses, including the cost of destroying the condemned Articles, and such further costs for which it is liable pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within ten (10) business days after

receiving notice of such costs from the United States Food and Drug Administration ("FDA"), the United States Marshals Service (the "USMS"), and/or the United States Department of Justice ("DOJ").

7. Within five (5) business days after the entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient penal bond ("Bond"), in the form of a cashier's check acceptable to the Clerk of this Court in the amount of Ten Thousand Dollars ($10,000) and payable to the United States of America, to be applied to Lot 1 (as described in Subpart A of Paragraph 10 of this Decree) and held for application to succeeding Lots (as described in Subparts B-C of Paragraph 10 of this Decree). The Bond shall be conditioned on Claimant abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

8. Within twenty (20) business days after filing the Bond pursuant to Paragraph 7, Claimant shall give written notice that Claimant, at its own expense and under FDA's supervision, is prepared to destroy the condemned Articles. Claimant's notice shall specify the proposed time, place, and method of destruction of the condemned Articles (the "Destruction Plan").

9. Claimant shall not commence or permit any other person to commence destroying the condemned Articles until it has received written authorization from FDA to commence the destruction.

10. Following Claimant's payment of costs and posting of the Bond, as required by Paragraphs 6 and 7 of this Decree, the USMS, upon notice from FDA that Claimant is authorized to commence destroying the condemned Articles, shall release the appropriate Lot of the condemned Articles (as described in Subparts A-C, below) from its custody to the custody of Claimant solely for Claimant to destroy it in compliance with the Destruction Plan described in Paragraph 8 and under FDA supervision. The schedule for release of the Articles is as follows:

A. The Articles in Lot 1, consisting of approximately 1/8 of the Articles (by value), to be further designated by the FDA representative, stored at the California Warehouse, shall be released to Claimant for the sole purpose of destroying it in compliance with the Destruction Plan described in Paragraph 8 under FDA supervision.

B. If and only if Claimant complies with all of the terms of this Decree with respect to Lot 1, and Lot 1 has been released to Claimant in writing by FDA, the Articles in Lot 2, consisting of approximately a second 1/8 of the seized Articles (by value), to be further designated by the FDA representative, at the California Warehouse, shall be released to Claimant for the sole purpose of destroying it in compliance with the Destruction Plan described in Paragraph 8 under FDA supervision.

C. Each successive Lot, *i.e.*, Lots 3 through 8, each consisting of approximately 1/8 of the Articles (by value), to be further designated by the FDA representative, stored at the California Warehouse, shall be released to Claimant for the sole purpose of destroying it in compliance with the Destruction Plan described in Paragraph 8 under FDA supervision, if and only if Claimant complies with all of the terms of this Decree with respect to each preceding Lot, and each preceding Lot has been released to Claimant in writing by FDA. Within fifteen (15) business days after receiving written authorization from FDA to commence destroying the condemned Articles, Claimant shall, under FDA supervision, complete the destruction of the condemned Articles in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in Paragraph 22 of this Decree, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

11. Claimant shall at all times, until all of the condemned Articles have been destroyed pursuant to Paragraph 10, retain the condemned Articles in its custody intact for examination or inspection by FDA in a place made known to and

approved by FDA, and shall maintain all records or other proof necessary to establish the identity of the condemned Articles to FDA's satisfaction.

12. Claimant shall not cause the condemned Articles to be disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which it is disposed.

13. If Claimant breaches any condition of this Decree, or any subsequent decree or order in this proceeding, it shall, at its own expense, immediately return to the USMS any and all remaining condemned Articles in its custody that have been released for destruction pursuant to Paragraph 10. Following return of the condemned Articles, the USMS shall destroy the condemned Articles and make due return to this Court regarding their disposition. In the event that return of any of the condemned Articles becomes necessary under this paragraph, Claimant shall be responsible for all costs of storage and disposition incurred by the United States.

14. If Claimant does not avail itself of the opportunity to repossess and destroy the condemned Articles in the manner provided in this Decree, or if any portion of the condemned Articles remains in the USMS's custody after expiration of the twenty (20) day time period described in Paragraph 8, the USMS will destroy such condemned Articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the United States pursuant to this paragraph, and shall pay such costs within ten (10) business days after receiving an invoice from FDA, the USMS, and/or DOJ.

15. If Claimant fails to abide by and perform all the terms and conditions of this Decree, or of the Bond, or any such further order or decree as may be entered in this proceeding relating to the condemned Articles, then, on motion of the United States in this proceeding, the Bond shall be forfeited in its entirety to the United States and judgment entered thereon in favor of Plaintiff, and any

condemned Articles remaining in the custody of the USMS shall be forfeited and disposed of pursuant to further order of this Court.

16. No later than ten (10) days after being advised by FDA that all of the condemned Articles have been destroyed in compliance with this Decree and that Claimant has paid all costs as of that date in accordance with Paragraphs 6 and 10, Plaintiff shall transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be discharged and returned to Claimant.

17. Upon entry of this Decree, Claimant and each and all of its agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (the "Associated Person(s)") who receive notice of this Decree are hereby 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 the Act, 21 U.S.C. § 331(d), and results in the introduction or delivery for introduction into interstate commerce of new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(b), nor exempt from approval pursuant to 21 U.S.C. § 355(i); or

B. Violates the Act, 21 U.S.C. § 331(a), and results in the introduction or delivery for introduction into interstate commerce of drugs that are misbranded in that their labeling fails to bear adequate directions for use.

18. Upon entry of this Decree, Claimant and each and all of its Associated Person(s) who receive notice of this Decree are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) from:

A. Introducing or delivering for introduction into interstate commerce or causing the introduction or delivery for introduction into interstate commerce of *Mitragyna speciosa* or kratom, or any product labeled similarly to such products and/or containing the same active ingredient; or any other product that is a new drug within the meaning of 21 U.S.C. § 321(p), unless and until an

approved new drug application or an investigational new drug application filed by Claimant pursuant to 21 U.S.C. §§ 355(b) or (i) is in effect for such drugs;

B. Introducing or delivering for introduction into interstate commerce or causing the introduction or delivery for introduction into interstate commerce of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use, including but not limited to *Mitragyna speciosa* or kratom.

19. Upon entry of this Decree, if at any time FDA determines, based on the results of an inspection, the analysis of a sample, a report, or any other information, that Claimant has failed to comply with any provision of this Decree, has violated the Act or its implementing regulations, and/or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Claimant in writing of the noncompliance and order Claimant to take appropriate corrective action, including, but not limited to, ordering Claimant to immediately take one or more of the following actions:

A. Cease importing and/or distributing any or all drugs that are unapproved new drugs, drugs that are misbranded because their labeling fails to bear adequate directions for use, and/or drugs that are otherwise in violation of this Decree, the Act, or its implementing regulations;

B. Recall, at Claimant's expense, any unapproved new drugs, drugs that are misbranded because their labeling fails to bear adequate directions for use, and/or drugs that are otherwise in violation of this Decree, the Act, or its implementing regulations, that were imported and/or distributed by Claimant;

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 as requested;

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

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

20. Upon receipt of any order issued by FDA pursuant to Paragraph 19, Claimant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 19 shall continue until Claimant receives written notification from FDA that Claimant appears to be in compliance with this Decree, the Act, and its implementing regulations, and that Claimant may, therefore, resume operations.

21. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of the Facility, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and FDA regulations. During inspections of the Facility, 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; take photographs and make video recordings; take samples of raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other material; and examine and copy all records relating to the manufacture, preparing, packing, labeling, holding, and distribution of any and all drugs and their respective components. 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.

22. Claimant shall reimburse the United States for the costs of supervising Claimant's destruction of the condemned Articles, and for costs associated with all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are

accomplished. As of the date this Decree is signed by the parties, the rates are $88.45 per hour or fraction thereof per representative for supervision other than laboratory and analytical work; $106.03 per hour or fraction thereof per representative for laboratory and analytical work; and $.56 per mile 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.

23. Within ten (10) business days after entry of this Decree, Claimant shall post a copy of this Decree in a common area at the Facility and shall ensure that the Decree remains posted for as long as it remains in effect. In the event that Claimant relocates its facility, Claimant shall ensure that a copy of the Decree is posted in a common area at the new facility. Within twenty (20) business days after entry of this Decree, Claimant shall provide an affidavit stating the fact and manner of its compliance with this paragraph.

24. Within ten (10) business days after entry of this Decree, Claimant shall provide a copy of the Decree by domestic or international express mail (*e.g.*, DHL, Federal Express, or U.S. Postal Service) (restricted delivery, written confirmation of receipt) to each of the Associated Person(s). Within ten (10) business days after entry of this Decree, Claimant shall provide a copy of the Decree by domestic or international express mail (*e.g.*, DHL, Federal Express, or U.S. Postal Service) (restricted delivery, written confirmation of receipt) to Wholesale Shamanic Herbs; C.V. Bali Herbal of Indonesia; and any other entity with which Claimant has contracted to distribute the Articles into interstate commerce. Within twenty (20) business days after entry of this Decree, Claimant

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.

25. In the event that Claimant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Claimant shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time Claimant becomes associated with an additional Associated Person(s), it shall, within ten (10) business days, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, identifying the names, addresses, and positions of all Associated Person(s) who 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, Claimant shall provide such information or documentation to FDA.

26. Claimant shall notify FDA in writing at least ten (10) 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 Claimant, or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Claimant shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Claimant shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

27. Claimant shall abide by the decisions of FDA and its representatives, which shall be final. All decisions specified in this Decree shall be vested in

FDA's discretion and, if necessary, shall be reviewed by this Court pursuant to the arbitrary and capricious standard as set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this Decree shall be based exclusively upon the written record before FDA at the time of the decision. No discovery shall be taken by either party.

28. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall reference the civil action number CV 14 6729 (C.D. Cal.), be prominently marked "Rosefield Management, Inc.," and be addressed to:

District Director
Los Angeles District Office
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

29. Should Claimant fail to comply with any provision of this Decree, the Act, or its implementing regulations, it shall pay to the United States of America the sum of twenty thousand dollars ($20,000) in liquidated damages for each day such violation continues and an additional sum of seven thousand five hundred dollars ($7,500) 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 unapproved new drug and/or a drug that is misbranded in that its labeling fails to bear adequate directions for use in liquidated damages for each such unlawful shipment. Claimant understands and agrees 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 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.

30. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, Claimant shall, in addition to other remedies,

reimburse the United States 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.

31. If Claimant has maintained to FDA's satisfaction a state of continuous compliance with the Act, applicable regulations, and this Decree for at least sixty (60) months after satisfying all of its obligations under this Decree, Claimant may petition this court for relief from this Decree, and the United States will not oppose such petition.

32. 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.

SO ORDERED.

DATED: December 1, 2014

THE HONORABLE PERCY ANDERSON
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Consent Decree:

Dated: November 26, 2014

STEPHANIE YONEKURA
Acting United States Attorney
ROBERT E. DUGDALE
Assistant United States Attorney
Chief, Criminal Division

/s/
STEVEN R. WELK
Assistant United States Attorney
Chief, Asset Forfeiture Section

Attorneys for Plaintiff
United States of America

Dated: November 24, 2014

/s/
PHILIP H.R. NEVINNY

Attorney for Claimant
Rosefield Management, Inc.

Dated: November 24, 2014

/s/
MARK H. ROSE
President of Claimant Rosefield Management, Inc., on behalf of Rosefield Management, Inc.