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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. VIVACEUTICALS, INC., et al., Defendants.	)	Civil No. 8:15-cv-01893-JLS-KES

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against VivaCeuticals, Inc., doing business as Regeneca Worldwide, a corporation, and Matthew A. Nicosia, an individual (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, without admitting or denying the allegations in the Complaint, and before any testimony has been taken, and the

United States of America having consented to this Decree;

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

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

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 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 articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"), set forth in 21 C.F.R. Part 111;

B. Adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i) in that they contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a); and/or

C. Misbranded within the meaning of 21 U.S.C. § 343(a)(1) because their labeling is false or misleading.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that are held for sale after shipment of one or more components in interstate commerce to become:

A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1);

B. Adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(i); and/or

C. Misbranded within the meaning of 21 U.S.C. § 343(a)(1).

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

for introduction, into interstate commerce a new drug, as defined by 21 U.S.C. § 321(p), that is neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing an article of drug that is held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1) because its labeling fails to bear adequate directions for use.

7. 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 (including parent companies, holding companies, subsidiaries, affiliates, franchisees, "doing business as" entities, "consultants," "independent contractors," "independent business owners," and any other persons engaged in any part of the manufacture, preparing, packing, labeling, holding, and/or distribution of Defendants' products) (hereinafter, collectively referred to as "Associated Persons"), who have received actual notice of this Decree by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any articles of food (including but not limited to dietary supplements and their components) and/or articles of drug, at or from 2 Park Plaza, Suite 1200, Irvine, California 92614, or 16 Technology Drive, Suite 124, Irvine, California 92618, or at or from any other location(s) at which Defendants now or in the future directly or indirectly receive, manufacture, prepare, pack, repack, label, hold, or distribute any articles of food (including but not limited to dietary supplements and their components) and/or articles of drug (referred to as "Defendants' Facility" or "the Facility") unless and until:

A. Defendants retain, at Defendants' expense, an independent

person (the "CGMP Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect the Facility to determine whether Defendants' methods, processes, and controls are: (1) operated and administered in conformity with Dietary Supplement CGMP (21 C.F.R. Part 111); (2) adequate to ensure that none of the dietary supplements that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a); and (3) adequate to ensure that none of the products that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that Defendants market as, or intend to market as, dietary supplements, contain an article "approved as a new drug" or "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B);

B. Defendants notify FDA in writing of the identity and qualifications of the CGMP Expert within three (3) business days of retaining such expert, and the CGMP Expert:

1. Performs a comprehensive inspection of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements;

2. Certifies in writing to FDA that:

(a) He or she has inspected the Facility, methods, processes, and controls;

(b) All deviations from Dietary Supplement CGMP, the requirements in 21 U.S.C. § 348(a), and the provisions in 21 U.S.C. § 321(ff)(3)(B), that have been brought to Defendants' attention by FDA, the CGMP Expert, and any other source since April 2011, have been corrected; and

(c) Defendants' Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, or

distribute dietary supplements are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations; and

3. Prepares a detailed report, which shall be submitted to FDA as part of the certification described in paragraph 7(B)(2), of the CGMP Expert's inspection that shall include, but not be limited to, a determination that:

(a) Defendants have implemented corrections to their facilities, methods, processes, and controls that are adequate to ensure that they comply with Dietary Supplement CGMP and at a minimum:

(i) Establish an identity specification for each component as well as component specifications to ensure that specifications for the purity, strength, and composition of the finished batch of dietary supplements manufactured using the component are met, as required by 21 C.F.R. § 111.70(b);

(ii) Establish product specifications for the identity, purity, strength, and composition of the finished batch of dietary supplements, and for limits on the types of contamination that may adulterate, or may lead to adulteration of, the finished batch of the dietary supplements to ensure its quality, as required by 21 C.F.R. § 111.70(e);

(iii) Conduct at least one appropriate test or examination to verify the identity of every component that is a dietary ingredient before using such component, as required by 21 C.F.R. § 111.75(a)(1)(i);

(iv) Determine whether component specifications that must be established in accordance with 21 C.F.R. § 111.70(b) are met before using such component, as required by 21 C.F.R. § 111.75(a)(2);

(v) Prepare and follow a complete written master manufacturing record for each unique formulation of dietary supplements, and for each batch size, to ensure uniformity in the finished product from batch to batch, as required by 21 C.F.R. § 111.205;

(vi) Prepare a batch production record every

time a batch of dietary supplements is manufactured, as required by 21 C.F.R. § 111.255;

(vii) Establish and follow written procedures for the responsibilities of the quality control operations set forth in 21 C.F.R. § 111.105, as required by 21 C.F.R. § 111.103;

(viii) Establish and follow written procedures for holding and distribution operations, as required by 21 C.F.R. § 111.453, and make and keep written procedures for holding and distribution operations and records of product distribution, as required by 21 C.F.R. § 111.475(b);

(ix) Establish and follow written procedures for returned dietary supplements, as required by 21 C.F.R. § 111.503; and

(x) Establish and follow written procedures for the review and investigation of product complaints, as required by 21 C.F.R. § 111.553.

(b) Defendants have methods, processes, and controls that are adequate to ensure that none of the dietary supplements that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a), and that none of the products that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that Defendants market as, or intend to market as, dietary supplements, contain an article "approved as a new drug" or "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B). Such methods, processes, and controls shall include but not be limited to:

(i) Establishing and maintaining written requirements, including quality requirements, that must be met by independent contractors and consultants who are engaged in manufacturing, packing, and/or labeling products for Defendants;

(ii) Documenting in writing that independent

contractors and consultants who engage in manufacturing, packing, and/or labeling products for Defendants meet the requirements established under this subparagraph, and retaining records of such documentation;

(iii) Conducting periodic evaluations of independent contractors and consultants who engage in manufacturing, packing, and/or labeling products for Defendants to ensure that the independent contractors and consultants continuously meet the requirements established under this subparagraph, and maintaining records of such evaluations; and

(iv) Establishing and implementing the laboratory testing program described in paragraph 9.A;

C. Defendants retain, at Defendants' expense, an independent person (the "Labeling Expert") who is without any personal or financial ties (other than a retention agreement) to Defendants and/or their families, except that this person may be the same as the CGMP Expert described in paragraph 7(A), and who, by reason of background, training, education, or experience, is qualified to review Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material to determine whether: (1) the labeling complies with 21 U.S.C. § 343(a)(1) and applicable regulations; and (2) Defendants' claims cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1);

D. Defendants notify FDA in writing of the identity and qualifications of the Labeling Expert within three (3) business days of retaining such expert, and the Labeling Expert:

1. Conducts a comprehensive review of Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material;

2. Certifies in writing to FDA that:

(a) He or she has reviewed Defendants' dietary supplement labeling and other promotional/informational material;

(b) All labeling violations brought to Defendants' attention by FDA, the Labeling Expert, or any other source since April 2011, have been corrected; and

(c) Defendants' dietary supplement claims are, in the Labeling Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations; and

3. Prepares a detailed report, which shall be submitted to FDA as part of the certification described in paragraph 7(D)(2), of the Labeling Expert's review that shall include, but not be limited to, a determination that:

(a) Defendants have implemented procedures that are adequate to ensure that their dietary supplement labeling complies with 21 U.S.C. § 343(a)(1) and applicable regulations; and

(b) Defendants have implemented procedures that are adequate to ensure that their claims do not cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), (j);

E. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 8, all dietary supplements and/or articles of drug that were received, manufactured, prepared, packed, repacked, labeled, held, or distributed between June 1, 2011, and the date of entry of this Decree;

F. Defendants report to FDA in writing the actions they have taken to:

1. Correct the Dietary Supplement CGMP and labeling deviations brought to Defendants' attention by FDA, the CGMP Expert, the Labeling Expert, and any other source;

2. Ensure that the facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are and will be continuously operated in conformity with Dietary Supplement CGMP;

3. Ensure that none of the dietary supplements that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a);

4. Ensure that Defendants' dietary supplement labeling complies with 21 U.S.C. § 343(a)(1) and applicable regulations;

5. Ensure that none of the products that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that Defendants market as, or intend to market as, dietary supplements, contain an article "approved as a new drug" or "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B)*;* and

6. Ensure that Defendants' claims do not cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

G. As and when FDA deems necessary, FDA representatives inspect Defendants' Facility, including the buildings, equipment, products, labeling, and all relevant records contained therein, to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Decree;

H. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 7, at the rates set forth in paragraph 15; and

I. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 7(A)-(F) and (H) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Within twenty (20) business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements and/or articles of drug that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any products 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 products are disposed.

9. Upon resuming operations after complying with paragraphs 7(A)-(F) and (H), and receiving FDA's written notification pursuant to paragraph 7(I), Defendants shall meet the following requirements:

A. Defendants shall select an independent laboratory that is without any personal or financial ties (other than a service contract) to Defendants and/or their families and that, by reason of background, training, education, or experience, is qualified to analyze dietary supplements and/or articles of drug to determine whether the products contain any unsafe food additive and/or active pharmaceutical ingredient, and Defendants notify FDA in writing of the identity and qualifications of the laboratory within three (3) business days of retaining such laboratory. Thereafter:

1. For each batch of product that Defendants directly or indirectly receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that is a dietary supplement or that Defendants market as, or intend to market

as, a dietary supplement, Defendants shall have the laboratory conduct testing, using analytical methods acceptable to FDA, to verify that the batch does not contain: (a) any unsafe food additive within the meaning of 21 U.S.C. § 348(a), including but not limited to 1,3-dimethylamylamine (DMAA) and its chemical equivalents; or (b) any phosphodiesterase type-5 (PDE-5) inhibitor that is an article "approved as a new drug" or "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B), including but not limited to sildenafil, tadalafil, vardenafil, and their analogs;

2. Defendants shall not release for distribution any batch of product until they have received and reviewed the laboratory analyses conducted pursuant to this paragraph, and such analyses have verified that the batch does not contain any of the substances described in subparagraph 9(A)(1);

3. If any laboratory analysis conducted pursuant to this paragraph detects the presence of any substance described in subparagraph 9(A)(1), Defendants shall:

(a) Have the laboratory contemporaneously provide to FDA and Defendants the results of those analyses within one (1) business day after the laboratory obtains such results;

(b) Destroy, at Defendants' expense and under FDA's supervision, all products from each batch that tested positive for the presence of any substance described in subparagraph 9(A)(1); and

(c) Reassess Defendants' methods, processes, and controls for ensuring that none of the dietary supplements that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute contain a food additive that is unsafe within the meaning of 21 U.S.C. § 348(a), and that none of the products that Defendants receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that Defendants market as, or intend to market as, dietary supplements, contain an article "approved as a new drug" or "authorized for

investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B); and revise their methods, processes, and/or controls accordingly, and submit such revisions in writing for FDA's written approval; and

4. If, after notifying FDA of the name of the laboratory retained to conduct testing pursuant to this paragraph, Defendants terminate their service contract with the laboratory, Defendants shall notify FDA within three (3) business days of such termination, select another laboratory that meets the criteria in paragraph 9(A) to conduct the testing described therein, and notify FDA in writing of the identity and qualifications of the newly retained laboratory within three (3) business days of retaining such laboratory; and

B. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for, and may be the same person(s) as, the CGMP Expert and Labeling Expert described in paragraphs 7(A) and 7(C), to conduct audit inspections of the Facility and the methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, and of Defendants' dietary supplement labeling (including but not limited to labels, catalogs, and websites) and other promotional/informational material. Thereafter:

1. The Auditor shall conduct audit inspections no less frequently than once every six (6) months for a period of no less than three (3) years and then at least once every year thereafter. The first audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 7(I);

2. 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 this Decree, the Act, and its implementing regulations and identifying any deviations from such requirements ("Audit Report Observations"). As a part of every Audit Report (except the first one), the Auditor

shall assess the adequacy of actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than five (5) business days after the audit inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' Facility and shall promptly make the Audit Reports available to FDA upon request; and

3. If an Audit Report contains any Audit Report Observations, Defendants shall, within ten (10) business days after 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 Audit Report Observations will take longer than ten (10) business days, Defendants shall, within five (5) business days after 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 completion of all corrections, Defendants shall submit documentation of their corrections to the Auditor. Within twenty (20) business days after the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or, if there is an FDA-approved Audit Correction Schedule, within the time period provided therein, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days after 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.

10. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 7(I), Defendants are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or U.S.C. § 342(a)(2)(C)(i);

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are misbranded within the meaning of 21 U.S.C. § 343(a)(1);

C. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements and their components) that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or U.S.C. § 342(a)(2)(C)(i);

D. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements and their components) that are held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343(a)(1);

E. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

F. Violating 21 U.S.C. § 331(k) by causing articles of drug that are held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

G. Failing to implement and continuously maintain the requirements of this Decree.

11. 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, Labeling Expert, Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, Defendants have violated the Act or its implementing regulations, or 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 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 receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing any and all products;

B. Recall, at Defendants' expense, any product that in FDA's judgment is 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, plans, procedures, or other records prepared, or laboratory testing program conducted, pursuant to this Decree;

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

E. Submit additional samples to a qualified laboratory for analysis;

F. Institute or reimplement any of the requirements set forth in this Decree;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or 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.

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

A. Unless a different time frame 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 so doing, 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 so choose, bring the matter before this 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 FDA's order. Judicial review of FDA's order shall be

made pursuant to paragraph 23.

D. The processes and procedures set forth in paragraphs 12.A-C shall not apply to any order issued pursuant to paragraph 11 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, 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 judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 23.

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 Act, and its implementing regulations, and that Defendants may resume operations. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 11, at the rates specified in paragraph 15.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business including, but not limited to all 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 receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of any and all of Defendants' products 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.

14. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, preparing, packing, repacking, labeling, holding, and distribution of Defendants' products.

15. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, 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. As of the date that this Decree is signed by the parties, these rates are: $90.65 per hour or fraction thereof per representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile 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 make payment in full to FDA within twenty (20) business days of receiving written notification from FDA of the costs.

16. Within five (5) business days after entry of this Decree, Defendants shall post a copy of this Decree in a conspicuous location in a common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten (10) business days after entry of this

Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

17. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree, either in person or via video conference or webinar. Within fifteen (15) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

18. Within ten (10) business days after 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 Associated Persons. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

19. 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 or certified mail (return receipt requested) to such Associated Person(s). Within five (5) business days of each time that any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and

positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

20. Defendants shall notify FDA in writing at least ten (10) business 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 VivaCeuticals, Inc., or Regeneca Worldwide, 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 twenty (20) business days prior to any sale or assignment. Defendants 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.

21. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: eight thousand dollars ($8,000) in liquidated damages for each day such violation continues; an additional sum of seven thousand dollars ($7, 000) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. 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 to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

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 (including overhead), 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 such contempt proceedings.

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, to the extent that these decisions are subject to review, shall be reviewed by the 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. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to the District Director, Los Angeles District Office, United States Food and Drug Administration, 19701 Fairchild, Irvine, California 92612-2506, and shall reference this civil action by case name and civil action number.

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

26. 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 ___ day of _____, 2016.

_____

HON. JOSEPHINE L. STATON

UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

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Individually and on behalf of
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Worldwide

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