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21 **UNITED STATES DISTRICT COURT**
 22 **FOR THE CENTRAL DISTRICT OF CALIFORNIA**

<p>23 UNITED STATES OF AMERICA, 24 25 Plaintiff, 26 27 v. 28 CLIFFORD WOODS LLC, a limited liability company d/b/a VIBRANT LIFE, and CLIFFORD WOODS, an individual, Defendants.</p>	<p>No. 2:15-cv-8889-DDP- JEM</p> <p>CONSENT DECREE OF PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF</p>
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Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Injunction and Other Equitable Relief against Clifford Woods, LLC, a limited liability company doing business as Vibrant Life, and Clifford Woods, an individual (collectively, “Defendants”), and Defendants having

1 appeared and consented to entry of this Decree without contest and before any
2 testimony has been taken, and the United States of America having consented to
3 this Decree;

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

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

7 2. The Complaint states a cause of action against Defendants under the
8 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the “Act”), and
9 the civil fraud injunction statute, 18 U.S.C. § 1345 (“Section 1345”).

10 3. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering
11 for introduction, or causing to be introduced or delivered for introduction, into
12 interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither
13 approved under 21 U.S.C. § 355 nor exempt from approval.

14 4. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for
15 introduction, or causing to be introduced or delivered for introduction, into
16 interstate commerce drugs that are misbranded within the meaning of 21 U.S.C.
17 § 352(f)(1) because their labeling fails to bear adequate directions for use.

18 5. Defendants violate 18 U.S.C. §§ 1341 and 1343 by promoting, selling,
19 and receiving money in exchange for products to cure, mitigate, treat, or prevent a
20 disease despite the absence of well-controlled clinical studies or any other credible
21 scientific substantiation to support those representations, and by (1) doing so using
22 the United States mail and/or a private or commercial interstate carrier and (2)
23 transmitting writings by wire in interstate commerce for the purpose of executing
24 such scheme or artifice.

25 6. This Court has authority pursuant to 21 U.S.C. § 332(a), and inherent
26 authority, to order injunctive and other equitable relief remedying the unlawful
27 activities described in paragraphs 3 and 4. This Court has authority pursuant to 18
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1 U.S.C. § 1345, and inherent authority, to order injunctive and other equitable relief
2 remedying the unlawful activities described in paragraph 5.

3 7. Defendant Clifford Woods LLC is a California company that does
4 business as Vibrant Life, and sells and distributes dietary supplements under the
5 brand name Vibrant Life. Defendant Clifford Woods owns and operates Clifford
6 Woods LLC and serves as executive director of Vibrant Life.

7 8. The Food and Drug Administration (“FDA”) sent a Warning Letter,
8 dated August 7, 2013, to Defendant Woods (operating at that time as Vibrant Life
9 or Vibrant Life Vitamins) concerning products and claims found on Defendants’
10 websites. The Warning Letter advised Defendant Woods that the products were
11 new drugs, which may not be legally introduced or delivered for introduction into
12 interstate commerce without prior FDA approval. The Warning Letter further
13 advised Defendant Woods that the products were misbranded drugs, whose
14 introduction or delivery into interstate commerce also violates the Act.

15 9. Upon entry of this Decree, Defendants represent to the Court that they
16 are not directly or indirectly engaged in processing, packing, repacking, labeling,
17 holding, or distributing any article of food (including but not limited to dietary
18 supplements and their components) and/or any article of drug.

19 10. If Defendants later intend to resume operation of Vibrant Life or any
20 other enterprise engaged in manufacturing, processing, packing, labeling, holding,
21 or distributing any article of food (including but not limited to dietary supplements
22 and their components) and/or any article of drug, Defendants must notify FDA in
23 writing at least ninety (90) days in advance of resuming operations and must
24 comply with Paragraph 13 of this Decree.

25 11. Defendants’ notice under Paragraph 10 shall identify the type(s) of
26 products that Defendants intend to process, pack, repack, label, hold, and/or
27 distribute, and the location(s) at which Defendants intend to resume operations.
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1 references, direct or indirect, to other websites or other sources that contain
2 representations that their products or the ingredients in their products cure,
3 mitigate, treat, or prevent disease, and representations that otherwise cause any of
4 their products to be a drug within the meaning of the Act;

5 2. Defendants provide notice, by letter or electronic mail, to
6 all persons who are or have been involved in the promotion, sale, distribution, or
7 use of Defendants' Taheebo Life Tea, Life Glow Plus, Germanium, Organic Sulfur
8 ("MSM"), or any other product labeled as containing organic sulfur or methyl
9 sulfonyl methane, informing those persons that, pursuant to an order of this Court,
10 those products should not have been and can no longer be promoted, sold, or
11 distributed for use in the cure, mitigation, treatment, or prevention of disease and
12 that continued promotion, sale, or distribution of the products for the cure,
13 mitigation, treatment, or prevention of disease is a violation of the Act. Prior to
14 distribution, the notification shall be submitted to, and approved in writing by,
15 FDA. After completing distribution of the notification required by this paragraph,
16 Defendants shall provide FDA with an affidavit, from a person with personal
17 knowledge of the facts stated therein, stating the fact and manner of compliance
18 with this paragraph, identifying the names and addresses of each recipient who has
19 received a copy of the notification.

20 3. Defendants retain, at Defendants' expense, an
21 independent person (the "Labeling Expert") who is without any personal or
22 financial ties (other than a retention agreement) to Defendants and/or their families
23 and who, by reason of background, training, education, or experience, is qualified
24 to review Defendants' product labels, labeling, promotional material, websites
25 (including but not limited to arthritisinformation.net, bulkmsm.com,
26 chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com,
27 vibrantlifemsm.com, and vibrantlifeneeds.com), branded Facebook pages, and
28 other media to assess compliance with the Act. Defendants shall notify FDA in

1 writing of the identity and qualifications of the Labeling Expert within three (3)
2 business days of retaining such expert; and

3 4. The Labeling Expert provides to FDA a written
4 certification that, based on a comprehensive review, Defendants' product labels,
5 labeling, promotional material, websites (including but not limited to
6 arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-
7 bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and
8 vibrantlifeneeds.com), branded Facebook pages, and other media comply with the
9 Act, and do not contain, or link or refer to other websites or other sources that
10 contain, representations that their products or the ingredients in their products cure,
11 mitigate, treat, or prevent disease, or representations that otherwise cause any
12 product to be a drug within the meaning of the Act. The written certification
13 described in this paragraph shall include a list of all of Defendants' websites,
14 including social media pages and online marketplace postings. The written
15 certification shall also contain a detailed report of the Labeling Expert's review
16 and include, but not be limited to, a determination that Defendants have
17 implemented procedures that are adequate to ensure that their claims do not cause
18 any of their products to be a drug within the meaning of 21 U.S.C. § 321(g)(1)
19 unless and until the product is the subject of an approved new drug application or
20 abbreviated new drug application, or is exempt from approval under an
21 investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j);

22 B. Defendants report to FDA in writing the actions they have
23 taken to ensure that their claims do not cause any of their products to be a drug
24 within the meaning of 21 U.S.C. § 321(g)(1) unless and until the product is the
25 subject of an approved new drug application or abbreviated new drug application,
26 or is exempt from approval under an investigational new drug application, 21
27 U.S.C. §§ 355(a), (b), (i), and (j);

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

6 D. Defendants have paid all costs of FDA's inspections,
7 investigations, supervision, analyses, examinations, and reviews with respect to
8 paragraph 13, at the rates set forth in paragraph 21; and

9 E. FDA notifies Defendants in writing that they appear to be in
10 compliance with the requirements set forth in paragraphs 13(A)-(B) and (D) of this
11 Decree. In no circumstance shall FDA's silence be construed as a substitute for
12 written notification.

13 14. Upon entry of this Decree, and after receiving FDA's written
14 notification pursuant to paragraph 13(E), Defendants and Associated Persons are
15 permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or
16 indirectly doing or causing to be done any of the following acts:

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

21 B. Violating 21 U.S.C. § 331(a) by introducing or delivering for
22 introduction, or causing to be introduced or delivered for introduction, into
23 interstate commerce drugs that are misbranded within the meaning of 21 U.S.C.
24 § 352(f)(1); and

25 C. Failing to implement and continuously maintain the
26 requirements of this Decree.

1 **COMPLIANCE REQUIREMENTS**

2 15. Upon resuming operations after complying with paragraphs 13(A)-(B)
3 and (D), and receiving FDA’s written notification pursuant to paragraph 13(E), the
4 following requirements shall be met:

5 A. Defendants shall notify FDA in writing, at least fourteen (14)
6 days before the creation of a new website or link or reference, direct or indirect, to
7 another website or other source that conveys information about Defendants’
8 products or the ingredients in their products; and

9 B. Defendants shall retain an independent person or persons (the
10 “Auditor”) who shall meet the criteria for, and may be the same person(s) as, the
11 Labeling Expert described in paragraph 13(A)(3), to conduct audits of Defendants’
12 product labels, labeling, promotional material, websites (including but not limited
13 to arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-
14 disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and
15 vibrantlifeneeds.com), branded Facebook pages, and other media to assess
16 compliance with the Act. Thereafter:

17 1. The Auditor shall conduct audit inspections no less
18 frequently than once every six (6) months for a period of no less than five (5) years
19 and then at least once every year thereafter. The first audit shall occur not more
20 than six (6) months after Defendants have received FDA’s written notification
21 pursuant to paragraph 13(E);

22 2. At the conclusion of each audit inspection, the Auditor
23 shall prepare a detailed written audit report (“Audit Report”) analyzing whether
24 Defendants are in compliance with this Decree, the Act, and its implementing
25 regulations and identifying any deviations from such requirements (“Audit Report
26 Observations”). As a part of every Audit Report (except the first one), the Auditor
27 shall assess the adequacy of actions taken by Defendants to correct all previous
28 Audit Report Observations. The Audit Reports shall be delivered

1 contemporaneously to Defendants and FDA by courier service or overnight
2 delivery service, no later than seven (7) days after the audit inspection is
3 completed. In addition, Defendants shall maintain the Audit Reports in separate
4 files at Defendants' facility and shall promptly make the Audit Reports available to
5 FDA upon request; and

6 3. If an Audit Report contains any Audit Report
7 Observations, Defendants shall, within fourteen (14) days after receipt of the Audit
8 Report, correct those observations, unless FDA notifies Defendants that a shorter
9 time period is necessary. If, after receiving the Audit Report, Defendants believe
10 that correction of the Audit Report Observations will take longer than fourteen (14)
11 days, Defendants shall, within seven (7) days after receipt of the Audit Report,
12 submit to FDA in writing a proposed schedule for completing corrections ("Audit
13 Correction Schedule"). The Audit Correction Schedule must be reviewed and
14 approved by FDA in writing prior to implementation by Defendants. In no
15 circumstance shall FDA's silence be construed as a substitute for written approval.
16 Defendants shall complete all corrections according to the approved Audit
17 Correction Schedule. Immediately upon completion of all corrections, Defendants
18 shall submit documentation of their corrections to the Auditor. Within twenty-
19 eight (28) days after the Auditor's receipt of Defendants' documentation of
20 corrections, unless FDA notifies Defendants that a shorter time period is necessary,
21 or, if there is an FDA-approved Audit Correction Schedule, within the time period
22 provided therein, the Auditor shall review the actions taken by Defendants to
23 correct the Audit Report Observations. Within seven (7) days after beginning that
24 review, the Auditor shall report in writing to FDA whether each of the Audit
25 Report Observations has been corrected and, if not, which Audit Report
26 Observations remain uncorrected.

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1 16. If Defendants engage in manufacturing, processing, packing, labeling,
2 holding or distributing any drug or dietary supplement, Defendants will comply
3 with the Act and its implementing regulations.

4 17. If, at any time after entry of this Decree, FDA determines, based on
5 the results of an inspection, review, the analysis of a sample, a report, or data
6 prepared or submitted by Defendants, the Labeling Expert, Auditor, or any other
7 information, that Defendants have failed to comply with any provision of this
8 Decree, Defendants have violated the Act or its implementing regulations, or
9 additional corrective actions are necessary to achieve compliance with this Decree,
10 the Act, or its implementing regulations, FDA may, as and when it deems
11 necessary, notify Defendants in writing of the noncompliance and order
12 Defendants to take appropriate corrective action, including, but not limited to,
13 ordering Defendants to immediately take one or more of the following actions:

- 14 A. Cease receiving, processing, packing, repacking, labeling,
15 holding, or distributing any and all products;
- 16 B. Recall, at Defendants' expense, any and all products;
- 17 C. Revise, modify, expand, or continue to submit any reports,
18 plans, procedures, or other records prepared pursuant to this Decree;
- 19 D. Submit additional reports or information to FDA as requested;
- 20 E. Institute or reimplement any of the requirements set forth in this
21 Decree;
- 22 F. Issue a safety alert; and/or
- 23 G. Take any other corrective actions as FDA, in its discretion,
24 deems necessary to protect the public health or bring Defendants into compliance
25 with this Decree, the Act, or its implementing regulations.

26 This remedy shall be separate and apart from, and in addition to, any other
27 remedy available to the United States under this Decree or under the law.

1 18. Upon receipt of any order issued by FDA pursuant to paragraph 17,
2 Defendants shall immediately and fully comply with the terms of the order. Any
3 cessation of operations or other action described in paragraph 17 shall continue
4 until Defendants receive written notification from FDA that Defendants appear to
5 be in compliance with this Decree, the Act, and its implementing regulations, and
6 that Defendants may resume operations. Defendants shall pay all costs of recalls
7 and other corrective actions, including the costs of FDA's inspections,
8 investigations, supervision, analyses, examinations, sampling, testing, reviews,
9 document preparation, travel, and subsistence expenses to implement and monitor
10 the remedies set forth in paragraph 17, at the rates specified in paragraph 21.

11 19. Representatives of FDA shall be permitted, without prior notice and
12 as and when FDA deems necessary, to inspect Defendants' operations and, without
13 prior notice, take any other measures necessary to monitor and ensure continuing
14 compliance with the terms of this Decree, the Act, and all applicable regulations.
15 During such inspections, FDA representatives shall be permitted to: have
16 immediate access to the Defendants' places of business including, but not limited
17 to all buildings, equipment, in-process materials, finished products, containers,
18 packaging material, labeling, and other material therein; take photographs and
19 make video recordings; take samples of the Defendants' in-process materials,
20 finished products, containers, packaging material, labeling, and other material; and
21 examine and copy all records relating to the receipt, processing, packing,
22 repacking, labeling, holding, and distribution of any and all of the Defendants'
23 products and their components. The inspections shall be permitted upon
24 presentation of a copy of this Decree and appropriate credentials. The inspection
25 authority granted by this Decree is separate from, and in addition to, the authority
26 to make inspections under the Act, 21 U.S.C. § 374.

1 compliance with this paragraph. If Defendants do not have a facility or website,
2 the affidavit shall so state.

3 23. Within fourteen (14) days after entry of this Decree, Defendants shall
4 hold a general meeting or series of smaller meetings for all Associated Persons, at
5 which they shall describe the terms and obligations of this Decree. Within twenty
6 (20) days after entry of this Decree, Defendants shall provide to FDA an affidavit,
7 from a person with personal knowledge of the facts stated therein, stating the fact
8 and manner of compliance with this paragraph and a copy of the agenda, list of
9 attendees, and meeting minutes from the meeting(s) held pursuant to this
10 paragraph. If there are no Associated Persons, the affidavit shall so state and no
11 affidavit is required under Paragraph 24.

12 24. Within fourteen (14) days after entry of this Decree, Defendants shall
13 provide a copy of the Decree by personal service or certified mail (return receipt
14 requested) to each and all of their Associated Persons. Within twenty-eight (28)
15 days after entry of this Decree, Defendants shall provide to FDA an affidavit, from
16 a person with personal knowledge of the facts stated therein, stating the fact and
17 manner of compliance with this paragraph, identifying the names, addresses, and
18 positions of all Associated Persons who have received a copy of this Decree, and
19 attaching a copy of the executed certified mail return receipts.

20 25. In the event that any of the Defendants becomes associated with any
21 additional Associated Person(s) at any time after entry of this Decree, Defendants
22 shall immediately provide a copy of this Decree, by personal service or certified
23 mail (return receipt requested) to such Associated Person(s). Within seven (7)
24 days of each time that any of the Defendants becomes associated with any
25 additional Associated Person, Defendants shall provide to FDA an affidavit, from a
26 person with personal knowledge of the facts stated therein, stating the fact and
27 manner of compliance with this paragraph, identifying the names, addresses, and
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1 positions of all Associated Persons who received a copy of this Decree pursuant to
2 this paragraph, and attaching a copy of the executed certified mail return receipts.

3 26. Defendants shall notify FDA in writing at least fourteen (14) days
4 before any change in ownership, name, or character of their business that occurs
5 after entry of this Decree, including an incorporation, reorganization, creation of a
6 subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other
7 change in the structure or identity of Clifford Woods LLC, or Vibrant Life, or the
8 sale or assignment of any business assets, such as buildings, equipment, or
9 inventory, that may affect obligations arising out of this Decree. Defendants shall
10 provide a copy of this Decree to any prospective successor or assign at least
11 twenty-eight (28) days prior to any sale or assignment. Defendants shall furnish
12 FDA with an affidavit of compliance with this paragraph no later than fourteen
13 (14) days prior to such assignment or change in ownership.

14 27. All notifications, correspondence, and communications to FDA
15 required by the terms of this Decree shall be prominently marked “Decree
16 Correspondence” and addressed to the Director, Division of Enforcement, Office
17 of Enforcement and Import Operations, Office of Regulatory Affairs, United States
18 Food and Drug Administration, 10903 New Hampshire Avenue, White Oak
19 Building 32 Room 4360, Silver Spring, Maryland 20993, and shall reference this
20 civil action by case name and civil action number.

21 **VIOLATIONS OF THIS DECREE**

22 28. If any Defendants fail to comply with any provision of this Decree,
23 the Act, or its implementing regulations, including any time frame imposed by this
24 Decree, then Defendants shall pay to the United States of America: four thousand
25 dollars (\$4,000) in liquidated damages for each day such violation continues; an
26 additional sum of four thousand dollars (\$4,000) in liquidated damages per day per
27 violation, for each violation of this Decree, the Act, or its implementing
28 regulations; and an additional sum in liquidated damages equal to twice the retail

1 value of any product distributed in violation of this Decree, the Act, or its
2 implementing regulations. Defendants understand and agree that the liquidated
3 damages specified in this paragraph are not punitive in nature and their imposition
4 does not in any way limit the ability of the United States to seek, or the Court to
5 impose, additional civil or criminal penalties to be paid by Defendants, or remedies
6 based on conduct that may also be the basis for payment of liquidated damages
7 pursuant to this paragraph.

8 29. Should the United States bring and prevail in a contempt action to
9 enforce the terms of this Decree, Defendants shall, in addition to other remedies,
10 reimburse the United States for its attorneys' fees (including overhead), expert
11 witness fees, travel expenses incurred by attorneys and witnesses, investigational
12 and analytical expenses, administrative and court costs, and any other costs or fees
13 relating to such contempt proceedings.

14 **OTHER PROVISIONS**

15 30. Defendants shall abide by the decisions of FDA, and FDA's decisions
16 shall be final. All decisions conferred upon FDA in this Decree shall be vested in
17 FDA's discretion and, to the extent that these decisions are subject to review, shall
18 be reviewed by the Court under the arbitrary and capricious standard set forth in
19 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered
20 pursuant to this Decree shall be based exclusively on the written record before
21 FDA at the time the decision was made. No discovery shall be taken by either
22 party.

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

25 32. This Court retains jurisdiction over this action and the parties thereto
26 for the purpose of enforcing and modifying this Decree and for the purpose of
27 granting such additional relief as may be necessary or appropriate.

28 SO ORDERED, this ___ day of _____, 2016.

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UNITED STATES DISTRICT JUDGE

1 Entry consented to:
2 FOR DEFENDANTS

3 *Clifford Woods*

4 CLIFFORD WOODS, Individually and
5 on behalf of CLIFFORD WOODS, LLC
6 d/b/a Vibrant Life

7 *Sharon Appelbaum*

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15 CLIFFORD WOODS, LLC d/b/a
16 Vibrant Life

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