

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

United States of America,

No. CV-22-01744-PHX-JJT

Plaintiff,

# **CONSENT DECREE OF PERMANENT INJUNCTION**

VS.

Global Vitality, Incorporated, *et al.*,

## Defendants.

## **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint (Doc. 1) and Motion to Enter Consent Decree (Doc. 2) for Permanent Injunction against Global Vitality, Inc., dba Enzyme Process International, a corporation, and Steven D. Roderick and Gorica Blagojevic, individuals (collectively, "Defendants"), and Defendants 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 (*See Doc. 2-1 at 17-18*);

**IT IS HEREBY ORDERED** granting the United States' Motion to Enter Consent Decree (Doc. 2).

**IT IS FURTHER ORDERED, ADJUDGED, AND DECREED** as follows:

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

1           2. The Complaint states a cause of action against Defendants under the Federal  
2 Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the “Act”).

3           3. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for  
4 introduction, or causing to be introduced or delivered for introduction, into interstate  
5 commerce articles of food (dietary supplements), as defined by 21 U.S.C. § 321(ff), that are:

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

10           B. Misbranded within the meaning of 21 U.S.C. § 343 because their  
11 labels, among other things, fail to list each ingredient; list the correct serving size and  
12 number of servings per container; and/or identify the part of the plant from which each  
13 botanical dietary ingredient in the product is derived.

14           4. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary  
15 supplements) that they hold for sale after shipment in interstate commerce to become  
16 adulterated and misbranded within the meaning of 21 U.S.C. §§ 342(g)(1) and 343.

17           5. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for  
18 introduction, or causing to be introduced or delivered for introduction, into interstate  
19 commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within  
20 the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear adequate directions  
21 for use.

22           6. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that they  
23 hold for sale after shipment in interstate commerce to become misbranded within the  
24 meaning of 21 U.S.C. § 352(f)(1).

25           7. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for  
26 introduction, or causing to be introduced or delivered for introduction, into interstate  
27 commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant  
28 to 21 U.S.C. § 355(a) nor exempt from approval.

1           8. Upon entry of this Decree, Defendants and each and all of their directors,  
2 officers, agents, representatives, employees, attorneys, successors and assigns, and any and  
3 all persons or entities in active concert or participation with any of them, who have received  
4 actual notice of this Decree by personal service or otherwise, are hereby subject to the  
5 following requirements:

6           A. Within ten (10) business days of the entry of this Decree, Defendants  
7 shall retain, at Defendants' expense, an independent person (the "CGMP Expert") who is  
8 without any personal or financial ties (other than a retention agreement) to Defendants  
9 and/or their families, and who, by reason of background, training, education, or experience,  
10 is qualified to inspect Defendants' facility located at 470 N. 56<sup>th</sup> Street, Chandler, Arizona,  
11 or at any other location(s) at which Defendants now or in the future directly or indirectly  
12 receive, manufacture, prepare, pack, repack, label, hold, or distribute any articles of food  
13 (including but not limited to dietary supplements and their components) and/or articles of  
14 drug ("Defendants' Facility," "the Facility," or "Facilities"), to determine whether the  
15 methods, processes, and controls are operated and administered in conformity with Dietary  
16 Supplement CGMP (21 C.F.R. Part 111). Defendants shall notify FDA in writing of the  
17 identity and qualifications of the CGMP Expert within three (3) business days of retaining  
18 such expert;

19           B. Within twenty (20) business days of the entry of this Decree, the  
20 CGMP Expert shall perform a comprehensive inspection of the Facility and the methods,  
21 processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold,  
22 and distribute dietary supplements and, within thirty (30) business of entry of this Decree,  
23 certifies in writing to FDA that: (1) he or she has inspected the Facility, methods, processes,  
24 and controls; (2) all Dietary Supplement CGMP deviations that have been brought to  
25 Defendants' attention by FDA, the CGMP Expert, and any other source have been  
26 corrected; and (3) the Facility and the methods, processes, and controls used to receive,  
27 manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements, are, in  
28 the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing

1 regulations. The CGMP Expert's report of the inspection, which shall be delivered  
2 contemporaneously to Defendants and FDA by courier service or overnight delivery  
3 service, within thirty (30) business of entry of this Decree, shall include, but not be limited  
4 to, a determination that Defendants have created and implemented a system of methods,  
5 processes, and controls to ensure that they, at a minimum:

6 (1) Establish component specifications that are necessary to ensure  
7 the purity, strength, and composition of dietary supplements manufactured using the  
8 components, as required by 21 C.F.R. § 111.70(b)(2);

9 (2) Ensure that all specifications necessary to support the quality  
10 of each finished dietary supplement are met, as required by 21 C.F.R. §§ 111.105(h) and  
11 111.70(a);

12 (3) Conduct at least one appropriate test or examination to verify  
13 the identity of each dietary ingredient, prior to its use, as required by 21 C.F.R. §  
14 111.75(a)(1)(i);

15 (4) Establish finished product specifications for each dietary  
16 supplement manufactured for the identity, purity, strength, and composition of the finished  
17 batch of dietary supplements, as required by 21 C.F.R. § 111.70(e);

18 (5) Ensure that the tests and examinations used to determine  
19 whether the specifications are met are appropriate and scientifically valid methods, as  
20 required in 21 C.F.R. § 111.75(h)(1);

21 (6) Maintain and clean equipment, utensils, and all food-contact  
22 surfaces, as required by 21 C.F.R. § 111.27; and

23 (7) Implement and follow hygienic practices during operations, as  
24 required by 21 C.F.R. § 111.10(b).

25 C. Within ten (10) business days of the entry of this Decree, Defendants  
26 shall retain, at Defendants' expense, an independent person (the "Labeling Expert") who  
27 is without any personal or financial ties (other than a retention agreement) to Defendants  
28 and/or their families, except that this person may be the same as the CGMP Expert

1 described in paragraph 8(A), and who, by reason of background, training, education, or  
2 experience, is qualified to review Defendants' dietary supplement labeling (including but  
3 not limited to labels, catalogs, and websites) and other promotional/informational material  
4 to determine whether: (1) the labeling complies with 21 U.S.C. § 343 and applicable  
5 regulations; and (2) Defendants' claims cause any dietary supplement (or purported dietary  
6 supplement) that they receive, manufacture, prepare, pack, repack, label, hold, or distribute  
7 to be a drug within the meaning of 21 U.S.C. § 321(g)(1). Defendants shall notify FDA in  
8 writing of the identity and qualifications of the Labeling Expert within three (3) business  
9 days of retaining such expert;

10                   D. Within twenty (20) business days of entry of this Decree, the Labeling  
11 Expert shall conduct an inspection of Defendants' Facility and comprehensive review of  
12 Defendants' dietary supplement labeling (including but not limited to labels, catalogs,  
13 social media pages, and websites) and other promotional/informational material and,  
14 within thirty (30) business days of entry of this Decree, certifies in writing to FDA that: (1)  
15 he or she has reviewed Defendants' dietary supplement labeling and other  
16 promotional/informational material; (2) all labeling violations brought to Defendants'  
17 attention by FDA, the Labeling Expert, and any other source, have been corrected; and (3)  
18 Defendants' dietary supplement labeling and claims are, in the Labeling Expert's opinion,  
19 in compliance with this Decree, the Act, and its implementing regulations. The Labeling  
20 Expert's written certification shall include the specific results of his or her inspection and  
21 review, including references to product names and copies of all materials reviewed and  
22 specific recommendations to achieve compliance. The Labeling Expert shall prepare a  
23 detailed report of this review, which shall be delivered contemporaneously to Defendants  
24 and FDA by courier service or overnight delivery service, within thirty (30) business days  
25 of entry of this Decree, that shall include, but not be limited to, a determination that:

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

(2) Defendants have implemented procedures that are adequate to ensure that their claims do not cause any dietary supplement (or purported 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, 21 U.S.C. §§ 355(a), (b), (j), or is otherwise exempt from approval under the Act;

E. Within forty (40) business days of the entry of this Decree, 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, Labeling Expert, and any other source:

(2) Ensure that the Defendants' Facility, 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 Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations; and

(4) Ensure that Defendants' claims do not cause any food or dietary supplement (or purported 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 the product is the subject of an approved new drug application or abbreviated new drug application, 21 U.S.C. §§ 355(a), (b), and (j), or is otherwise exempt from approval under the Act;

F. 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;

1                   G. Defendants shall pay all costs of FDA's inspections, investigations,  
2 supervision, analyses, examinations, and reviews with respect to paragraph 8, at the rates  
3 set forth in paragraph 15; and

4                   H. FDA shall notify Defendants in writing that they appear to be in  
5 compliance with the requirements set forth in paragraphs 8(A)-(E) and (G) of this Decree.  
6 In no circumstance shall FDA's silence be construed as a substitute for written notification.

7                   9. Within sixty (60) calendar days after entry of this Decree, Defendants shall  
8 retain, at Defendants' expense, a) an independent person (the "CGMP Auditor") who shall  
9 meet the criteria for and may be the same person as the CGMP Expert described in  
10 paragraph 8(A), and b) an independent person (the "Labeling Auditor") who shall meet the  
11 criteria for and may be the same person as the Labeling Expert in paragraph 8(C), and may  
12 be the same person as the CGMP Auditor described in this paragraph (collectively, the  
13 "CGMP and Labeling Auditor(s)"), to conduct audit inspections of the Facility and the  
14 methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label,  
15 hold, and distribute dietary supplements, and of Defendants' dietary supplement labeling  
16 (including but not limited to labels, catalogs, social media pages, and websites) and other  
17 promotional/informational material. Thereafter:

18                   A. The CGMP and Labeling Auditor(s) shall conduct audit inspections  
19 no less frequently than once annually for a period of no less than five (5) years and then at  
20 least once every year thereafter. The first audit shall occur not more than six (6) months  
21 after Defendants have received FDA's written notification pursuant to paragraph 8(H).

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

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

5           C. If an Audit Report contains any Audit Report Observations,  
6 Defendants shall, within ten (10) business days after receipt of the Audit Report, correct  
7 those observations, unless FDA notifies Defendants that a shorter time period is necessary.  
8 If, after receiving the Audit Report, Defendants believe that correction of the Audit Report  
9 Observations will take longer than ten (10) business days, Defendants shall, within five (5)  
10 business days after receipt of the Audit Report, submit to FDA in writing a proposed  
11 schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction  
12 Schedule must be approved by FDA in writing prior to implementation by Defendants. In  
13 no circumstance shall FDA's silence be construed as a substitute for written approval.  
14 Defendants shall complete all corrections according to the approved Audit Correction  
15 Schedule. Within twenty (20) business days after Defendants' receipt of an Audit Report,  
16 unless FDA notifies Defendants that a shorter time period is necessary, or within the time  
17 period provided in an FDA-approved Audit Correction Schedule, the CGMP and Labeling  
18 Auditor(s) shall review the actions taken by Defendants to correct the Audit Report  
19 Observations. Within five (5) business days after beginning that review, the CGMP and  
20 Labeling Auditor(s) shall report in writing to FDA, delivered contemporaneously to  
21 Defendants and FDA by courier service or overnight delivery service, whether each of the  
22 Audit Report Observations has been corrected and, if not, which Audit Report  
23 Observations remain uncorrected.

24           10. Upon entry of this Decree, and after receiving FDA's written notification  
25 pursuant to paragraph 8(H), Defendants are permanently restrained and enjoined under  
26 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the  
27 following acts:

28

1                   A.     Violating 21 U.S.C. § 331(a), by introducing or delivering for  
2 introduction, or causing to be introduced or delivered for introduction, into interstate  
3 commerce articles of food (including but not limited to dietary supplements and their  
4 components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or  
5 misbranded within the meaning of 21 U.S.C. § 343;

6                   B.     Violating 21 U.S.C. § 331(k), by causing articles of food (including  
7 but not limited to dietary supplements and their components) that Defendants hold for sale  
8 after shipment in interstate commerce to become adulterated within the meaning of 21  
9 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

10                  C.     Violating 21 U.S.C. § 331(a) by introducing or delivering for  
11 introduction, or causing to be introduced or delivered for introduction, into interstate  
12 commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1);

13                  D.     Violating 21 U.S.C. § 331(k) by causing articles of drug that  
14 Defendants hold for sale after shipment in interstate commerce to become misbranded  
15 within the meaning of 21 U.S.C. § 352(f)(1);

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

20                  F.     Failing to implement and continuously maintain the requirements of  
21 this Decree.

22                 11.    If, at any time after entry of this Decree, FDA determines, based on the  
23 results of an inspection, the analysis of a sample, a report, or data prepared or submitted by  
24 Defendants, the CGMP Expert, Labeling Expert, CGMP and Labeling Auditor(s), or any  
25 other information, that Defendants have failed to comply with any provision of this Decree,  
26 Defendants have violated the Act or its implementing regulations, or additional corrective  
27 actions are necessary to achieve compliance with this Decree, the Act, or its implementing  
28 regulations, FDA may, as and when it deems necessary, but subject to Paragraph 12 below,

1 notify Defendants in writing of the noncompliance and order Defendants to take  
2 appropriate corrective action, including, but not limited to, ordering Defendants to  
3 immediately take one or more of the following actions:

- 4 A. Cease receiving, manufacturing, preparing, packing, repacking,  
5 labeling, holding, or distributing any and all products;
- 6 B. Recall, at Defendants' expense, any product that in FDA's judgment  
7 is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its  
8 implementing regulations;
- 9 C. Revise, modify, expand, or continue to submit any reports, plans,  
10 procedures, or other records prepared pursuant to this Decree;
- 11 D. Submit additional reports or information to FDA as requested;
- 12 E. Institute or reimplement any of the requirements set forth in this  
13 Decree;
- 14 F. Issue a safety alert; and/or
- 15 G. Take any other corrective actions as FDA, in its discretion, deems  
16 necessary to protect the public health or bring Defendants into compliance with this  
17 Decree, the Act, or its implementing regulations.

18 12. The following process and procedures apply when FDA issues an order  
19 under paragraph 11 except as provided in subparagraph D. below:

- 20 A. Unless a different timeframe is specified by FDA in its order, within  
21 ten (10) business days after receiving an order under paragraph 11, Defendants shall notify  
22 FDA in writing either that: (i) Defendants are undertaking or have undertaken corrective  
23 action, in which event Defendants also shall describe the specific actions taken or to be  
24 taken and the proposed schedule for completing the actions; or (ii) Defendants do not agree  
25 with FDA's order. If Defendants notify FDA that they do not agree with FDA's order,  
26 Defendants shall explain in detail and in writing the basis for their disagreement; in doing  
27 so, Defendants also may propose specific alternative actions and specific timeframes for  
28 achieving FDA's objectives.

1                   B.     If Defendants notify FDA that they do not agree with FDA's order,  
2 FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or  
3 withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will  
4 explain the basis for its decision in writing. This written notification shall constitute final  
5 agency action.

6                   C.     If FDA affirms or modifies its order, Defendants shall, upon receipt  
7 of FDA's order, immediately implement the order (as modified, if applicable). Defendants  
8 shall continue to diligently implement FDA's order while the matter is before the Court  
9 and unless and until the Court reverses, stays, or modifies FDA's order. Any review of  
10 FDA's decision under this paragraph shall be made in accordance with the terms set forth  
11 in paragraph 23.

12                  D.     The process and procedures set forth in paragraphs 12.A.-C. shall not  
13 apply to any order issued under paragraph 11 if such order states that, in FDA's judgment,  
14 the matter raises significant public health concerns. In such case, Defendants shall  
15 immediately and fully comply with the terms of that order. Should Defendants seek to  
16 challenge any such order, they may petition this Court for relief. Any cessation of  
17 operations under this Paragraph 12(D) shall continue until Defendants receive written  
18 notice from FDA that Defendants appear to be in compliance with the Act, its  
19 implementing regulations, and this Decree.

20                  13.    The costs of recalls and other corrective actions, including the costs of FDA's  
21 inspections, investigations, supervision, analyses, examinations, sampling, testing,  
22 reviews, document preparation, travel, and subsistence expenses to implement and monitor  
23 the remedies set forth in paragraph 11 shall be borne by Defendants at the rates specified  
24 in paragraph 16.

25                  14.    Representatives of FDA shall be permitted, without prior notice and as and  
26 when FDA deems necessary, to inspect Defendants' operations and, without prior notice,  
27 take any other measures necessary to monitor and ensure continuing compliance with the  
28 terms of this Decree, the Act, and all applicable regulations. During such inspections, FDA

1 representatives shall be permitted to: have immediate access to Defendants' places of  
2 business including, but not limited to all Facilities, buildings, equipment, raw ingredients,  
3 in-process materials, finished products, containers, packaging material, labeling, and other  
4 material therein; take photographs and make video recordings; take samples of Defendants'  
5 raw ingredients, in-process materials, finished products, containers, packaging material,  
6 labeling, and other material; and examine and copy all records relating to the receipt,  
7 manufacture, preparing, packing, repacking, labeling, holding, and distribution of any and  
8 all of Defendants' products and their components. The inspections shall be permitted upon  
9 presentation of a copy of this Decree and appropriate credentials. The inspection authority  
10 granted by this Decree is separate from, and in addition to, the authority to make  
11 inspections under the Act, 21 U.S.C. § 374.

12 15. Defendants shall promptly provide any information or records to FDA upon  
13 request regarding the receipt, manufacture, preparing, packing, repacking, labeling,  
14 holding, and distribution of Defendants' products. Within fifteen (15) business days after  
15 FDA's request for Defendants' product labels; labeling; leaflets; websites or social media  
16 pages owned, created by, controlled by, or related to Defendants (including, but not limited  
17 to, <http://enzymeprocess.co/>, and any future website(s) or social media page(s) owned by,  
18 created by, controlled by, or related to Defendants); promotional materials; and any other  
19 media over which Defendants have control, Defendants shall submit a copy of the  
20 requested materials (in electronic format unless otherwise specified) to FDA at the address  
21 specified in Paragraph 24.

22 16. Defendants shall pay all costs of FDA's inspections, investigations,  
23 supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate  
24 Defendants' compliance with any part of this Decree at the standard rates prevailing at the  
25 time the costs are incurred. As of the date that this Decree is signed by the parties, these  
26 rates are: \$105.46 per hour or fraction thereof per representative for inspection and  
27 investigative work; \$126.24 per hour or fraction thereof per representative for analytical or  
28 review work; \$0.59 per mile for travel expenses by automobile; government rate or the

1 equivalent for travel by air or other means; and the published government per diem rate for  
2 subsistence expenses where necessary. In the event that the standard rates applicable to  
3 FDA supervision of court-ordered compliance are modified, these rates shall be increased  
4 or decreased without further order of the Court. Defendants shall make payment in full to  
5 FDA within thirty (30) business days of receiving written notification from FDA of the  
6 costs.

7       17. Within five (5) business days after entry of this Decree, Defendants shall post  
8 a copy of this Decree in a conspicuous location in a common area at Defendants' Facility,  
9 and at any other location at which Defendants conduct business, and shall ensure that the  
10 Decree remains posted for as long as the Decree remains in effect. Within ten (10) business  
11 days after entry of this Decree, Defendants shall provide to FDA an affidavit, from a person  
12 with personal knowledge of the facts stated therein, stating the fact and manner of  
13 compliance with this paragraph.

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

21       19. Within ten (10) business days after entry of this Decree, Defendants shall  
22 provide a copy of the Decree by personal service or certified mail (return receipt requested)  
23 to each and all of their directors, officers, agents, representatives, employees, attorneys,  
24 successors, and assigns, and any and all persons or entities in active concert or participation  
25 with any of them ("Associated Persons"). Within twenty (20) business days after entry of  
26 this Decree, Defendants shall provide to FDA an affidavit, from a person with personal  
27 knowledge of the facts stated therein, stating the fact and manner of compliance with this  
28 paragraph, identifying the names, addresses, and positions of all Associated Persons who

1 have received a copy of this Decree, and attaching a copy of the executed certified mail  
2 return receipts.

3       20. In the event that any of the Defendants becomes associated with any  
4 additional Associated Person(s) at any time after entry of this Decree, Defendants shall  
5 immediately provide a copy of this Decree, by personal service or certified mail (return  
6 receipt requested) to such Associated Person(s). Within five (5) business days of each time  
7 that any of the Defendants becomes associated with any additional Associated Person,  
8 Defendants shall provide to FDA an affidavit, from a person with personal knowledge of  
9 the facts stated therein, stating the fact and manner of compliance with this paragraph,  
10 identifying the names, addresses, and positions of all Associated Persons who received a  
11 copy of this Decree pursuant to this paragraph, and attaching a copy of the executed  
12 certified mail return receipts.

13       21. Defendants shall notify FDA in writing at least ten (10) business days before  
14 any change in ownership, name, or character of their business that occurs after entry of this  
15 Decree, including an incorporation, reorganization, creation of a subsidiary, relocation,  
16 dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity  
17 of Global Vitality, Inc., dba Enzyme Process International, or the sale or assignment of any  
18 business assets, such as buildings, equipment, or inventory, that may affect obligations  
19 arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective  
20 successor or assign at least twenty (20) business days prior to any sale or assignment.  
21 Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later  
22 than ten (10) business days prior to such assignment or change in ownership.

23       22. Should the United States bring and prevail in a contempt action to enforce  
24 the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the  
25 United States for its attorneys' fees (including overhead), expert witness fees, travel  
26 expenses incurred by attorneys and witnesses, investigational and analytical expenses,  
27 administrative and court costs, and any other costs or fees relating to such contempt  
28 proceedings.

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

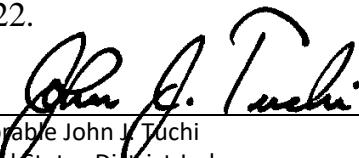
8       24. All notifications, correspondence, and communications to FDA required by  
9 the terms of this Decree shall be prominently marked "Decree Correspondence" and  
10 addressed to the Program Division Director, Office of Human and Animal Food Operations  
11 West 4 (HAFW-4), Denver District Office, U.S. Food and Drug Administration, 6<sup>th</sup>  
12 Avenue and Kipling Street, P.O. Box 25087, Building 20-DFC, Denver, Colorado 80225-  
13 0087, and via email at orahafwest4firmresponses@fda.hhs.gov, and shall reference this  
14 civil action by case name and civil action number.

15       25. If Defendants (i) after receiving written notice from FDA, as described in  
16 Paragraph 8(H), (ii) petition the Court for relief from this Decree and, (iii) at the time of  
17 the petition, in FDA's judgment, Defendants have maintained a state of continuous  
18 compliance with the Act, its implementing regulations, and this Decree for the sixty (60)  
19 months preceding the petition, Plaintiff will not oppose such petition.

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

23       **IT IS FURTHER ORDERED** directing the Clerk of the Court to close this matter.

24       Dated this 26th day of October, 2022.

25         
26       \_\_\_\_\_  
27       Honorable John J. Tuchi  
28       United States District Judge