JS-6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. HEALTH ONE PHARMACEUTICALS, INC., a California corporation; and RICHARD S. YEH, an individual, Defendants.	CASE NO. 2:14-cv-09734 CONSENT DECREE OF PERMANENT INJUNCTION

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Permanent Injunction against Health One Pharmaceuticals, Inc., a corporation, and Richard S. Yeh, an individual (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;

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. 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; and

B. Misbranded under 21 U.S.C. § 343 because their labels fail to: (1) list the common or usual names of all product ingredients, as required by 21 U.S.C. § 343(i)(2); (2) identify the part of the plant (e.g., root, leaves) from which a botanical dietary ingredient is derived, as required by 21 U.S.C. § 343(s)(2)(C); (3) bear nutrition information that provides serving size and the number of servings or other units of measure per container, as required by 21 U.S.C. § 343(q)(1)(A) and (B); (4) bear nutrition information required by regulation, namely a "Supplement Facts" panel, as required by 21 U.S.C. § 343(q)(5)(F); (5) bear the place of business (city, state, ZIP) of the manufacturer, packer, or distributor, as required by 21 U.S.C. § 343(e)(1); and/or (6) include a domestic address or domestic telephone number through which the responsible person (as described in

21 U.S.C. § 379aa-1) may receive a report of a serious adverse event associated with the product, as required by 21 U.S.C. § 343(y).

4. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be adulterated within the meaning of 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343, as described above in paragraph 3.

5. 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 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).

6. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment of one or more of their components in interstate commerce to be misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labels fail to bear adequate directions for use.

7. Upon entry of this Decree, Defendants represent to this Court that Defendants are not directly or indirectly engaged in manufacturing, preparing, packing, labeling, holding, and/or distributing any articles of food (including but not limited to dietary supplements and their components) and/or any articles of

drug. If Defendants later intend to resume any such operations, Defendants must first notify FDA in writing at least sixty (60) business days in advance of resuming operations and comply with paragraphs 8(A)-(D) of this Decree. Defendants' notice shall identify the type(s) of food and/or drug that Defendants intend to manufacture, prepare, pack, label, hold, and/or distribute, and the location at which Defendants intend to resume operations. Defendants shall not resume operations until FDA has inspected Defendants' facility and operations pursuant to paragraph 8(E), Defendants have paid all costs pursuant to paragraph 8(F), and Defendants have received written notice from FDA, as required by paragraph 8(G), and then shall resume operations only to the extent authorized in FDA's written notice.

8. 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 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 equitable authority of this Court, from directly or indirectly manufacturing, preparing, packing, labeling, holding, or distributing any articles of food (including but not limited to dietary supplements and their components) and/or drug, unless and until:

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

person ("CGMP Expert") who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP, 21 C.F.R. Part 111, and:

(1) Defendants notify FDA in writing of the identity and qualifications of the CGMP Expert as soon as they retain such expert; and

(2) The CGMP Expert performs a comprehensive inspection of Defendants' facility and the methods, processes, and controls used to manufacture, prepare, pack, label, and hold dietary supplements, and certifies in writing to FDA the following: he or she has inspected Defendants' facility, methods, processes, and controls; all Dietary Supplement CGMP deviations brought to Defendants' attention by FDA, the CGMP Expert, and any other source have been corrected; and Defendants' facility and the methods, processes, and controls used to manufacture, prepare, pack, label, and hold dietary supplements are, in the CGMP Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The CGMP Expert's report of the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination that Defendants have methods, processes, and controls to ensure that

they:

(a) 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);

(b) 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);

(c) Establish specifications for each component that include the following: an identity specification; component specifications to ensure that specifications for the purity, strength, and composition of the finished batch of the dietary supplement are met; and limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement, as required by 21 C.F.R. § 111.70(b);

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

(e) Determine whether finished dietary supplement batches

meet the product specifications that must be established in accordance with 21 C.F.R. § 111.70(e), as required by 21 C.F.R. § 111.75(c);

(f) Establish and implement quality control operations for reviewing and approving all master manufacturing records and batch production records, as required by 21 C.F.R. § 111.123(a)(1), (a)(2), and for making and keeping documentation of the review and approval of those records, as required by 21 C.F.R. § 111.140(b); and

(g) Establish and implement quality control operations for conducting material review and making disposition decisions in accordance with 21 C.F.R. § 111.113, as required by 21 C.F.R. § 111.123(a)(4), and for making and keeping documentation of any material review and disposition decision, as required by 21 C.F.R. § 111.140(b);

B. Defendants retain, at Defendants' expense, an independent person ("Labeling Expert") who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, except that this person may be the same as the CGMP Expert described in paragraph 8(A), and who, by reason of background, training, education, or experience, is qualified to review Defendants' dietary supplement labeling to determine whether the labeling complies with 21 U.S.C. § 343 and applicable regulations and whether it contains claims that cause any dietary supplement that Defendants manufacture, prepare,

pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21 U.S.C. § 321(g), and:

(1) Defendants notify FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert; and

(2) The Labeling Expert performs a comprehensive review of all of Defendants' dietary supplement labeling and certifies in writing to FDA the following: he or she has reviewed Defendants' dietary supplement labeling; Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations; and, Defendants' dietary supplement labeling does not contain claims that cause any dietary supplement that Defendants manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21 U.S.C. § 321(g). The Labeling Expert's report of the labeling review shall be submitted to FDA;

C. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 9, all dietary supplements that were manufactured, prepared, packed, labeled, held, or distributed between September 1, 2011, and the date of entry of this Decree;

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

(1) correct the Dietary Supplement CGMP deviations

brought to Defendants' attention by FDA, the CGMP Expert, and any other source;

(2) ensure that the methods used in, and the facilities and controls used for, manufacturing, preparing, packing, labeling, holding, and distributing dietary supplements are operated and will be continuously administered in conformity with Dietary Supplement CGMP;

(3) correct the labeling deviations brought to Defendants' attention by FDA, the Labeling Expert, and any other source; and

(4) ensure that the dietary supplement labeling used by Defendants (i) complies with 21 U.S.C. § 343 and its implementing regulations, and (ii) does not contain claims that cause any dietary supplement that Defendants manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21 U.S.C. § 321(g);

E. As and when FDA deems necessary, FDA representatives inspect Defendants' facility 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;

F. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to paragraph 8, at the rates set forth in paragraph 16; and

G. FDA notifies Defendants in writing that they appear to be in

compliance with the requirements set forth in paragraphs 8(A)-(D) and (F) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Within twenty (20) business days after entry of this Decree, Defendants shall recall all dietary supplements that were manufactured, prepared, packed, labeled, held, or distributed between September 1, 2011, and the date of entry of this Decree. Within thirty (30) business days after entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements 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 dietary supplement 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 dietary supplements are disposed.

10. Upon resuming operations after complying with paragraphs 8(A)-(D) and (F), and receiving FDA's written notification pursuant to paragraph 8(G), Defendants shall:

A. Retain an independent person (the "CGMP Auditor") who shall meet the criteria for the CGMP Expert described in paragraph 8(A), and who may be the same person retained as an Expert pursuant to paragraphs 8(A) or 8(B), to conduct CGMP audit inspections of Defendants' facility no less frequently than

once every six (6) months for a period of no less than five (5) years and then at least once every year thereafter. The first CGMP audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 8(G);

B. At the conclusion of each CGMP audit inspection, the CGMP Auditor shall prepare a detailed written audit report ("CGMP Audit Report") analyzing whether Defendants are in compliance with Dietary Supplement CGMP and identifying any deviations from such requirements ("CGMP Audit Report Observations"). As a part of every CGMP Audit Report (except the first one), the CGMP Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous CGMP Audit Report observations. The CGMP 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 CGMP Audit Inspection is completed. In addition, Defendants shall maintain the CGMP Audit Reports in separate files at Defendants' facility and shall promptly make the CGMP Audit Reports available to FDA upon request;

C. If a CGMP Audit Report contains any observations indicating that Defendants' dietary supplements are not in compliance with the Dietary Supplement CGMP, Defendants shall, within ten (10) business days after receipt of the CGMP Audit Report, correct those observations, unless FDA notifies

Defendants that a shorter time period is necessary. If, after receiving the CGMP Audit Report, Defendants believe that correction of the deviations will take longer than ten (10) business days, Defendants shall, within five (5) business days after receipt of the CGMP Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("CGMP Audit Correction Schedule"). The CGMP 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 CGMP Audit Correction Schedule. Immediately upon completion of all corrections, Defendants shall submit documentation of their corrections to the CGMP Auditor. Within twenty (20) business days after the CGMP 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 CGMP Audit Correction Schedule, within the time period provided therein, the CGMP Auditor shall review the actions taken by Defendants to correct the CGMP Audit Report Observations. Within five (5) business days after beginning that review, the CGMP Auditor shall report in writing to FDA whether each of the CGMP Audit Report Observations has been corrected and, if not, which CGMP Audit Report Observations remain uncorrected;

D. Retain an independent person (the "Labeling Auditor") who

shall meet the criteria for the Labeling Expert described in paragraph 8(B), and who may be the same person as the CGMP Auditor or the person retained as an Expert pursuant to paragraphs 8(A) or 8(B), to conduct audit reviews of Defendants' labeling no less frequently than once every six (6) months for a period of no less than five (5) years and then at least once every year thereafter. The first labeling audit shall occur not more than six (6) months after Defendants have received FDA's written notification pursuant to paragraph 8(G);

E. At the conclusion of each labeling audit, the Labeling Auditor shall prepare a detailed written audit report ("Labeling Audit Report") analyzing whether Defendants comply with 21 U.S.C. § 343 and its implementing regulations, and whether they cause any dietary supplement that they manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21 U.S.C. § 321(g), and identifying any deviations from such requirements for dietary supplement labeling ("Labeling Audit Report Observations"). As a part of every Labeling Audit Report, the Labeling Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Labeling Audit Report observations. The Labeling 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 Labeling Audit Inspection is completed. In addition, Defendants shall maintain the

Labeling Audit Reports in separate files at Defendants' facility and shall promptly make the Labeling Audit Reports available to FDA upon request; and

F. If a Labeling Audit Report contains any observations indicating that Defendants do not comply with 21 U.S.C. § 343 and its implementing regulations, or cause any dietary supplement that they manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21 U.S.C. § 321(g), Defendants shall, within ten (10) business days after receipt of the Labeling Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Labeling Audit Report, Defendants believe that correction of the deviations will take longer than ten (10) business days, Defendants shall, within five (5) business days after receipt of the Labeling Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Labeling Audit Correction Schedule"). The Labeling 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 Labeling Audit Correction Schedule. Immediately upon completion of all corrections, Defendants shall submit documentation of their corrections to the Labeling Auditor. Within twenty (20) business days after the Labeling 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 Labeling Audit Correction Schedule, within the time period provided therein, the Labeling Auditor shall review the actions taken by Defendants to correct the Labeling Audit Report Observations. Within five (5) business days after beginning that review, the Labeling Auditor shall report in writing to FDA whether each of the Labeling Audit Report Observations has been corrected and, if not, which Labeling Audit Report Observations remain uncorrected.

11. 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) or misbranded within the meaning of 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements and their components) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C.

§ 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

C. 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);

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

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

12. 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, CGMP Auditor, Labeling 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 manufacturing, preparing, packing, 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 or plans prepared pursuant to this Decree;

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

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

F. Issue a safety alert; and/or

G. 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.

13. Upon receipt of any order issued by FDA pursuant to paragraph 12,

Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 12 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 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 12, at the rates specified in paragraph 16.

14. 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

manufacture, preparing, packing, 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.

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

16. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, 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: $88.45 per hour or fraction thereof per representative for inspection and investigative work; $106.03 per hour or fraction thereof per representative for analytical or review work; $0.56 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.

17. 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 at any other location at which Defendants manufacture, prepare, pack, label, hold, or distribute articles of food 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.

18. Within ten (10) business days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. 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.

19. 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 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 ("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.

20. 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.

21. 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 Health One Pharmaceuticals, Inc., 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.

22. 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: seven thousand five hundred dollars ($7,500) in liquidated damages for each day such violation continues; an additional sum of seven thousand five hundred dollars ($7,500) 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.

23. 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.

24. 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.

25. 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.

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

27. 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 15th day of January, 2015.

IT IS SO ORDERED.

Dated: January 15, 2015

HONORABLE BEVERLY REID O'CONNELL
UNITED STATES DISTRICT COURT JUDGE

Entry consented to:

For Defendants

_____
RICHARD S. YEH
Individually and on behalf of Health One
Pharmaceuticals, Inc., as its President

_____
[ATTORNEY NAME]
Attorney for Defendants

For Plaintiff

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Acting Assistant Attorney General
JONATHAN F. OLIN
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