

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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4	UNITED STATES OF AMERICA,) CASE NO. 2:14-cv-09734
5	Plaintiff,)
6) CONSENT DECREE OF
7	v.) PERMANENT INJUNCTION
8	HEALTH ONE PHARMACEUTICALS,)
9	INC., a California corporation; and)
10	RICHARD S. YEH, an individual,)
11	Defendants.)
12)

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

1 Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the “Act”).

2 3. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for
3 introduction, or causing to be introduced or delivered for introduction, into
4 interstate commerce articles of food (dietary supplements), as defined by 21 U.S.C.
5 § 321(ff), that are:
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8 A. Adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that
9 they have been prepared, packed, or held in violation of current good
10 manufacturing practice regulations for dietary supplements (“Dietary Supplement
11 CGMP”), set forth in 21 C.F.R. Part 111; and
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13 B. Misbranded under 21 U.S.C. § 343 because their labels fail to:
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15 (1) list the common or usual names of all product ingredients, as required by 21
16 U.S.C. § 343(i)(2); (2) identify the part of the plant (e.g., root, leaves) from which
17 a botanical dietary ingredient is derived, as required by 21 U.S.C. § 343(s)(2)(C);
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19 (3) bear nutrition information that provides serving size and the number of servings
20 or other units of measure per container, as required by 21 U.S.C. § 343(q)(1)(A)
21 and (B); (4) bear nutrition information required by regulation, namely a
22 “Supplement Facts” panel, as required by 21 U.S.C. § 343(q)(5)(F); (5) bear the
23 place of business (city, state, ZIP) of the manufacturer, packer, or distributor, as
24 required by 21 U.S.C. § 343(e)(1); and/or (6) include a domestic address or
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26 domestic telephone number through which the responsible person (as described in
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1 21 U.S.C. § 379aa-1) may receive a report of a serious adverse event associated
2 with the product, as required by 21 U.S.C. § 343(y).

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4 4. Defendants violate 21 U.S.C. § 331(k) by causing articles of food
5 (dietary supplements) that Defendants hold for sale after shipment of one or more
6 of their components in interstate commerce to be adulterated within the meaning of
7 21 U.S.C. § 342(g)(1) and/or misbranded within the meaning of 21 U.S.C. § 343,
8 as described above in paragraph 3.
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11 5. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering
12 for introduction, or causing to be introduced or delivered for introduction, into
13 interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither
14 approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21
15 U.S.C. § 355(i).
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18 6. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that
19 Defendants hold for sale after shipment of one or more of their components in
20 interstate commerce to be misbranded within the meaning of 21 U.S.C. § 352(f)(1)
21 because their labels fail to bear adequate directions for use.
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24 7. Upon entry of this Decree, Defendants represent to this Court that
25 Defendants are not directly or indirectly engaged in manufacturing, preparing,
26 packing, labeling, holding, and/or distributing any articles of food (including but
27 not limited to dietary supplements and their components) and/or any articles of
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1 drug. If Defendants later intend to resume any such operations, Defendants must
2 first notify FDA in writing at least sixty (60) business days in advance of resuming
3 operations and comply with paragraphs 8(A)-(D) of this Decree. Defendants'
4 notice shall identify the type(s) of food and/or drug that Defendants intend to
5 manufacture, prepare, pack, label, hold, and/or distribute, and the location at which
6 Defendants intend to resume operations. Defendants shall not resume operations
7 until FDA has inspected Defendants' facility and operations pursuant to paragraph
8 8(E), Defendants have paid all costs pursuant to paragraph 8(F), and Defendants
9 have received written notice from FDA, as required by paragraph 8(G), and then
10 shall resume operations only to the extent authorized in FDA's written notice.
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15 8. Upon entry of this Decree, Defendants and each and all of their
16 directors, officers, agents, representatives, employees, attorneys, successors and
17 assigns, and any and all persons or entities in active concert or participation with
18 any of them who have received actual notice of this Decree by personal service or
19 otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a), and
20 the equitable authority of this Court, from directly or indirectly manufacturing,
21 preparing, packing, labeling, holding, or distributing any articles of food (including
22 but not limited to dietary supplements and their components) and/or drug, unless
23 and until:
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27 A. Defendants retain, at Defendants' expense, an independent
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1 person (“CGMP Expert”) who is without any personal or financial ties (other than
2 the retention agreement) to Defendants and/or their families, and who, by reason of
3 background, training, education, or experience, is qualified to inspect Defendants’
4 facility to determine whether the facility, methods, processes, and controls are
5 operated and administered in conformity with Dietary Supplement CGMP, 21
6 C.F.R. Part 111, and:
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8
9 (1) Defendants notify FDA in writing of the identity and
10 qualifications of the CGMP Expert as soon as they retain such expert; and
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12 (2) The CGMP Expert performs a comprehensive inspection
13 of Defendants’ facility and the methods, processes, and controls used to
14 manufacture, prepare, pack, label, and hold dietary supplements, and certifies in
15 writing to FDA the following: he or she has inspected Defendants’ facility,
16 methods, processes, and controls; all Dietary Supplement CGMP deviations
17 brought to Defendants’ attention by FDA, the CGMP Expert, and any other source
18 have been corrected; and Defendants’ facility and the methods, processes, and
19 controls used to manufacture, prepare, pack, label, and hold dietary supplements
20 are, in the CGMP Expert’s opinion, in compliance with this Decree, the Act, and
21 its implementing regulations. The CGMP Expert’s report of the inspection,
22 which shall be submitted to FDA, shall include, but not be limited to, a
23 determination that Defendants have methods, processes, and controls to ensure that
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1 they:

2 (a) Conduct at least one appropriate test or examination to
3 verify the identity of every component that is a dietary ingredient before using such
4 component, as required by 21 C.F.R. § 111.75(a)(1)(i);
5

6 (b) Determine whether component specifications that must
7 be established in accordance with 21 C.F.R. § 111.70(b) are met before using such
8 component, as required by 21 C.F.R. § 111.75(a)(2);
9

10 (c) Establish specifications for each component that include
11 the following: an identity specification; component specifications to ensure that
12 specifications for the purity, strength, and composition of the finished batch of the
13 dietary supplement are met; and limits on those types of contamination that may
14 adulterate or may lead to adulteration of the finished batch of the dietary
15 supplement to ensure the quality of the dietary supplement, as required by 21
16 C.F.R. § 111.70(b);
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18 (d) Establish product specifications for the identity, purity,
19 strength, and composition of the finished batch of the dietary supplement, and for
20 limits on those types of contamination that may adulterate, or that may lead to
21 adulteration of, the finished batch of the dietary supplement to ensure its quality, as
22 required by 21 C.F.R. § 111.70(e);
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24 (e) Determine whether finished dietary supplement batches
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1 meet the product specifications that must be established in accordance with 21
2 C.F.R. § 111.70(e), as required by 21 C.F.R. § 111.75(c);

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4 (f) Establish and implement quality control operations for
5 reviewing and approving all master manufacturing records and batch production
6 records, as required by 21 C.F.R. § 111.123(a)(1), (a)(2), and for making and
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8 keeping documentation of the review and approval of those records, as required by
9 21 C.F.R. § 111.140(b); and

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11 (g) Establish and implement quality control operations for
12 conducting material review and making disposition decisions in accordance with
13 21 C.F.R. § 111.113, as required by 21 C.F.R. § 111.123(a)(4), and for making and
14
15 keeping documentation of any material review and disposition decision, as
16 required by 21 C.F.R. § 111.140(b);

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18 B. Defendants retain, at Defendants' expense, an independent
19 person ("Labeling Expert") who is without any personal or financial ties (other
20 than the retention agreement) to Defendants and/or their families, except that this
21 person may be the same as the CGMP Expert described in paragraph 8(A), and
22 who, by reason of background, training, education, or experience, is qualified to
23 review Defendants' dietary supplement labeling to determine whether the labeling
24 complies with 21 U.S.C. § 343 and applicable regulations and whether it contains
25 claims that cause any dietary supplement that Defendants manufacture, prepare,
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1 pack, label, hold, or distribute to meet the Act's definition of a drug set forth in 21
2 U.S.C. § 321(g), and:

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

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7 (2) The Labeling Expert performs a comprehensive review
8 of all of Defendants' dietary supplement labeling and certifies in writing to FDA
9 the following: he or she has reviewed Defendants' dietary supplement labeling;
10 Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and
11 applicable regulations; and, Defendants' dietary supplement labeling does not
12 contain claims that cause any dietary supplement that Defendants manufacture,
13 prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set
14 forth in 21 U.S.C. § 321(g). The Labeling Expert's report of the labeling review
15 shall be submitted to FDA;
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19 C. Defendants recall and destroy, under FDA's supervision and in
20 accordance with the procedures provided in paragraph 9, all dietary supplements
21 that were manufactured, prepared, packed, labeled, held, or distributed between
22 September 1, 2011, and the date of entry of this Decree;
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24 D. Defendants report to FDA in writing the actions they have
25 taken to:
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27 (1) correct the Dietary Supplement CGMP deviations
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1 brought to Defendants' attention by FDA, the CGMP Expert, and any other source;

2 (2) ensure that the methods used in, and the facilities and
3 controls used for, manufacturing, preparing, packing, labeling, holding, and
4 distributing dietary supplements are operated and will be continuously
5 administered in conformity with Dietary Supplement CGMP;
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7 (3) correct the labeling deviations brought to Defendants'
8 attention by FDA, the Labeling Expert, and any other source; and
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10 (4) ensure that the dietary supplement labeling used by
11 Defendants (i) complies with 21 U.S.C. § 343 and its implementing regulations,
12 and (ii) does not contain claims that cause any dietary supplement that Defendants
13 manufacture, prepare, pack, label, hold, or distribute to meet the Act's definition of
14 a drug set forth in 21 U.S.C. § 321(g);
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17 E. As and when FDA deems necessary, FDA representatives
18 inspect Defendants' facility to determine whether the requirements of this Decree
19 have been met and whether Defendants are operating in conformity with the Act,
20 its implementing regulations, and this Decree;
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22 F. Defendants have paid all costs of FDA's inspections,
23 investigations, supervision, analyses, examinations, and reviews with respect to
24 paragraph 8, at the rates set forth in paragraph 16; and
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27 G. FDA notifies Defendants in writing that they appear to be in
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1 compliance with the requirements set forth in paragraphs 8(A)-(D) and (F) of this
2 Decree. In no circumstance shall FDA's silence be construed as a substitute for
3 written notification.
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5 9. Within twenty (20) business days after entry of this Decree,
6 Defendants shall recall all dietary supplements that were manufactured, prepared,
7 packed, labeled, held, or distributed between September 1, 2011, and the date of
8 entry of this Decree. Within thirty (30) business days after entry of this Decree,
9 Defendants, under FDA's supervision, shall destroy all dietary supplements that
10 are in Defendants' possession, custody, or control. Defendants shall bear the
11 costs of destruction and the costs of FDA's supervision. Defendants shall not
12 dispose of any dietary supplement in a manner contrary to the provisions of the
13 Act, any other federal law, or the laws or any State or Territory, as defined in the
14 Act, in which the dietary supplements are disposed.
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19 10. Upon resuming operations after complying with paragraphs 8(A)-(D)
20 and (F), and receiving FDA's written notification pursuant to paragraph 8(G),
21 Defendants shall:
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23 A. Retain an independent person (the "CGMP Auditor") who shall
24 meet the criteria for the CGMP Expert described in paragraph 8(A), and who may
25 be the same person retained as an Expert pursuant to paragraphs 8(A) or 8(B), to
26 conduct CGMP audit inspections of Defendants' facility no less frequently than
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1 once every six (6) months for a period of no less than five (5) years and then at
2 least once every year thereafter. The first CGMP audit shall occur not more than
3 six (6) months after Defendants have received FDA's written notification pursuant
4 to paragraph 8(G);
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6 B. At the conclusion of each CGMP audit inspection, the CGMP
7 Auditor shall prepare a detailed written audit report ("CGMP Audit Report")
8 analyzing whether Defendants are in compliance with Dietary Supplement CGMP
9 and identifying any deviations from such requirements ("CGMP Audit Report
10 Observations"). As a part of every CGMP Audit Report (except the first one), the
11 CGMP Auditor shall assess the adequacy of corrective actions taken by Defendants
12 to correct all previous CGMP Audit Report observations. The CGMP Audit
13 Reports shall be delivered contemporaneously to Defendants and FDA by courier
14 service or overnight delivery service, no later than five (5) business days after the
15 CGMP Audit Inspection is completed. In addition, Defendants shall maintain the
16 CGMP Audit Reports in separate files at Defendants' facility and shall promptly
17 make the CGMP Audit Reports available to FDA upon request;
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23 C. If a CGMP Audit Report contains any observations indicating
24 that Defendants' dietary supplements are not in compliance with the Dietary
25 Supplement CGMP, Defendants shall, within ten (10) business days after receipt of
26 the CGMP Audit Report, correct those observations, unless FDA notifies
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1 Defendants that a shorter time period is necessary. If, after receiving the CGMP
2 Audit Report, Defendants believe that correction of the deviations will take longer
3 than ten (10) business days, Defendants shall, within five (5) business days after
4 receipt of the CGMP Audit Report, submit to FDA in writing a proposed schedule
5 for completing corrections (“CGMP Audit Correction Schedule”). The CGMP
6 Audit Correction Schedule must be reviewed and approved by FDA in writing
7 prior to implementation by Defendants. In no circumstance shall FDA’s silence
8 be construed as a substitute for written approval. Defendants shall complete all
9 corrections according to the approved CGMP Audit Correction Schedule.
10
11 Immediately upon completion of all corrections, Defendants shall submit
12 documentation of their corrections to the CGMP Auditor. Within twenty (20)
13 business days after the CGMP Auditor’s receipt of Defendants’ documentation of
14 corrections, unless FDA notifies Defendants that a shorter time period is necessary,
15 or, if there is an FDA-approved CGMP Audit Correction Schedule, within the time
16 period provided therein, the CGMP Auditor shall review the actions taken by
17 Defendants to correct the CGMP Audit Report Observations. Within five (5)
18 business days after beginning that review, the CGMP Auditor shall report in
19 writing to FDA whether each of the CGMP Audit Report Observations has been
20 corrected and, if not, which CGMP Audit Report Observations remain uncorrected;
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27 D. Retain an independent person (the “Labeling Auditor”) who
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1 shall meet the criteria for the Labeling Expert described in paragraph 8(B), and
2 who may be the same person as the CGMP Auditor or the person retained as an
3 Expert pursuant to paragraphs 8(A) or 8(B), to conduct audit reviews of
4 Defendants' labeling no less frequently than once every six (6) months for a period
5 of no less than five (5) years and then at least once every year thereafter. The
6 first labeling audit shall occur not more than six (6) months after Defendants have
7 received FDA's written notification pursuant to paragraph 8(G);
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10 E. At the conclusion of each labeling audit, the Labeling Auditor
11 shall prepare a detailed written audit report ("Labeling Audit Report") analyzing
12 whether Defendants comply with 21 U.S.C. § 343 and its implementing
13 regulations, and whether they cause any dietary supplement that they manufacture,
14 prepare, pack, label, hold, or distribute to meet the Act's definition of a drug set
15 forth in 21 U.S.C. § 321(g), and identifying any deviations from such requirements
16 for dietary supplement labeling ("Labeling Audit Report Observations"). As a
17 part of every Labeling Audit Report, the Labeling Auditor shall assess the
18 adequacy of corrective actions taken by Defendants to correct all previous
19 Labeling Audit Report observations. The Labeling Audit Reports shall be
20 delivered contemporaneously to Defendants and FDA by courier service or
21 overnight delivery service, no later than five (5) business days after the Labeling
22 Audit Inspection is completed. In addition, Defendants shall maintain the
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1 Labeling Audit Reports in separate files at Defendants' facility and shall promptly
2 make the Labeling Audit Reports available to FDA upon request; and

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4 F. If a Labeling Audit Report contains any observations indicating
5 that Defendants do not comply with 21 U.S.C. § 343 and its implementing
6 regulations, or cause any dietary supplement that they manufacture, prepare, pack,
7 label, hold, or distribute to meet the Act's definition of a drug set forth in 21
8 U.S.C. § 321(g), Defendants shall, within ten (10) business days after receipt of the
9 Labeling Audit Report, correct those observations, unless FDA notifies Defendants
10 that a shorter time period is necessary. If, after receiving the Labeling Audit
11 Report, Defendants believe that correction of the deviations will take longer than
12 ten (10) business days, Defendants shall, within five (5) business days after receipt
13 of the Labeling Audit Report, submit to FDA in writing a proposed schedule for
14 completing corrections ("Labeling Audit Correction Schedule"). The Labeling
15 Audit Correction Schedule must be reviewed and approved by FDA in writing
16 prior to implementation by Defendants. In no circumstance shall FDA's silence
17 be construed as a substitute for written approval. Defendants shall complete all
18 corrections according to the approved Labeling Audit Correction Schedule.
19 Immediately upon completion of all corrections, Defendants shall submit
20 documentation of their corrections to the Labeling Auditor. Within twenty (20)
21 business days after the Labeling Auditor's receipt of Defendants' documentation of
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1 corrections, unless FDA notifies Defendants that a shorter time period is necessary,
2 or, if there is an FDA-approved Labeling Audit Correction Schedule, within the
3 time period provided therein, the Labeling Auditor shall review the actions taken
4 by Defendants to correct the Labeling Audit Report Observations. Within five (5)
5 business days after beginning that review, the Labeling Auditor shall report in
6 writing to FDA whether each of the Labeling Audit Report Observations has been
7 corrected and, if not, which Labeling Audit Report Observations remain
8 uncorrected and, if not, which Labeling Audit Report Observations remain
9 uncorrected.
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12 11. Defendants are permanently restrained and enjoined under 21 U.S.C.
13 § 332(a) from directly or indirectly doing or causing to be done any of the
14 following acts:
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16 A. Violating 21 U.S.C. § 331(a), by introducing or delivering for
17 introduction, or causing to be introduced or delivered for introduction, into
18 interstate commerce articles of food (including but not limited to dietary
19 supplements and their components) that are adulterated within the meaning of 21
20 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;
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22 B. Violating 21 U.S.C. § 331(k), by causing articles of food
23 (including but not limited to dietary supplements and their components) that
24 Defendants hold for sale after shipment of one or more of their components in
25 interstate commerce to become adulterated within the meaning of 21 U.S.C.
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1 § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

2 C. Violating 21 U.S.C. § 331(d) by introducing or delivering for
3 introduction, or causing to be introduced or delivered for introduction, into
4 interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither
5 approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval pursuant to 21
6 U.S.C. § 355(i);
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9 D. Violating 21 U.S.C. § 331(k) by causing articles of drug that
10 Defendants hold for sale after shipment of one or more of their components in
11 interstate commerce to become misbranded within the meaning of 21 U.S.C.
12 § 352(f)(1); and
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14 E. Failing to implement and continuously maintain the
15 requirements of this Decree.
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18 12. If, at any time after entry of this Decree, FDA determines, based on
19 the results of an inspection, the analysis of a sample, a report, or data prepared or
20 submitted by Defendants, the CGMP Expert, Labeling Expert, CGMP Auditor,
21 Labeling Auditor, or any other information, that Defendants have failed to comply
22 with any provision of this Decree, Defendants have violated the Act or its
23 implementing regulations, or additional corrective actions are necessary to achieve
24 compliance with this Decree, the Act, or its implementing regulations, FDA may,
25 as and when it deems necessary, notify Defendants in writing of the
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1 noncompliance and order Defendants to take appropriate corrective action,
2 including, but not limited to, ordering Defendants to immediately take one or more
3 of the following actions:
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5 A. Cease manufacturing, preparing, packing, labeling, holding, or
6 distributing any and all products;
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8 B. Recall, at Defendants' expense, any product that in FDA's
9 judgment is adulterated, misbranded, or otherwise in violation of this Decree, the
10 Act, or its implementing regulations;
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12 C. Revise, modify, expand, or continue to submit any reports or
13 plans prepared pursuant to this Decree;
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15 D. Submit additional reports or information to FDA as requested;

16 E. Institute or reimplement any of the requirements set forth in this
17 Decree;
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19 F. Issue a safety alert; and/or

20 G. Take any other corrective actions as FDA, in its discretion,
21 deems necessary to protect the public health or bring Defendants into compliance
22 with this Decree, the Act, or its implementing regulations.
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24 This remedy shall be separate and apart from, and in addition to, any other
25 remedy available to the United States under this Decree or under the law.
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27 13. Upon receipt of any order issued by FDA pursuant to paragraph 12,
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1 Defendants shall immediately and fully comply with the terms of the order. Any
2 cessation of operations or other action described in paragraph 12 shall continue
3 until Defendants receive written notification from FDA that Defendants appear to
4 be in compliance with this Decree, the Act, and its implementing regulations, and
5 that Defendants may resume operations. Defendants shall pay all costs of FDA's
6 inspections, investigations, supervision, analyses, examinations, sampling, testing,
7 reviews, document preparation, travel, and subsistence expenses to implement and
8 monitor the remedies set forth in paragraph 12, at the rates specified in paragraph
9 16.
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13 14. Representatives of FDA shall be permitted, without prior notice and
14 as and when FDA deems necessary, to inspect Defendants' operations and, without
15 prior notice, take any other measures necessary to monitor and ensure continuing
16 compliance with the terms of this Decree, the Act, and all applicable regulations.
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18 During such inspections, FDA representatives shall be permitted to: have
19 immediate access to Defendants' places of business including, but not limited to all
20 buildings, equipment, raw ingredients, in-process materials, finished products,
21 containers, packaging material, labeling, and other material therein; take
22 photographs and make video recordings; take samples of Defendants' raw
23 ingredients, in-process materials, finished products, containers, packaging material,
24 labeling, and other material; and examine and copy all records relating to the
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1 manufacture, preparing, packing, labeling, holding, and distribution of any and all
2 of Defendants' products and their components. The inspections shall be
3 permitted upon presentation of a copy of this Decree and appropriate credentials.
4 The inspection authority granted by this Decree is separate from, and in addition
5 to, the authority to make inspections under the Act, 21 U.S.C. § 374.
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8 15. Defendants shall promptly provide any information or records to FDA
9 upon request regarding the manufacturing, preparing, packing, labeling, holding,
10 and distribution of Defendants' products.
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12 16. Defendants shall pay all costs of FDA's inspections, investigations,
13 supervision, analyses, examinations, and reviews that FDA deems necessary to
14 evaluate Defendants' compliance with any part of this Decree at the standard rates
15 prevailing at the time the costs are incurred. As of the date that this Decree is
16 signed by the parties, these rates are: \$88.45 per hour or fraction thereof per
17 representative for inspection and investigative work; \$106.03 per hour or fraction
18 thereof per representative for analytical or review work; \$0.56 per mile for travel
19 expenses by automobile; government rate or the equivalent for travel by air or
20 other means; and the published government per diem rate for subsistence expenses
21 where necessary. In the event that the standard rates applicable to FDA
22 supervision of court-ordered compliance are modified, these rates shall be
23 increased or decreased without further order of the Court. Defendants shall make
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1 payment in full to FDA within twenty (20) business days of receiving written
2 notification from FDA of the costs.

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4 17. Within five (5) business days after entry of this Decree, Defendants
5 shall post a copy of this Decree in a conspicuous location in a common area at
6 Defendants' facility and at any other location at which Defendants manufacture,
7 prepare, pack, label, hold, or distribute articles of food and shall ensure that the
8 Decree remains posted for as long as the Decree remains in effect. Within ten (10)
9 business days after entry of this Decree, Defendants shall provide to FDA an
10 affidavit, from a person with personal knowledge of the facts stated therein, stating
11 the fact and manner of compliance with this paragraph.
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15 18. Within ten (10) business days after entry of this Decree, Defendants
16 shall hold a general meeting or series of smaller meetings for all employees, at
17 which they shall describe the terms and obligations of this Decree. Within fifteen
18 (15) business days after entry of this Decree, Defendants shall provide to FDA an
19 affidavit, from a person with personal knowledge of the facts stated therein, stating
20 the fact and manner of compliance with this paragraph and a copy of the agenda,
21 list of attendees, and meeting minutes from the meeting(s) held pursuant to this
22 paragraph.
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26 19. Within ten (10) business days after entry of this Decree, Defendants
27 shall provide a copy of the Decree by personal service or certified mail (return
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1 receipt requested) to each and all of their directors, officers, agents,
2 representatives, employees, attorneys, successors, and assigns, and any and all
3 persons or entities in active concert or participation with any of them (“Associated
4 Persons”). Within twenty (20) business days after entry of this Decree,
5 Defendants shall provide to FDA an affidavit, from a person with personal
6 knowledge of the facts stated therein, stating the fact and manner of compliance
7 with this paragraph, identifying the names, addresses, and positions of all
8 Associated Persons who have received a copy of this Decree, and attaching a copy
9 of the executed certified mail return receipts.
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13 20. In the event that any of the Defendants becomes associated with any
14 additional Associated Person(s) at any time after entry of this Decree, Defendants
15 shall immediately provide a copy of this Decree, by personal service or certified
16 mail (return receipt requested) to such Associated Person(s). Within five (5)
17 business days of each time that any of the Defendants becomes associated with any
18 additional Associated Person, Defendants shall provide to FDA an affidavit, from a
19 person with personal knowledge of the facts stated therein, stating the fact and
20 manner of compliance with this paragraph, identifying the names, addresses, and
21 positions of all Associated Persons who received a copy of this Decree pursuant to
22 this paragraph, and attaching a copy of the executed certified mail return receipts.
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27 21. Defendants shall notify FDA in writing at least ten (10) business days
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1 before any change in ownership, name, or character of their business that occurs
2 after entry of this Decree, including an incorporation, reorganization, creation of a
3 subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other
4 change in the structure or identity of Health One Pharmaceuticals, Inc., or the sale
5 or assignment of any business assets, such as buildings, equipment, or inventory
6 that may affect obligations arising out of this Decree. Defendants shall provide a
7 copy of this Decree to any prospective successor or assign at least twenty (20)
8 business days prior to any sale or assignment. Defendants shall furnish FDA with
9 an affidavit of compliance with this paragraph no later than ten (10) business days
10 prior to such assignment or change in ownership.
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15 22. If any Defendant fails to comply with any provision of this Decree,
16 the Act, or its implementing regulations, including any time frame imposed by this
17 Decree, then Defendants shall pay to the United States of America: seven
18 thousand five hundred dollars (\$7,500) in liquidated damages for each day such
19 violation continues; an additional sum of seven thousand five hundred dollars
20 (\$7,500) in liquidated damages per day, per violation for each violation of this
21 Decree, the Act, or its implementing regulations; and an additional sum in
22 liquidated damages equal to twice the retail value of any product distributed in
23 violation of this Decree, the Act, or its implementing regulations. Defendants
24 understand and agree that the liquidated damages specified in this paragraph are
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1 not punitive in nature and their imposition does not in any way limit the ability of
2 the United States to seek, or the Court to impose, additional civil or criminal
3 penalties to be paid by Defendants, or remedies based on conduct that may also be
4 the basis for payment of liquidated damages pursuant to this paragraph.
5

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

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

22 25. All notifications, correspondence, and communications to FDA
23 required by the terms of this Decree shall be prominently marked "Decree
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1 Correspondence” and addressed to the District Director, Los Angeles District
2 Office, United States Food and Drug Administration, 19701 Fairchild, Irvine,
3 California 92612-2506, and shall reference this civil action by case name and civil
4 action number.
5

6 26. Except as provided in the foregoing provisions of this Decree, the
7 parties shall bear their own costs and attorneys’ fees in this action.
8

9 27. This Court retains jurisdiction over this action and the parties thereto
10 for the purpose of enforcing and modifying this Decree and for the purpose of
11 granting such additional relief as may be necessary or appropriate.
12

13 SO ORDERED, this 15th day of January, 2015.
14

15 **IT IS SO ORDERED.**
16

17 Dated: January 15, 2015

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19 _____
20 HONORABLE BEVERLY REID O’CONNELL
21 UNITED STATES DISTRICT COURT JUDGE
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1 Entry consented to:
2 For Defendants

3
4 _____
5 RICHARD S. YEH
6 Individually and on behalf of Health
7 One
8 Pharmaceuticals, Inc., as its President

9
10 _____
11 [ATTORNEY NAME]
12 Attorney for Defendants

For Plaintiff

JOYCE R. BRANDA
Acting Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director

By: _____
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