

1 IN THE CIRCUIT COURT OF THE STATE OF OREGON 17CV11267
2 FOR THE COUNTY OF MULTNOMAH

3 IN THE MATTER OF:
4 VITAMIN SHOPPE, INC.
5

Case No.
ASSURANCE OF VOLUNTARY
COMPLIANCE
6
7

8 1.

9 Vitamin Shoppe, Inc. does business in Oregon and is the Respondent herein. This
10 agreement is between Respondent and the Oregon Department of Justice (DOJ) (herein
11 "Parties"), acting pursuant to ORS 646.632.

12 **PROCEDURE**

13 2.

14 This Assurance of Voluntary Compliance (AVC) is a settlement of a disputed
15 matter. It shall not be considered an admission of a violation for any purpose. Respondent and
16 DOJ agree that no provision of the AVC operates as a penalty, forfeiture, or punishment under
17 the Constitution of the United States, under the Constitution of the State of Oregon, or under any
18 other provision of law. Neither the fact that the Parties entered into this AVC nor anything
19 contained in this AVC is or implies an admission that the Respondent has engaged in any trade
20 practices prohibited by the Oregon Unlawful Trade Practices Act or any other federal or state
21 law, administrative rule or regulation, or of any other matter of fact or law, or of any liability or
22 wrongdoing, all of which Respondent expressly denies. Respondent does not admit any
23 violation of ORS 646.605 to 646.656 and does not admit any wrongdoing that was or could have
24 been alleged by DOJ under that law. Respondent is entering into this AVC solely for the
25 purpose of settlement.

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3.

Respondent understands and agrees that this AVC applies to Respondent, its subsidiaries, Affiliates, successors, or assigns and each of their respective officers, employees, directors and agents (in both their official and personal capacities) (collectively, the "Released Parties"). "Affiliate" means any business entity that is controlled by or is under common control with the Respondent. "Controlled by" and "under common control with" as used in the definition of "Affiliate" means the power to direct or cause the direction or the management and policies of the business entity.

4.

Respondent understands and agrees that if this AVC is accepted by DOJ, it will be submitted to the Circuit Court of the State of Oregon for Multnomah County for approval, and, if approved, will be filed with the court pursuant to ORS 646.632(2).

5.

Respondent waives any further notice of submission to and filing with the court of this AVC. Respondent agrees to accept service of a conformed or court certified copy by prepaid first class mail sent to the address following its respective signature.

6.

Respondent understands that violation of any of the terms of this AVC may result in contempt of court proceedings, civil penalties of up to \$25,000 for each violation, and such further relief as the court may deem appropriate, ORS 646.632(4), ORS 646.642(1) and ORS 646.642(2), provided that for the purposes of resolving disputes with respect to compliance with this AVC:

- A. Should DOJ have a reasonable basis to believe that Respondent has engaged in a practice that violates a provision of this AVC subsequent to the date of the Court's approval of this AVC, then DOJ shall notify Respondent in writing of the specific objection, identify with particularity the provisions of this AVC that the practice

1 appears to violate, and give Respondent ten (10) days to respond to the notification
2 prior to filing any court action; provided, however, DOJ may act before the ten (10)
3 days expires if DOJ concludes that, because of the specific practice, a threat to the
4 health or safety of the public requires immediate action.

5 B. Respondent's written response to DOJ shall contain either a statement explaining why
6 Respondent believes it is in compliance with the AVC or an explanation of how the
7 alleged violation occurred and a statement explaining how Respondent has cured or
8 intends to cure the alleged violation.

9 C. Upon giving Respondent ten (10) days to respond to the notification described above,
10 DOJ shall also be permitted reasonable access to inspect and copy relevant, non-
11 privileged, non-work product records and documents in the possession, custody or
12 control of Respondent that relate to Respondent's compliance with each provision of
13 this AVC.

14 D. Nothing in this paragraph shall be interpreted to limit the DOJ's Civil Investigative
15 Demand ("CID") or subpoena authority, to the extent such authority exists under
16 applicable state law, and Respondent reserves all of its rights with respect to a CID or
17 subpoena issued pursuant to such authority.

18 E. Nothing in this paragraph shall be interpreted to limit DOJ's ability to bring an action
19 to enforce this AVC against Respondent after Respondent has provided the statement
20 or explanation described in B above.

21 7.

22 The Parties acknowledge that no other promises, representations or agreements of any
23 nature have been made or entered into by the Parties. The Parties further acknowledge that this
24 AVC constitutes a single and entire agreement that is not severable or divisible, except that if
25 any provision herein is found to be legally insufficient or unenforceable, the remaining
26 provisions shall continue in full force and effect.

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8.

This AVC shall be inadmissible in any case for any purpose, or otherwise used to support any claim, cause of action, right asserted or request for relief of any kind in any action against Respondent, except an action to enforce this AVC. This AVC shall not create a private cause of action or confer any right to any third party for violation of any federal or state statute except that DOJ may file an action to enforce the terms of this AVC, subject to Paragraph 6. No part of this AVC, including its statements and commitments, shall constitute evidence of any liability, fault, or wrongdoing by Respondent. This AVC shall not be construed or used as a waiver or limitation of any defense otherwise available to Respondent in any action, or of Respondent's right to defend itself from, or make any arguments in, any private individual, regulatory, governmental, or class claims or suits relating to the subject matter or terms of this AVC. This AVC is made without trial or adjudication of any issue of fact or law or finding of liability of any kind.

9.

This AVC represents the full and complete terms of the settlement entered into by the Parties. In any action undertaken by DOJ, or Respondent, no prior versions of this AVC, and no prior versions of any of its terms, that were not entered by the Court in this AVC, may be introduced for any purpose whatsoever.

REMEDIES

10.

Respondent shall comply with ORS 646.605 *et seq.* and ORS 166.715 *et seq.* relating to the marketing, sale and promotion of dietary supplements. Respondent shall not make any false, misleading or deceptive representation regarding any dietary supplement in violation of ORS 646.605 *et seq.* and ORS 166.715 *et seq.*

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11.

Respondent agrees that it shall not sell products that contain DMAA. DMAA is also known as 1,3 DMAA; 1,3 Dimethylamylamine; 1,3 Dimethylpentylarnine; 2-Amino-4-methylhexane; 2-Hexanamine, 4-methyl- (9CI); 4-Methyl-2-23 hexanamine; 4-Methyl-2-hexylamine; Dimethylamylamine; Geranamine; Methylhexanamine; Methylhexanenamine; geranium extract; Pelargonium graveolens extract; and InChIKey=YAHRDLICUYEDAU-UHFFFAOYSA-N.

12.

Respondent agrees that it shall not sell products that contain picamilon. Picamilon is also known as nicotinoyl-GABA, pycamilon, picamilone, pikatropin, pikamilon, nicotinyl-gamma-aminobutyric acid, and pikamilon.

13.

Respondent agrees that it shall not sell products that contain oxilofrine. Oxilofrine is also known as methylsynephrine and p-hydroxyephedrine.

14.

Respondent agrees that it shall not sell products that contain aegeline. Aegeline is also known as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamamide.

15.

Respondent agrees that it shall not sell products that contain the botanical cynanchum auriculatum.

16.

After the Court's approval of this AVC, in the event Respondent becomes aware of a public announcement, warning, alert, publication, notice or report issued by a governmental agency in the United States, Australia, Canada, Britain, or the European Union that does not rise to the level of an FDA Public Written Notice (as defined in Paragraph 18(A) below) asserting that a purported dietary ingredient fails to qualify as such under 21 U.S.C. § 321(ff)(1), that a

1 pre-market notification should have been submitted to the U.S. Food and Drug Administration
2 (“FDA”) under 21 U.S.C. § 350b and 21 CFR § 190.6 but was not so submitted, or that a dietary
3 ingredient is unsafe, and Respondent at that time either offers for sale any dietary supplement
4 containing such ingredient or is considering a request by a third party to offer for sale a dietary
5 supplement containing such ingredient (“Government Publication”), Respondent shall within
6 thirty (30) days conduct a reasonable due diligence review of the ingredient. If Respondent
7 reasonably determines that the purported dietary ingredient fails to qualify as such under 21
8 U.S.C. § 321 (ff)(1), that a pre-market notification should have been submitted to the FDA under
9 21 U.S.C. § 350b and 21 CFR § 190.6 but was not so submitted, or that the dietary ingredient is
10 unsafe, then Respondent shall: (i) if Respondent has not yet commenced offering for sale the
11 dietary ingredient, refrain from doing so in the future; or (ii) if Respondent then currently offers
12 for sale the dietary ingredient, promptly suspend sales. When conducting its reasonable due
13 diligence review, Respondent shall not rely exclusively on the Purchase Agreement warranties
14 required by Paragraph 17, and shall consider the totality of the facts and circumstances relating
15 to the product. DOJ shall be permitted to seek relevant, non-privileged, non-work product
16 information from Respondent about its reasonable due diligence review and decision to continue
17 or initiate sale of products containing a dietary ingredient that is the subject of a Government
18 Publication.

19 17.

20 Each Purchase Agreement between Respondent and a third-party vendor shall require
21 that the vendor explicitly warrant, as stated below or in substantively similar language, that each
22 of its dietary supplements sold to Respondent shall:

- 23 A. Have cleared or be exempt from pre-market notification or approval requirements,
24 and be manufactured, packed for shipment, stored and shipped in accordance with
25 applicable current Good Manufacturing Practices regulations promulgated by the
26 FDA under the federal Food, Drug and Cosmetic Act (“FDCA”);

- 1 B. Be marked with the information required by law or regulation; and
2 C. Be, as of the date of such shipment or delivery, on such date, not adulterated or
3 misbranded within the meaning of the FDCA, and not an article which may not, under
4 the provisions of section 404, 505, or 512 of the FDCA, be introduced into interstate
5 commerce.

6 These warranties are understood by the Parties to mean that the vendor warrants, among
7 other things, that each dietary supplement contains dietary ingredients and non-dietary
8 ingredients that are in compliance with the FDCA.

9 18.

10 When Respondent receives or learns of the issuance of any FDA Public Written Notice
11 (defined below) wherein the FDA has indicated its belief that any purported dietary supplement
12 or any ingredient in a purported dietary supplement is not legal under federal law and/or is not
13 safe, Respondent will take immediate action to suspend the sale of such product or products
14 known to contain the ingredient.

- 15 A. FDA Public Written Notice means: (i) a document identified by the FDA as a
16 "Warning Letter" (a) that is addressed directly to and received by Respondent or is
17 addressed to any other company or individual and is accessible to the general public
18 on the FDA's website and (b) that explicitly calls for Respondent or such other
19 company or individual to cease distribution of a dietary supplement product; (ii) an
20 FDA Public Health Advisory that is accessible to the general public on the FDA's
21 website; (iii) the commencement of legal action by the U.S. Department of Justice
22 that is announced to the general public on the FDA's website; or (iv) a Declaration by
23 an official of the FDA acting in an official capacity that concludes that a purported
24 dietary ingredient does not qualify as a dietary ingredient under 21 U.S.C.
25 § 321(ff)(1) which is received by Respondent.

- 26 B. This provision is subject to the Parties' understanding that, in the event the FDA

1 in a written statement subsequent to the FDA Public Written Notice concludes or
2 determines that the dietary supplement or ingredient is legal under federal law and/or
3 is safe, Respondent shall be permitted to resume sales of such supplement or
4 ingredient in a manner consistent with the FDA's subsequent written statement.

5 19.

6 Within fifteen (15) days of the Court's approval of this AVC, Respondent shall pay the
7 sum of \$545,000 for deposit to the Department of Justice Account established pursuant to
8 ORS 180.095 to be used by DOJ as provided by law.

9 **RELEASE**

10 20.

11 The State of Oregon, by DOJ's execution of this AVC, releases the Released Parties from
12 the following: all known and unknown claims, causes of action, damages, restitution, fines,
13 costs, requests for injunctive relief, and penalties that were or could have been asserted by the
14 State of Oregon pursuant to ORS 646.605 *et seq.* and ORS 166.715 *et seq.* up to and including
15 the date of the Court's approval of this AVC, arising from the Covered Conduct that is the
16 subject of this AVC. "Covered Conduct" shall mean the marketing, promotion and sale of
17 dietary supplement products.

18 **JURISDICTION**

19 21.

20 Nothing in this AVC shall require Respondent to take an action that is prohibited by the
21 FDCA or any regulation promulgated thereunder, or by the FDA; or fail to take an action that is
22 required by the FDCA or any regulation promulgated thereunder, or by FDA.

23 22.

24 This Court retains jurisdiction of this AVC and the Parties hereto for the purpose of
25 enforcing and modifying this AVC. Either Party may propose a modification to this AVC to the
26 other Party. If the other Party agrees, the proposed revised AVC shall be submitted jointly to

1 this Court for approval. If the other Party does not agree, the proposing Party may petition this
2 Court for modification and the objecting Party shall have sixty (60) days within which to submit
3 an objection. Any modification will not be in effect until such time as it is approved by this
4 Court.

5 **NOTICE**

6 23.

7 Any written notice required or permitted to be given by one Party to the other Party under
8 this AVC shall be sent by facsimile or by an overnight courier service to the person(s) named
9 below:

10 If to Respondent:

11 Vitamin Shoppe, Inc.
12 ATTN: General Counsel
13 300 Harmon Meadow Blvd.
14 Secaucus, NJ 07094
15 Fax: (201) 552-6464

16 If to DOJ:

17 David A. Hart, Assistant Attorney-in-Charge
18 Oregon Department of Justice
19 100 SW Market Street
20 Portland, OR 97201
21 Fax: (971) 673-1884

22 And

23 ATTN: Attorney-in-Charge
24 Consumer Protection Section
25 Oregon Department of Justice
26 1162 Court Street
Salem, OR 97301

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1 Notice shall be considered given when (1) for facsimile, the facsimile is sent with
2 confirmation of complete transmission or (2) for overnight courier service, when the notice is
3 received.

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6 **APPROVAL BY COURT**

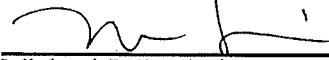
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8 APPROVED FOR FILING and SO ORDERED this 16 day of March, 2017.

9
10 **NAN G. WALLER**

11 Circuit Court Judge

1 REVIEW BY RESPONDENTS' ATTORNEY

2 Approved as to form.

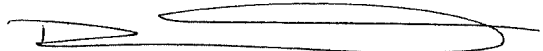
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4 Michael J. Sandmire
5 Ater Wynne LLP
6 1331 NW Lovejoy Street, Suite 900
7 Portland, OR 97209-3280
8 503-226-8639 direct
9 mjs@aterwynne.com

10 Attorney for Respondent

11 RESPONDENT

12 I, David M. Kastin, being first duly sworn on oath depose and say that I am the Senior
13 Vice President, General Counsel, and Corporate Secretary of Vitamin Shoppe, Inc., and am fully
14 authorized and empowered to sign this Assurance of Voluntary Compliance on behalf of Vitamin
15 Shoppe, Inc., and bind the same to the terms hereof.

16 

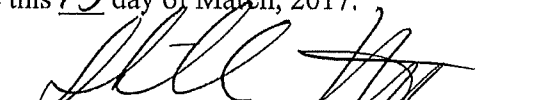
17 Signature

18 David M. Kastin
19 Print Name

20 The Vitamin Shoppe
21 300 Harmon Meadow Blvd.
22 2nd Floor
23 Secaucus, NJ 07094
24 Address

25 SUBSCRIBED AND SWORN to before me this 13 day of March, 2017.

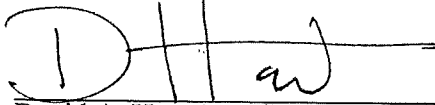
26 **SHATESHA S HUGGINS**
Notary Public, State of New Jersey
No. 50039759
Qualified in Bergen County
Commission Expires June 9, 2021


Notary Public for New Jersey

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3 **ACCEPTANCE OF DOJ**

4 Accepted this 15th day of March, 2017.

5 ELLEN F. ROSENBLUM
6 Attorney General

7 

8 David A. Hart OSB #002750
9 Assistant Attorney General
10 Department of Justice
11 Of Attorneys for Plaintiff
12 Financial Fraud/Consumer Protection Section
13 100 SW Market Street
14 Portland, OR 97201
15 Phone: (971) 673-1880
16 Fax: (971) 673-1884
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