

FILED
SEP 2 - 2014
RICHARD W. WIEKING
CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE

1 MELINDA HAAG (CABN 132612)
United States Attorney

8 UNITED STATES DISTRICT COURT
9 NORTHERN DISTRICT OF CALIFORNIA
10 SAN JOSE DIVISION

11 UNITED STATES OF AMERICA,
12 Plaintiff,

13 v.

14 ARIS ARISTIDIS VAVASIS,
15 Defendant.

) No. CR-14-00360 LHK
)
) VIOLATIONS: 21 U.S.C. § 331(d) --
) Introduction/Delivery for Introduction of Unapproved
) New Drug With Intent to Defraud and Mislead-
) Methasterone; 21 U.S.C. § 331(a) --
) Introduction/Delivery for Introduction of Misbranded
) Drug With Intent to Defraud and Mislead- Ephedrine.
)
) SAN JOSE VENUE

17
18 SUPERSEDING INFORMATION

19 The United States Attorney charges:

20 INTRODUCTORY ALLEGATIONS

21 At all times relevant to this Indictment:

- 22 1. Nutrition Dome, Inc. was a business located at 4518 11th Avenue, 2nd level, Brooklyn,

23
24 SUPERSEDING INFORMATION
CR-14-00360 LHK

1 New York, 11219. Nutrition Dome, Inc. sold and shipped purported dietary supplements in interstate
2 commerce, including to the Northern District of California, between on or about November, 2010 and
3 July, 2012.

4 2. The defendant, ARIS ARISTIDIS VAVASIS (“VAVASIS”) was the owner of Nutrition
5 Dome, Inc. and controlled and directed its employees and business dealings. Beginning in approximately
6 November, 2010, and continuing through July, 2012, VAVASIS knowingly caused to be manufactured
7 and distributed in interstate commerce two purported dietary supplements, “Methastadrol,” and
8 “Lipodrene,” both of which contained drugs that were not approved by the Food and Drug
9 Administration.

10 3. Specifically, VAVASIS knowingly caused to be manufactured and distributed in
11 interstate commerce the product “Methastadrol” (also known as “Superdrol”) as a purported dietary
12 supplement. “Methastadrol” was knowingly labeled in a manner that was intended to deceive the Food
13 and Drug Administration, in that it was labeled as a dietary supplement, when in fact “Methastadrol”
14 could not be defined as a dietary supplement. The active ingredient in “Methastadrol” was the Schedule
15 III anabolic steroid, Methasterone (also known by the chemical name 17α -methylandrostanolone). 21
16 U.S.C. §§ 802(41(A), 812(b), Schedule III (e); 21 C.F.R §§ 1300.01(b)(32),
17 1308.13(f).
18

19 4. Also, VAVASIS knowingly caused to be manufactured and distributed in interstate
20 commerce the product “Lipodrene” as a purported dietary supplement. “Lipodrene” was knowingly
21 labeled in a manner that was intended to deceive the Food and Drug Administration, in that it was
22

1 labeled as a dietary supplement, when in fact "Lipodrene" could not be defined as a dietary supplement.

2 The active ingredient in "Lipodrene" was the unapproved drug Ephedrine.

3 COUNT ONE: (Title 21, United States Code, Sections 331(d) – Introduction/Delivery for
4 Introduction of Unapproved New Drug With Intent to Defraud and Mislead-
Methasterone)

5 5. Paragraphs 1-4 above are hereby re-alleged and incorporated by reference as if set forth
6 in full herein.

7 6. Beginning at a date unknown but believed to be no later than November, 2010, and
8 continuing until on or about July, 2012, in the Northern District of California and elsewhere, the
9 defendant,

10 ARIS ARISTIDIS VAVASIS,

11 with the intent to defraud and mislead, did introduce, and deliver for introduction, into interstate
12 commerce, "Methastadrol," which contained Methasterone, a Schedule III controlled substance, which
13 was a "new drug" as defined at Title 21, United States Code, Section 321(p), which lacked the FDA
14 approval required by Title 21, United States Code, section 355, in violation of Title 21, United States
15 Code, Sections 331(d) & 331(a)(1).

16 COUNT TWO: (Title 21, United States Code, Section 331(a) – Introduction/Delivery for
17 Introduction of Misbranded Drug With Intent to Defraud and Mislead- Ephedrine)

18 7. Paragraphs 1-4 above are hereby re-alleged and incorporated by reference as if set forth
19 in full herein.

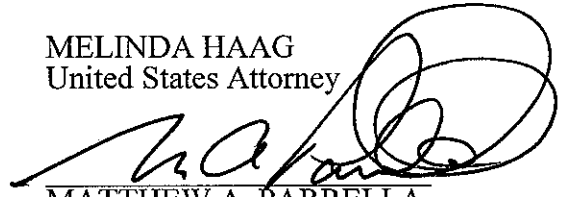
20 8. Beginning at a date unknown but believed to be no later than November, 2010, and
21 continuing until on or about July, 2012, in the Northern District of California and elsewhere, the
22 defendant,

ARIS ARISTIDIS VAVASIS,

with the intent to defraud and mislead, did introduce, and deliver for introduction, into interstate commerce "Lipodrene," a drug as defined at Title 21, United States Code, Section 321(g), which was misbranded as defined at Title 21, United States Code, Section 352(a), in that the label falsely represented that "Lipodrene" was a dietary supplement when it did not qualify as such, and also misbranded as defined at Title 21, United States Code, Section 352(f)(1), in that the drug lacked adequate directions for its intended use, all in violation of Title 21, United States Code, Sections 331(a) & 333(a)(2).

DATED: 09-02-14

MELINDA HAAG
United States Attorney



MATTHEW A. PARRELLA
Chief, CHIP Unit

(Approved as to form: MAP)
AUSA PARRELLA

SEP 2 2014 10:23 AM
SUPERSEDING INFORMATION
CR-14-00360 LHK

AO 257 (Rev. 6/78)

DEFENDANT INFORMATION RELATIVE TO A CRIMINAL ACTION - IN U.S. DISTRICT COURT

BY: COMPLAINT INFORMATION INDICTMENT
 SUPERSEDING

OFFENSE CHARGED

Count 1: Petty
21 USC 331(d) - Introduction /Delivery for Introduction of Unapproved New Drug with Intent to Defraud and Mislead Minor
Count 2: Misdemeanor
21 USC 331(a) - Introduction /Delivery for Introduction of Misbranded Drug with Intent to Defraud and Mislead Felony

PENALTY: Counts 1 & 2 (each count):
Up to 3 years imprisonment, \$10,000 fine (or twice the gross gain or gross loss), 1 year term of supervised release, \$100 special assessment.

Name of District Court, and/or Judge/Magistrate Location

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DISTRICT COURT
FILED

DEFENDANT - U.S.

SEP 2 - 2014
HILTIARD W. WICKING
CLERK U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE
ARIS ARISTIDIS VAM...
DISTRICT COURT NUMBER

PROCEEDING

Name of Complainant Agency, or Person (& Title, if any)

S/A Jeff Novitzky, FDA-OCI

person is awaiting trial in another Federal or State Court, give name of court

this person/proceeding is transferred from another district per (circle one) FRCrp 20, 21, or 40. Show District

this is a re prosecution of charges previously dismissed which were dismissed on motion of:
 U.S. ATTORNEY DEFENSE } SHOW DOCKET NO.

this prosecution relates to a pending case involving this same defendant } MAGISTRATE CASE NO.

prior proceedings or appearance(s) before U.S. Magistrate regarding this defendant were recorded under } CR-14-360 LHK

Name and Office of Person Furnishing Information on this form MELINDA HAAG

U.S. Attorney Other U.S. Agency

Name of Assistant U.S. Attorney (if assigned) MATTHEW A. PARRELLA

DEFENDANT

IS NOT IN CUSTODY

Has not been arrested, pending outcome this proceeding.

- 1) If not detained give date any prior summons was served on above charges
- 2) Is a Fugitive
- 3) Is on Bail or Release from (show District)

IS IN CUSTODY

- 4) On this charge
- 5) On another conviction } Federal State
- 6) Awaiting trial on other charges

If answer to (6) is "Yes", show name of institution

Has detainer been filed? Yes No } If "Yes" give date filed

DATE OF ARREST Month/Day/Year

Or... if Arresting Agency & Warrant were not

DATE TRANSFERRED TO U.S. CUSTODY Month/Day/Year

This report amends AO 257 previously submitted

ADDITIONAL INFORMATION OR COMMENTS

PROCESS:

SUMMONS NO PROCESS* WARRANT Bail Amount: _____

If Summons, complete following:
 Arraignment Initial Appearance

Defendant Address: _____
c/o _____

* Where defendant previously apprehended on complaint, no new summons or warrant needed, since Magistrate has scheduled arraignment

Date/Time: Sept. 3, 2014/8:30 a.m. Before Judge: Paul S. Grewal

Comments: