UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF LOUISIANA

SUPERSEDING INDICTMENT FOR CONSPIRACY TO DISTRIBUTE AND POSSESS WITH THE INTENT TO DISTRIBUTE SIBUTRAMINE, DISTRIBUTION OF SIBUTRAMINE, INTRODUCTION OF MISBRANDED DRUG INTO INTERSTATE COMMERCE, AND FORFEITURE

UNITED STATES OF AMERICA : CRIMINAL NO. 15-120-JWD-RLB

:

: 21 U.S.C. § 846

versus : 21 U.S.C. § 841(a)(1)

21 U.S.C. § 331(a)

18 U.S.C. § 2

DARLENE V. KRUEGER : 21 U.S.C. § 853

THE GRAND JURY CHARGES:

At all times relevant to this Indictment:

GENERAL ALLEGATIONS

- 1. The defendant, **DARLENE V. KRUEGER** (hereinafter referred to as "**KRUEGER**"), operated a business, based in or about LaPlace, Louisiana and Destrehan, Louisiana, which principally offered for sale a variety of purported weight loss products that she promoted as "all natural" dietary supplements.
- 2. J.H. operated a business, based in or about Ft. Lauderdale, Florida, which principally offered for sale a variety of purported weight loss products that he promoted as "all natural" dietary supplements. In addition, J.H. supplied bulk amounts of the purported weight loss products to **KRUEGER** and others for further distribution.
- 3. The United States Food and Drug Administration (FDA) was the federal agency charged with ensuring that drugs sold to the public were safe and effective for their intended uses and bore labeling containing true, complete, and accurate information.

- 4. The Controlled Substances Act (CSA), the Federal Food, Drug, and Cosmetic Act (FDCA), and the Code of Federal Regulations (CFR) governed the manufacture, distribution, and dispensing of all drugs and drug components in the United States.
- 5. Under federal law, controlled substances were placed into five categories, or "Schedules," according to their potential for abuse, dependence, and accepted medical use. Schedule II, III, IV and V controlled substances required written prescriptions issued for a legitimate medical purpose by a licensed medical practitioner.
- 6. Under federal law, only persons or entities registered with the Drug Enforcement Administration (DEA) could import a Schedule IV controlled substance into the United States or be involved in its lawful distribution in the United States.

SIBUTRAMINE

- 7. Sibutramine, an amphetamine analogue pharmacologically similar to other anorectic agents that produce central nervous system stimulation and amphetamine-like effects in humans, was classified as a Schedule IV controlled substance.
- In 1997, the FDA approved a prescription drug under the trade name "Meridia"
 for the management of obesity. The active pharmaceutical ingredient in that prescription drug was sibutramine.
- 9. Due to safety concerns resulting from studies that showed significantly increased risk of strokes and heart attacks, "Meridia" was voluntarily withdrawn from the marketplace in 2010. Since the removal of "Meridia," no drug containing sibutramine has been approved for use in humans in the United States.
- 10. Testing conducted by the FDA revealed the presence of sibutramine in numerous illegal weight loss products, which were sold over-the-counter and on the internet. Many of

these products were falsely marketed as dietary supplements; however, these products contain sibutramine and were not approved for sale in the United States under the applicable rules and regulations.

THE DRUGS

11. "Slim Forte Slimming Capsules," "Slim Forte Double Power Slimming Capsules," "Slim-Vie Slimming Capsules," and "Slim-Vie Double Power Slimming Capsules" (hereinafter referred to as "The Drugs") were misbranded drugs containing sibutramine, which were falsely labeled as all natural dietary supplements, none of which listed the ingredient sibutramine anywhere in the labeling, and which were marketed and sold in the United States in contravention of federal law.

(Conspiracy)

- 12. Paragraphs 1 through 11 of this Indictment are re-alleged and incorporated herein as factual allegations.
- 13. Beginning on an exact date unknown to the Grand Jury, but in or about 2009, and continuing through on or about November 13, 2014, in the Middle District of Louisiana and elsewhere, **DARLENE V. KRUEGER**, the defendant herein, and J.H. did conspire with each other and others, both known and unknown to the Grand Jury, to knowingly and intentionally distribute and possess with intent to distribute a substance containing a detectable amount of sibutramine, a Schedule IV controlled substance, in violation of Title 21, United States Code, Section 841(a)(1), and did aid and abet the commission of said conspiracy.

OBJECT OF THE CONSPIRACY

14. The object of the conspiracy was to import, possess, distribute, and profit from the illegal sale of The Drugs that were falsely labeled as all natural dietary supplements when, in

fact, they were misbranded drugs containing sibutramine, a Schedule IV controlled substance, and were not approved for sale in the United States under the applicable rules and regulations.

MANNER AND MEANS OF ACCOMPLISHING THE CONSPIRACY

- 15. In order to accomplish the purposes of the conspiracy, **KRUEGER**, J.H., and others known and unknown to the Grand Jury employed, among others, the following manners and means:
 - a. J.H. operated the internet website "slimvie.com," which he and KRUEGER used to advertise and to falsely market their weight loss products as all natural dietary supplements. Among other things, the website "slimvie.com" falsely claimed that "SlimVie" was manufactured in "FDA-approved" facilities and had "no reported side effects."
 - b. **KRUEGER** operated the internet website "you4healthy.com," which she used to advertise and to falsely market her weight loss products as all natural dietary supplements. Among other things, the website "you4healthy.com" falsely claimed that "Slim-Vie" was "a weight loss product made from all natural ingredients" and had "no harmful side [e]ffects."
 - c. KRUEGER and J.H. communicated with each other via telephone and email about the acquisition, marketing, and sale of The Drugs.
 - d. KRUEGER and J.H. established accounts with PayPal, an internet-based electronic payment system, to process credit card and other electronic payments for the sale of The Drugs.
 - e. J.H. illegally imported The Drugs from unauthorized suppliers in China for unlawful distribution within the United States. At no times material to this

- Indictment was either J.H. or **KRUEGER**, or businesses with which they were associated, registered with the DEA to import Schedule IV controlled substances into the United States or to lawfully distribute Schedule IV controlled substances in the United States.
- f. To fill orders, J.H. repackaged and relabeled The Drugs from the bulk quantities he had received from his Chinese suppliers and then shipped The Drugs in interstate commerce to KRUEGER, other distributors, and consumers throughout the United States, including in the Middle District of Louisiana, using commercial shippers.
- g. Louisiana-based customers, who sought to purchase The Drugs in person, either met with KRUEGER or were directed to contact her local distributors, some of whom sold and distributed The Drugs from their homes and businesses located throughout the state, including Port Allen and Denham Springs. Proceeds from these sales were deposited into bank accounts controlled by KRUEGER.
- h. Online customers, who sought to purchase The Drugs through KRUEGER, contacted her via an email address provided on the website "you4healthy.com." Upon receipt of an order, KRUEGER directed customers to either mail a check to her or pay by credit card through PayPal. Once a customer paid for an order by check or credit card, the payment was processed and deposited into bank accounts controlled by KRUEGER.
- After receipt and payment for an online order, KRUEGER shipped, and caused to be shipped, The Drugs in interstate commerce to consumers

- throughout the United States, including in the Middle District of Louisiana, using the United States Postal Service and commercial shippers.
- j. Through various sources of information, KRUEGER and J.H. knew that The Drugs were not "all natural" dietary supplements in that they contained sibutramine, a Schedule IV controlled substance, and that sibutramine had known harmful side effects.
 - i. For example, on or about July 8, 2011, the FDA issued a public notification concerning "Slim Forte Slimming Capsules" and "Slim Forte Double Power Slimming Capsules" that confirmed the presence sibutramine in those products and identified significant health risks associated with use of those products. On or about July 11, 2011, KRUEGER sent an email to J.H. in which she included an internet link to the aforementioned FDA notification.
 - ii. As another example, in an email dated June 17, 2013, an undercover FDA Special Agent informed **KRUEGER** that "Slim Vie" purchased from her tested positive for sibutramine, a Schedule IV controlled substance; described negative side effects of "Slim Vie"; and included internet links to online resources for sibutramine. Later that day,

KRUEGER forwarded the aforementioned email to J.H.

k. In addition to the "slimvie.com" and "you4healthy.com" websites described above in Paragraphs 15(a) and (b), KRUEGER disseminated false and misleading information about efficacy of, and health risks associated with, The Drugs through online discussion groups, including on "topix.com," and email communications with her customers.

- i. For example, in an email to a customer dated December 27, 2011, KRUEGER explained that "Slim Forte" and "SlimVie" were the same product and contained identical ingredients; however, a business dispute resulted in the product being renamed. In the same email, KRUEGER stated: "[a]s for horrible side [e]ffects, there aren't any horrible problems."
- ii. As another example, in a series of posting on "topix.com,"
 KRUEGER, using the online identity "Molly," responded to inquiries from a "Slim Vie" customer, who had experienced negative side effects, about the ingredients in "Slim Vie." In a March 16, 2012, posting, after refusing to identify the ingredients in "Slim Vie,"
 KRUEGER stated: "IF the product had something terrible in it,
 EVERYBODY would be complaining, myself included."
- KRUEGER derived a direct financial benefit from her illegal sale of The
 Drugs. From July 27, 2011, to November 4, 2014, KRUEGER generated
 approximately \$126,135 in proceeds from the sale of The Drugs in the United
 States, including the Middle District of Louisiana.

ACTS IN FURTHERANCE OF THE CONSPIRACY

- 16. In furtherance of the conspiracy and to accomplish its purposes, the defendant herein did commit, and did cause to be committed, acts in the Middle District of Louisiana and elsewhere, which included the following:
 - a. On or about April 16, 2012, KRUEGER caused the delivery of 60 dosage units of "Slim-Vie Slimming Capsules," which contained sibutramine, a Schedule IV controlled substance, to a person in Mandeville, Louisiana, whom she believed to be a customer.
 - b. On or about June 5, 2013, KRUEGER caused the delivery of 90 dosage units of "Slim-Vie Slimming Capsules," which contained sibutramine, a Schedule IV controlled substance, to a person in Ft. Lauderdale, Florida, whom she believed to be a customer.
 - c. On or about November 5, 2013, KRUEGER caused the delivery of 60 dosage units of "Slim-Vie Slimming Capsules," which contained sibutramine, a Schedule IV controlled substance, to a person in Baton Rouge, Louisiana, whom she believed to be a customer.
 - d. On or about May 12, 2014, KRUEGER caused the delivery of 180 dosage units of "Slim-Vie Slimming Capsules," which contained sibutramine, a Schedule IV controlled substance, to a person in Baton Rouge, Louisiana, whom she believed to be a customer.
 - e. On or about October 29, 2014, **KRUEGER** caused the delivery of 450 dosage units of "Slim-Vie Slimming Capsules," which contained sibutramine, a

Schedule IV controlled substance, to a person in Baton Rouge, Louisiana, whom she believed to be a customer.

The above is a violation of Title 21, United States Code, Section 846, and Title 18, United States Code, Section 2.

COUNT TWO

(Distribution)

- 17. Paragraphs 1 through 15 and 16(c) of this Indictment are incorporated herein as factual allegations.
- On or about November 5, 2013, in the Middle District of Louisiana, DARLENE
 V. KRUEGER, the defendant herein, knowingly and intentionally did distribute a substance containing a detectable quantity of sibutramine, a Schedule IV controlled substance.

The above is a violation of Title 21, United States Code, Section 841(a)(1).

COUNT THREE

(Distribution)

- 19. Paragraphs 1 through 15 and 16(d) of this Indictment are incorporated herein as factual allegations.
- 20. On or about May 12, 2014, in the Middle District of Louisiana, **DARLENE V. KRUEGER**, the defendant herein, knowingly and intentionally did distribute a substance containing a detectable quantity of sibutramine, a Schedule IV controlled substance.

The above is a violation of Title 21, United States Code, Section 841(a)(1).

(Distribution)

- 21. Paragraphs 1 through 15 and 16(e) of this Indictment are incorporated herein as factual allegations.
- 22. On or about October 29, 2014, in the Middle District of Louisiana, DARLENE V. KRUEGER, the defendant herein, knowingly and intentionally did distribute a substance containing a detectable quantity of sibutramine, a Schedule IV controlled substance.

The above is a violation of Title 21, United States Code, Section 841(a)(1).

COUNT FIVE

(Introduction of Misbranded Drug)

- Paragraphs 1 through 18 of this Indictment are re-alleged and incorporated herein 23. as factual allegations.
- On or about November 5, 2013, in the Middle District of Louisiana, DARLENE 24. V. KRUEGER, the defendant herein, with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce a drug, which was misbranded as defined in Title 21, United States Code. Sections 352(a), (e), and (f), to wit: "Slim-Vie Slimming Capsules" as described in Paragraph 11 above.

The above is a violation of Title 21, United States Code, Section 331(a), and Title 18, United States Code, Section 2.

COUNT SIX

(Introduction of Misbranded Drug)

- 25. Paragraphs 1 through 16, 19, and 20 of this Indictment are re-alleged and incorporated herein as factual allegations.
- 26. On or about May 12, 2014, in the Middle District of Louisiana, **DARLENE V. KRUEGER**, the defendant herein, with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce a drug, which was misbranded as defined in Title 21, United States Code, Sections 352(a), (e), and (f), to wit: "Slim-Vie Slimming Capsules" as described in Paragraph 11 above.

The above is a violation of Title 21, United States Code, Section 331(a), and Title 18, United States Code, Section 2.

COUNT SEVEN

(Introduction of Misbranded Drug)

- 27. Paragraphs 1 through 16, 21, and 22 of this Indictment are re-alleged and incorporated herein as factual allegations.
- V. KRUEGER, the defendant herein, with the intent to defraud and mislead, introduced, delivered for introduction, and caused the introduction and delivery for introduction into interstate commerce a drug, which was misbranded as defined in Title 21, United States Code, Sections 352(a), (e), and (f), to wit: "Slim-Vie Slimming Capsules" as described in Paragraph 11 above.

The above is a violation of Title 21, United States Code, Section 331(a), and Title 18, United States Code, Section 2.

FORFEITURE ALLEGATIONS

- 29. Upon conviction of any of the offenses set forth in Counts One through Seven above, **DARLENE V. KRUEGER**, defendant herein, shall forfeit to the United States, pursuant to Title 21, United States Code, Section 853, any and all property constituting, or derived from, any proceeds obtained, directly or indirectly, as a result of said violations, and any property used, or intended to be used, in any manner or part, to commit, or to facilitate the commission of, the violations, specifically including, but not limited to, a forfeiture money judgment of at least One Hundred Twenty-Six Thousand, One Hundred Thirty-Five Dollars (\$126,135.00) based on the value of the drugs involved in the commission of the offenses.
- 30. If any of the property or proceeds obtained directly or indirectly as a result of the offenses charged, or any property used, or intended to be used in any manner, to commit, or to facilitate the commission of the offenses, or proceeds traceable to the commission of the offenses, as a result of any act or omission of the defendant:
 - a. cannot be located upon the exercise of due diligence;
 - b. has been transferred, sold to, or deposited with a third party:
 - c. has been placed beyond the jurisdiction of the court;
 - d. has been substantially diminished in value; or
 - has been commingled with other property which cannot be divided without difficulty,

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the United States of America shall be entitled to a forfeiture money judgment and shall be allowed to forfeit substitute property pursuant to Title 21, United States Code, Section 853(p) in satisfaction of the forfeiture money judgment.

UNITED STATES OF AMERICA, by

ASSISTANT U.S. ATTORNEY

ASSISTANT U. S. ATTORNEY

A TRUE BILL

REDACTED PER PRIVACY ACT

GRAND JURY FOREPERSON

Place of Offense:			Matter to be sealed: X No Yes		
City	Baton Rouge		Related Case Information:		
County/Parish <u>East Baton Rouge Parish</u> FDA – Alex Shane Davis			Superseding Indictment Docket Number Docket Number New Defendant New Defendant Search Warrant Case No R 20/ R 40 from District of		
Defendant Information:			Any Other Related Cases:	Cr No.: 15-98	-JWD-SCR
Defendant Name: Darlene Viola Krueger					
U.S. Attorney Information:					
AUSA: Cam T. Le				BBO#: 663328	
Interpreter: ★ No □ Yes List language and/or dialect:					
Location Status:					
Arrest Date Already in Federal Custody as of Already in State Custody On Pretrial Release U.S.C. Citations:					
Total # of Coun		7			
Index Key/Co	2001/09/0	Description of Of	fense Charged	Count(s)	Petty/ Misdemeanor/ <u>Felony</u>
21 U.S.C. § 84	16	Conspiracy to distribute sib		_1	Felony
21 U.S.C. § 84	11(a)(1)	Distribution of sibutra	nmine	2, 3, 4	Felony
21 U.S.C. § 33	31(a)	Introduction of misbra interstate commerce	anded drug into	5, 6, 7	Felony
Date:	7-15	Signature of A	AUSA: Cerm	Le	
District Court Case Number (To be filled in by deputy clerk):					