2019 JAN - 7 AM II: 51

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

V.

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KHK INTERNATIONAL TRADE
ENTERPRISE, INC.,
SHH WORLD TRADING ENTERPRISES,
INC., and
JOHN SEIL LEE,

Defendants.

INFORMATION

[18 U.S.C. § 371: Conspiracy;
18 U.S.C. § 545: Importing
Merchandise Contrary to Law; 21
U.S.C. §§ 331(a), 333(a)(2):
Introducing Misbranded Drugs Into
Interstate Commerce; 26 U.S.C.
§ 7206(1): Subscribing to a False
Tax Return; 18 U.S.C.
§§ 981(a)(1)(C), 982, 982(a)(7),
26 U.S.C. § 7206, 28 U.S.C.
§ 2461(c): Criminal Forfeiture; 18
U.S.C. § 2(b): Causing an Act To
Be Done]

The United States Attorney charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Information:

A. THE DEFENDANTS AND CO-CONSPIRATOR

1. Defendant JOHN SEIL LEE ("LEE") owned, controlled, and operated four businesses between 2011 and 2017 for the purpose of manufacturing and distributing male sexual enhancement pills that he marketed as herbal remedies but that in fact contained undisclosed Tadalafil, an active pharmaceutical ingredient. From approximately

March 2014 to January 2016, defendant LEE owned, controlled, and operated defendant KHK INTERNATIONAL TRADE ENTERPRISE, INC. ("KHK") Beginning in approximately January 2016, defendant LEE owned, controlled, and operated defendant SHH WORLD TRADING ENTERPRISES, INC. ("SHH").

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- 2. Defendant KHK was a California corporation registered in March 2014 and located in Diamond Bar, California. Defendant LEE established defendant KHK in order to replace two of his other pill businesses. Defendant KHK marketed and distributed pills that contained undisclosed Tadalafil. Defendant LEE shut down defendant KHK after one of its brands, "X Again" pills, was listed on the website of the United States Food and Drug Administration ("FDA") in December 2015 as a tainted product that contained undisclosed Tadalafil.
- January 2016 and located in Walnut, California. Defendant LEE established defendant SHH in order to replace defendant KHK. Like defendant KHK, defendant SHH marketed and distributed pills that contained undisclosed Tadalafil. In June 2017, several of defendant SHH's brands, including "X Monster," "Royal Master," and "Own the Knight" were listed the FDA's website as tainted products that contained undisclosed Tadalafil.
- 4. In 2014, defendant LEE hired Co-conspirator #1 as an office assistant to help him operate defendant KHK and then defendant SHH.

 Co-conspirator #1 worked for defendant LEE until early 2017.

B. THE FOOD, DRUG, AND COSMETIC ACT

5. The FDA was the federal agency responsible for protecting the health and safety of the American public by enforcing the Food,

Drug, and Cosmetic Act ("FDCA"). One of the main purposes of the FDCA was to ensure that human drugs sold were safe, effective, and bore labeling containing only true and accurate information. The FDA's responsibilities under the FDCA included regulating the manufacture, labeling, and distribution of all drugs shipped or received in interstate commerce.

- 6. The FDCA defined a "drug" to include "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," and "articles (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(B) and (C).
- 7. A "prescription drug" was any drug which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, [was] not safe for use except under the supervision of a practitioner licensed by law to administer such drug"; or any drug which was "limited by an approved new drug application . . . to use under the professional supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1).
- 8. Under the FDCA, "label" was defined as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The term "labeling," in turn, was defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).
- 9. The FDCA prohibited the introduction, delivery for introduction, or causing the introduction or delivery for

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introduction into interstate commerce of any drug that was misbranded. 21 U.S.C. § 331(a).

10. Under the FDCA, a drug was deemed to be "misbranded" if, among other things, its labeling was false or misleading in any particular way, 21 U.S.C. § 352(a), or if its labeling failed to bear adequate directions for use, 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions under which a layman could use a drug safely and for the purposes for which it was intended. 21 C.F.R. § 201.5. By definition, it was not possible to write "adequate directions for use" for a prescription drug.

C. TADALAFIL

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- 11. Tadalafil was the active pharmaceutical ingredient in the prescription drug Cialis. Cialis was FDA-approved for the treatment of erectile dysfunction.
- 12. Other products containing Tadalafil that were intended to treat a disease in man and/or affect the structure or function of the body of man were "drugs" within the meaning of the FDCA.
- 13. Drugs containing Tadalafil could be particularly harmful to persons taking medications containing nitrates, such as nitroglycerin, because Tadalafil could interact with the nitrates and lower blood pressure to dangerous levels. Men with high blood pressure or heart disease often took nitrates.
- 14. The FDA's approval for Cialis was limited to use under the professional supervision of a practitioner licensed by law to administer such drug; therefore, Cialis was a "prescription drug" under 21 U.S.C. § 353(b)(1)(B). Due to toxicity and other potentially harmful effects (e.g., life-threatening drops in blood pressure, loss of vision, loss of hearing, and prolonged, painful

erections that result in permanent injury to the penis), drugs similar to Cialis were not safe for use except under the supervision of a practitioner licensed by law to administer them, and they were thus prescription drugs as well.

15. Paragraphs 1-14 are hereby re-alleged and incorporated into each and every count of this Information.

COUNT ONE

[18 U.S.C. § 371]

A. OBJECTS OF THE CONSPIRACY

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Beginning on a date unknown to the United States Attorney and continuing to on or about February 22, 2017, in Los Angeles County, within the Central District of California, and elsewhere, defendant LEE, together with others known and unknown to the United States Attorney, including Co-conspirator #1, knowingly conspired and agreed to:

- 1. Import and bring merchandise (namely, unlabeled bulk Tadalafil), and receive, conceal, buy, sell, and facilitate the transportation, concealment, and sale of such merchandise after importation, knowing the same to have been imported and brought into the United States contrary to law, namely, 21 U.S.C. §§ 331(a) and 352, in violation of Title 18, United States Code, Section 545;
- 2. Introduce and cause the introduction of misbranded drugs into interstate commerce, with the intent to defraud and mislead, in violation of Title 21, United States Code, Sections 331(a), 352, 333(a)(2); and
- 3. Defraud the United States or one of its agencies or departments, that is, impede, impair, obstruct, and defeat the lawful and legitimate functions of the FDA in investigating and enforcing federal laws and regulations related to misbranded drugs, in violation of Title 18, United States Code, Section 371.
- B. MEANS BY WHICH THE OBJECTS OF THE CONSPIRACY WERE TO BE ACCOMPLISHED

The objects of the conspiracy were to be accomplished, in substance, as follows:

- 2. To avoid scrutiny from law enforcement, defendant LEE's suppliers would ship the bulk Tadalafil in packages whose labeling (a) falsely described the packages' contents; (b) failed to disclose that the packages contained Tadalafil; and (c) failed to include adequate descriptions for the use of Tadalafil.
- 3. To avoid scrutiny from law enforcement, defendant LEE would have his Chinese suppliers ship the bulk Tadalafil to commercial mailboxes that he controlled in New Jersey and Pennsylvania.
- 4. Defendant LEE would have the commercial mailbox companies that received the Chinese shipments in New Jersey and Pennsylvania repackage the Tadalafil shipments and forward them to mailboxes that defendant LEE controlled in Southern California.
- 5. After defendant LEE received the packages containing the bulk Tadalafil in Southern California, he would cause the bulk Tadalafil to be manufactured into at least 5,500,000 pills that defendant LEE and Co-conspirator #1 would sell to distributors across the United States.
- 6. Defendant LEE would cause the pills sold by defendant LEE and Co-conspirator #1 to be manufactured with levels of Tadalafil significantly higher than the levels in FDA-approved prescription drugs such as Cialis, in order to boost the pills' strength and commercial success, despite his knowledge that Tadalafil could harm the pills' consumers.
 - 7. Defendant LEE and Co-conspirator #1 would sell at least \$11 million worth of the pills to distributors across the United States in packages with labeling that did not disclose the presence of

Tadalafil, and with labeling that falsely stated that no prescription was necessary, even though the pills were in fact prescription drugs.

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- 8. When the FDA announced that a certain brand of pills sold by defendant LEE and Co-conspirator #1 was tainted because the pills contained undeclared Tadalafil, defendant LEE and Co-conspirator #1 would continue selling their inventories of the same brand despite the FDA's announcement.
- 9. When the FDA announced in December 2015 that co-conspirator KHK's "X Again" pills were tainted because they contained undeclared Tadalafil, defendant LEE would establish a new company, co-conspirator SHH, to sell pills with the same formulas but different brand names, in an attempt to evade federal regulators.
- 10. When the FDA announced that a certain brand of pills sold by co-conspirators KHK or SHH was tainted because the pills contained undeclared Tadalafil, defendant LEE would begin manufacturing pills with identical formulas (including Tadalafil) and coloring, but defendant LEE would change the brand names of the pills in an effort to evade federal regulators. For example:
- a. After the FDA announced in December 2015 that coconspirator KHK's white "X Again" pills were tainted because they
 contained undisclosed Tadalafil, defendant LEE would begin
 manufacturing a replacement white pill for defendant LEE and Coconspirator #1 to sell, branded "X Monster," which had the same
 formula and price as the tainted "X Again" pills and similar labeling
 that failed to disclose the presence of Tadalafil.
- b. After the FDA announced in August 2016 that coconspirator SHH's gold "Master Zone" pills were tainted because they contained undisclosed Tadalafil, defendant LEE would begin

manufacturing a replacement gold pill for defendant LEE and Coconspirator #1 to sell, branded "Royal Master," which had the same formula and price as the tainted "Master Zone" pills and similar labeling that failed to disclose the presence of Tadalafil.

- c. After the FDA announced in August 2016 that coconspirator SHH's silver "One More Knight" pills were tainted because
 they contained undisclosed Tadalafil, defendant LEE would begin
 manufacturing a replacement silver pill for defendant LEE and Coconspirator #1 to sell, branded "Own The Knight," which had the same
 formula and price as the tainted "One More Knight" pills and similar
 labeling that failed to disclose the presence of Tadalafil.
- 11. Defendant LEE and Co-conspirator #1 would market, sell, and distribute the newly branded pills by informing their distributors that the newly branded pills had formulas that were identical to the pills that they were replacing due to the FDA's notices.

C. OVERT ACTS

On or about the following dates, in furtherance of the conspiracy and to accomplish its objects, defendant LEE, and others both known and unknown to the United States Attorney, including Coconspirator #1, committed various overt acts within the Central District of California and elsewhere, including, but not limited to, the following:

Overt Act No. 1: On or about March 5, 2014, defendant LEE caused co-conspirator KHK to be established as a corporation to replace defendant LEE's previous companies as the entity through which defendant LEE would manufacture and sell misbranded drugs containing undeclared Tadalafil.

Overt Act No. 2: On or about December 18, 2015, when the FDA issued a public notice on its website announcing that co-conspirator KHK's white "X Again" pills were tainted because they contained undisclosed Tadalafil, defendant LEE continued selling the white "X Again" pills despite the FDA's notice.

Overt Act No. 3: On or about December 21, 2015, Co-conspirator #1 shipped approximately 6,000 white "X Again" pills to defendant LEE's distributor in Northridge, California.

Overt Act No. 4: On or about December 22, 2015, Co-conspirator #1 shipped approximately 5,300 white "X Again" pills to defendant LEE's distributor in Santa Clarita, California.

Overt Act No. 5: On or about December 22, 2015, Co-conspirator #1 shipped approximately 3,312 white "X Again" pills to defendant LEE's distributor in Tampa, Florida.

Overt Act No. 6: On or about December 29, 2015, Co-conspirator #1 shipped approximately 2,040 white "X Again" pills to defendant LEE's distributor Salem, Oregon.

Overt Act No. 7: In or about January 2016, defendant LEE caused co-conspirator SHH to be established as a corporation to replace co-conspirator KHK as the entity through which defendant LEE would manufacture and sell misbranded drugs containing undeclared Tadalafil.

Overt Act No. 8: In or about February 2016, following the FDA's public notice that co-conspirator KHK's white "X Again" pills were tainted because they contained undisclosed Tadalafil, defendant LEE and Co-Conspirator #1 began marketing a replacement white pill, branded "X Monster," which had the same formula and price as the

tainted "X Again" pills and similar labeling that failed to disclose the presence of Tadalafil.

Overt Act No. 9: On or about February 25, 2016, Co-conspirator #1 informed one of defendant LEE's distributors in Paramount, California that "[u]nfortunately we are out of the XA [X Again] products. We will be replacing it with X-Monster (same product but different name) and will be ready to ship next Wednesday."

Overt Act No. 10: On or about March 1, 2016, Co-conspirator #1 informed defendant LEE's distributor in Southern Pines, North Carolina that the new "X Monster" white pills were now in stock and that "[t]he formula hasn't changed" from its predecessor, the white "X Again" pills.

Overt Act No. 11: On or about March 1, 2016, Co-conspirator #1 shipped approximately 12,918 white "X Monster" pills to defendant LEE's distributor in Southern Pines, North Carolina.

Overt Act No. 12: On or about March 1, 2016, Co-conspirator #1 shipped approximately 2,880 white "X Monster" pills to one of defendant LEE's distributors in Paramount, California.

Overt Act No. 13: On or about March 2, 2016, Co-conspirator #1 informed defendant LEE's distributor in Salem, Oregon that "[n]ot sure if you were aware but X-Again was pulled by the FDA. So now, we are replacing XA with a new brand called X-monster that has the same formula but slight changes on package artwork."

Overt Act No. 14: On or about March 2, 2016, Co-conspirator #1 shipped approximately 1,200 white "X Monster" pills to defendant LEE's distributor in Salem, Oregon.

Overt Act No. 15: On or about March 14, 2016, Co-conspirator #1 informed defendant LEE's distributor in Broomfield, Colorado that "[o]ur new item is called X-Monster and it has the same specs and pricing as the X-Again."

Overt Act No. 16: On or about March 25, 2016, Co-conspirator #1 shipped approximately 1,200 white "X Monster" pills to defendant LEE's distributor in Broomfield, Colorado.

Overt Act No. 17: On or about August 16, 2016, when the FDA issued a public notice on its website announcing that co-conspirator SHH's gold "Master Zone" pills were tainted because they contained undisclosed Tadalafil, defendant LEE continued selling the gold "Master Zone" pills despite the FDA's notice.

Overt Act No. 18: On or about August 16, 2016, when the FDA issued a public notice on its website announcing that co-conspirator SHH's silver "One More Knight" pills were tainted because they contained undisclosed Tadalafil, defendant LEE continued selling the silver "One More Knight" pills despite the FDA's notice.

Overt Act No. 19: On or about August 16, 2016, Co-conspirator #1 shipped approximately 11,040 gold "Master Zone" pills to defendant LEE's distributor in Santa Clarita, California.

Overt Act No. 20: On or about August 16, 2016, Co-conspirator #1 shipped approximately 15,360 silver "One More Knight" pills to defendant LEE's distributor in Santa Clarita, California.

Overt Act No. 21: On or about August 16, 2016, Co-conspirator #1 shipped approximately 1,471 gold "Master Zone" pills to defendant LEE's distributor in Northridge, California.

Overt Act No. 22: On or about August 16, 2016, Co-conspirator 1 #1 shipped approximately 5,160 silver "One More Knight" pills to 2 defendant LEE's distributor in Northridge, California. 3 Overt Act No. 23: On or about August 18, 2016, Co-conspirator 4 #1 shipped approximately 6,120 silver "One More Knight" pills to 5 defendant LEE's distributor in Southern Pines, North Carolina. 6 Overt Act No. 24: On or about August 26, 2016, Co-conspirator 7 #1 shipped approximately 1,800 gold "Master Zone" pills to defendant 8 LEE's distributor in Catonsville, Maryland. 9 Overt Act No. 25: On or about August 26, 2016, Co-conspirator 10 #1 shipped approximately 1,200 silver "One More Knight" pills to 11 defendant LEE's distributor in Catonsville, Maryland. 12 Overt Act No. 26: On or about August 26, 2016, Co-conspirator 13 #1 shipped approximately 5,400 gold "Master Zone" pills to defendant 14 LEE's distributor in Santa Clarita, California. 15 On or about August 26, 2016, Co-conspirator Overt Act No. 27: 16 #1 shipped approximately 5,360 silver "One More Knight" pills to 17 defendant LEE's distributor in Santa Clarita, California. 18 On or about August 26, 2016, Co-conspirator Overt Act No. 28: 19 #1 shipped approximately 3,000 silver "One More Knight" pills to one 20 of defendant LEE's distributors in Paramount, California. 21 Overt Act No. 29: On or about August 26, 2016, Co-conspirator 22 #1 shipped approximately 4,800 silver "One More Knight" pills to 23 defendant LEE's distributor in Claymont, Delaware. 24 On or about August 29, 2016, Co-conspirator Overt Act No. 30: 25 #1 shipped approximately 1,800 silver "One More Knight" pills to 26 defendant LEE's distributor in Southern Pines, North Carolina. 27 28

Overt Act No. 31: On or about August 29, 2016, Co-conspirator #1 informed defendant LEE's distributor in Toronto, Canada that "OMK [One More Knight] and MZ [Master Zone] were recalled by the FDA and we are currently out of stock. But if you want the products, we can ship it out by Friday."

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Overt Act No. 32: On or about August 29, 2016, Co-conspirator #1 informed defendant LEE's distributor in Toronto, Canada that "We are working to change the name of both OMK [One More Knight] and MZ [Master Zone] like we did with XMonster but it will take a few weeks. Same price and formula just different name and small changes on packaging."

Overt Act No. 33: On or about September 6, 2016, Co-conspirator #1 shipped approximately 9,600 gold "Master Zone" pills to defendant LEE's distributor in Toronto, Canada.

Overt Act No. 34: On or about September 28, 2016, Co-conspirator #1 informed defendant LEE's distributor in Augusta, Georgia that "unfortunately OMK [One More Knight] was put on the FDA list but we have a replacement product coming out soon. The new product will have same formula and similar package but using [a] different name and should be ready to ship around the second week of October."

Overt Act No. 35: In or about early October 2016, following the FDA's public notice that co-conspirator SHH's gold "Master Zone" pills were tainted because they contained undisclosed Tadalafil, defendant LEE and Co-conspirator #1 began marketing a replacement gold pill, branded "Royal Master," which had the same formula and price as the tainted "Master Zone" pills and similar labeling that failed to disclose the presence of Tadalafil.

Overt Act No. 36: In or about early October 2016, following the FDA's public notice that co-conspirator SHH's silver "One More Knight" pills were tainted because they contained undisclosed Tadalafil, defendant LEE and Co-conspirator #1 began marketing a replacement silver pill, branded "Own The Knight," which had the same formula and price as the tainted "One More Knight" pills and similar labeling that failed to disclose the presence of Tadalafil.

Overt Act No. 37: On or about October 5, 2016, Co-conspirator #1 informed defendant LEE's distributor in Baltimore, Maryland that

Overt Act No. 37: On or about October 5, 2016, Co-conspirator #1 informed defendant LEE's distributor in Baltimore, Maryland that "All prices and specs are the same" for the new gold "Royal Master" pill (as compared to its predecessor, the gold "Master Zone" pill) and for the new silver "Own The Knight" pill (as compared to its predecessor, the silver "One More Knight" pill).

Overt Act No. 38: On or about October 14, 2016, Co-conspirator #1 shipped approximately 600 gold "Royal Master" pills to one of defendant LEE's distributors in Paramount, California.

Overt Act No. 39: On or about October 14, 2016, Co-conspirator #1 shipped approximately 600 silver "Own The Knight" pills to one of defendant LEE's distributors in Paramount, California.

Overt Acts Nos. 40 through 45: On or about the following dates, defendant LEE, and others, caused the following shipments containing unlabeled bulk Tadalafil to be imported from China into the United States:

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OVERT ACT 40	DATE	PARCEL WEIGHT	DESTINATION Windsor, New Jersey	
	10/22/2016	5.094 kg		
41	10/27/2016	5.176 kg	East Windsor, New Jersey	
42	11/1/2016	10.9 kg	East Windsor, New Jersey	
43	12/3/2016	5.118 kg	Hillsborough, New Jersey	
44	12/9/2016	5.12 kg	East Windsor, New Jersey	
45	1/27/2017	5.65 kg	Hillsborough, New Jersey	

Overt Acts Nos. 46 through 58: On or about the following dates, defendant LEE, and others, caused the following shipments containing unlabeled bulk Tadalafil to be delivered to defendant LEE in the Central District of California from commercial mailbox companies on the East Coast that, on defendant LEE's behalf, had received and repackaged the same shipments from China:

OVERT ACT	DATE	TRACKING NUMBER	
46	11/22/2016	784695188477	
47	12/30/2016	785170993499	
48	1/5/2017	809523700312	
49	1/5/2017	809523700312	
50	1/6/2017	785230093828	
51	1/20/2017	785355591159	
52	1/26/2017	785398051636	
53	1/26/2017	785398051636	
54	2/2/2017	718084775869	
55	2/2/2017	718084775869	
56	2/10/2017	785506983365	
57	2/9/2017	718084776637	
58	2/9/2017	718084776637	

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Overt Act No. 59: On or about October 26, 2016, Co-conspirator #1 shipped approximately 600 gold "Royal Master" pills to defendant LEE's distributor in Baltimore, Maryland.

Overt Act No. 60: On or about October 26, 2016, Co-conspirator #1 informed defendant LEE's distributor in Salem, Oregon, in response to being asked, "Is Royal master replacing Master Zone? Is one More Knight being replaced?," that "Yes, both items were put on the FDA list back in August. . . . Sorry if we forgot to let you know!

Master Zone is being replaced by Royal Master and One More Knight is being replaced by Own The Knight, but nothing changes on the formula."

Overt Act No. 61: On or about October 27, 2016, Co-conspirator #1 informed defendant LEE's distributor in Augusta Georgia, in response to being asked, "do u have another pill for one more knight," that "Yes, we replaced it with Own The Knight, same formula."

Overt Act No. 62: On or about October 28, 2016, Co-conspirator #1 shipped approximately 600 silver "Own The Knight" pills to defendant LEE's distributor in Baltimore, Maryland.

Overt Act No. 63: On or about October 28, 2016, Co-conspirator #1 shipped approximately 1,200 silver "Own The Knight" pills to defendant LEE's distributor in Salem, Oregon.

Overt Act No. 64: On or about November 1, 2016, Co-conspirator #1 shipped approximately 600 silver "Own The Knight" pills to defendant LEE's distributor in Augusta, Georgia.

Overt Act No. 65: On or about January 27, 2017, Co-conspirator #1 shipped approximately 3,000 white "X Monster" pills to defendant LEE's distributor in Tampa, Florida.

Overt Act No. 66: On or about January 27, 2017, Co-conspirator #1 shipped approximately 600 silver "Own The Knight" pills to defendant LEE's distributor in Tampa, Florida.

COUNT TWO

[18 U.S.C. §§ 545, 2(b)]

On or about February 9, 2017, in Los Angeles County, within the Central District of California, defendant LEE fraudulently and knowingly imported and brought, and willfully caused to be imported and brought, merchandise, namely, two parcels of unlabeled bulk Tadalafil, into the United States contrary to law, that is, with labeling that was false and misleading as to the parcels' contents, labels that did not contain accurate statements of the packages' contents in terms of weight, measure, and numerical count, and labeling that did not bear adequate directions for use, contrary to the FDCA, Title 21, United States Code, Sections 331(a) and 352(a)(1), (b), (f).

COUNTS THREE AND FOUR

[21 U.S.C. §§ 331(a), 352, 333(a)(2)]

On or about the following dates, in Los Angeles County, within the Central District of California, defendants KHK and LEE introduced and willfully caused the introduction of the following misbranded drugs into interstate commerce, with the intent to defraud and mislead the Food and Drug Administration. The drugs were misbranded because their labeling was false and misleading, in violation of the FDCA, in one or more of the following ways: (1) the drugs' labeling falsely and misleadingly stated "no prescription necessary," even though they were prescription drugs that contained high doses of Tadalafil; and (2) none of the labeling disclosed the presence of the active pharmaceutical ingredient Tadalafil in the drugs.

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
THREE	12/22/2015	X Again	3,312	Tampa, Florida
FOUR	12/29/2015	T	2,040	Salem, Oregon

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COUNTS FIVE AND SIX

[21 U.S.C. §§ 331(a), 352, 333(a)(2)]

On or about the following dates, in Los Angeles County, within the Central District of California, defendants SHH and LEE introduced and willfully caused the introduction of the following misbranded drugs into interstate commerce, with the intent to defraud and mislead the Food and Drug Administration. The drugs were misbranded because their labeling was false and misleading, in violation of the FDCA, in one or more of the following ways: (1) the drugs' labeling falsely and misleadingly stated "no prescription necessary," even though they were prescription drugs that contained high doses of Tadalafil; and (2) none of the labeling disclosed the presence of the active pharmaceutical ingredient Tadalafil in the drugs.

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
FIVE	8/26/2016	One More Knight	4,800	Claymont, Delaware
	7 7			Southern Pines, North
SIX	8/29/2016	One More Knight	1,800	Carolina

COUNT SEVEN

[26 U.S.C. § 7206(1); 18 U.S.C. § 2(b)]

On or about October 15, 2017, in Los Angeles County, within the Central District of California, defendant LEE willfully made and subscribed, and willfully caused to be made and subscribed, to a materially false U.S. Individual Income Tax Return (Form 1040), for the calendar year 2016, which was filed with the Internal Revenue Service and verified in a written declaration that it was made under penalty of perjury, and which income tax return defendant LEE did not believe to be true as to every material matter, in that defendant LEE willfully omitted from that return income of approximately \$1,148,716.

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FORFEITURE ALLEGATION ONE

[18 U.S.C. §§ 982, 545; 28 U.S.C. § 2461(c)]

- 1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal Procedure, notice is hereby given that the United States of America will seek forfeiture as part of any sentence, pursuant to Title 18, United States Code, Sections 982 and 545, and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offenses set forth in either or both of Counts One and/or Two of this Information.
- 2. Any defendant so convicted shall forfeit to the United States the following:
- (a) All right, title, and interest in any and all property, real or personal constituting, or derived from, any proceeds obtained, directly or indirectly, as a result of each such offense;
- (b) Any and all merchandise introduced into the United States in violation of Title 18, United States Code, Section 545, or the value thereof; and
- (c) To the extent such property is not available for forfeiture, a sum of money equal to the total value of the property described in subparagraphs (a) and (b).
- 3. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b) and Title 28, United States Code, Section 2461(c), any defendant so convicted shall forfeit substitute property, up to the total value of the property described in the preceding paragraph if, as the result of any act or omission of said defendant, the property described in the preceding paragraph, or any portion thereof: (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 (e) has been commingled with other property that cannot be divided without difficulty. . 27

FORFEITURE ALLEGATION TWO

[18 U.S.C. § 982(a)(7); 28 U.S.C. § 2461(c)]

- 1. Pursuant to Rule 32.2(a), Fed. R. Crim. P., notice is hereby given that the United States will seek forfeiture as part of any sentence, pursuant to Title 18, United States Code, Section 982(a)(7) and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offenses set forth in any of Counts Three through Six of this Information.
- 2. Any defendant so convicted shall forfeit to the United States of America the following:
- (a) All right, title, and interest in any and all property, real or personal, that constitutes or is derived, directly or indirectly, from the gross proceeds traceable to the commission of any offense of conviction; and
- (b) To the extent such property is not available for forfeiture, a sum of money equal to the total value of the property described in subparagraph (a).
- 3. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), and Title 18, United States Code, Section 982(b), the convicted defendant shall forfeit substitute property, up to the total value of the property described in the preceding paragraph if, as a result of any act or omission of said defendant, the property described in the preceding paragraph, or any portion thereof (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

FORFEITURE ALLEGATION THREE

[26 U.S.C. § 7206; 28 U.S.C. § 2461(c)]

- 1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal Procedure, notice is hereby given that the United States of America will seek forfeiture as part of any sentence, pursuant to Title 26, United States Code, Section 7206, and Title 28, United States Code, Section 2461(c), in the event of any defendant's conviction of the offense set forth in Count Seven of this Information.
- 2. Any defendant so convicted shall forfeit to the United States of America the following:
- (a) Any property sold or removed by the defendant in fraud of the internal revenue laws, or with design to avoid payment of such tax, or which was removed, deposited, or concealed, with intent to defraud the United States of such tax or any part thereof;
- (b) All property manufactured into property of a kind subject to tax for the purpose of selling such taxable property in fraud of the internal revenue laws, or with design to evade the payment of such tax;
- (c) All property whatsoever, in the place or building, or any yard or enclosure, where the property described in subsection (a) or (b) is found, or which is intended to be used in the making of property described in subsection (a), with intent to defraud the United States of tax or any part thereof, on the property described in subsection (a);
- (d) All property used as a container for, or which shall have contained, property described in subsection (a) or (b);
- (e) Any property (including aircraft, vehicles, vessels, or draft animals) used to transport or for the deposit or concealment

of property described in subsection (a) or (b), or any property used to transport or for the deposit or concealment of property which is intended to be used in the making or packaging of property described in subsection (a); and

- (f) To the extent that such property is not available for forfeiture, a sum of money equal to the total value of the property described in this paragraph.
- 3. Pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b) and Title 28, United States Code, Section 2461(c), the defendant, if so convicted, shall forfeit substitute property, up to the total value of the property described in the preceding paragraph if, as the result of any act or omission of the defendant, the property described in the preceding paragraph, or any portion thereof (a) cannot be located upon the exercise of due diligence; (b) has been

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transferred, sold to or deposited with a third party; (c) has been 1 placed beyond the jurisdiction of the court; (d) has been 2 substantially diminished in value; or (e) has been commingled with 3 other property that cannot be divided without difficulty. 4 5 NICOLA T. HANNA 6 United States Attorney 7 South Garringer paperty Chief, Criminal Division For: 8 LAWRENCE S. MIDDLETON 9 Assistant United States Attorney Chief, Criminal Division 10 JOSEPH O. JOHNS 11 Assistant United States Attorney Chief, Environmental and 12 Community Safety Crimes Section 13 MARK A. WILLIAMS Assistant United States Attorney 14 Deputy Chief, Environmental and Community Safety Crimes Section 15 MATTHEW W. O'BRIEN 16 Assistant United States Attorney Environmental and Community 17 Safety Crimes Section 18 SONIA W. NATH Special Assistant United States 19 Attorney 20 21 22 23 24 25 26 27