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CENTRAL DIST. OF CALIF.  
SANTA ANA  
BY \_\_\_\_\_

UNITED STATES DISTRICT COURT  
FOR THE CENTRAL DISTRICT OF CALIFORNIA  
SOUTHERN DIVISION

September 2018 Grand Jury

UNITED STATES OF AMERICA,  
Plaintiff,  
v.  
NAM HYUN LEE,  
aka "Daniel Lee,"  
aka "Daniel Nam Lee,"  
aka "Nam Lee,"  
Defendant.

SACR 18-00226 JVS

I N D I C T M E N T

[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; 18 U.S.C.  
§ 2: Aiding and Abetting, Causing  
an Act to Be Done; 18 U.S.C.  
§§ 981(a)(1)(C), 982(a)(2)(B), and  
28 U.S.C. § 2461(c): Criminal  
Forfeiture]

**UNDER SEAL**

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Indictment:

A. THE DEFENDANT

1. Defendant NAM HYUN LEE, also known as ("aka") "Daniel Lee,"  
aka "Daniel Nam Lee," aka "Nam Lee" ("LEE"), owned, controlled, and  
operated Hasim Distribution, Inc. ("Hasim Distribution") from

1 approximately June 2016 to October 2018, Dalee Supply, Inc. ("Dalee  
2 Supply") from approximately October 2016 to October 2018, Rainbow  
3 Natural Production, Inc. ("Rainbow Natural Production") from  
4 approximately October 2016 to October 2018, and Hasim Enterprise, LLC  
5 ("Hasim Enterprise") from approximately January 2017 to October 2018.

6 a. Hasim Distribution was a California corporation  
7 registered in June 2016 and located in Buena Park, California.  
8 Defendant LEE was the registered Chief Executive Officer, Secretary,  
9 Chief Financial Officer, Director, and Agent for Service of Process  
10 for Hasim Distribution.

11 b. Dalee Supply was a California corporation registered  
12 in October 2016 and located in Buena Park, California. Defendant LEE  
13 was the registered Chief Executive Officer, Secretary, Chief  
14 Financial Officer, and Director for Dalee Supply.

15 c. Rainbow Natural Production was a California  
16 corporation registered in October 2016 and located in Buena Park,  
17 California. Defendant LEE was the registered Chief Executive  
18 Officer, Secretary, Chief Financial Officer, Director, and Agent for  
19 Service of Process for Rainbow Natural Production.

20 d. Hasim Enterprise was a California corporation  
21 registered in February 2017 and located in Cypress, California.  
22 Defendant LEE was registered as the sole Manager/Member for Hasim  
23 Enterprise, and no individual was listed as the Chief Executive  
24 Officer.

25 2. Defendant LEE did not possess a valid wholesale drug  
26 distribution license, a valid pharmacy license, or a license to  
27 prescribe prescription drugs in the State of California.

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1           3. Under defendant LEE's direction, Hasim Distribution, Dalee  
2 Supply, Rainbow Natural Production, and Hasim Enterprise marketed and  
3 distributed male sexual enhancement capsules that contained the  
4 undisclosed active pharmaceutical ingredients Tadalafil and  
5 Sildenafil. The male sexual enhancement capsules were marketed under  
6 a variety of brand names, including, among others, "Rhino 7  
7 Platinum," "Rhino 7 Blue," "Rhino Big Horn," "Orgazen 3000," "Orgazen  
8 3500," "Rhino 69 Platinum 9000," "libigrow," "Spanish Fly," "Rhino 8  
9 8000," "Black Panther," "Black Stallion," "Black Mamba," "Tiger,"  
10 "Rhino 9," "Rhino 8," "Rhino 12," and "Dragon 69."

11 B. THE FOOD, DRUG, AND COSMETIC ACT

12           4. The Food and Drug Administration ("FDA") was the federal  
13 agency responsible for protecting the health and safety of the  
14 American public by enforcing the Food, Drug, and Cosmetic Act, 21  
15 U.S.C. § 301 et seq. ("FDCA"). One of the main purposes of the FDCA  
16 was to ensure that human drugs sold were safe, effective, and bore  
17 labeling containing only true and accurate information. The FDA's  
18 responsibilities under the FDCA included regulating the manufacture,  
19 labeling, and distribution of all drugs shipped or received in  
20 interstate commerce.

21           5. The FDCA defined a "drug" to include "articles intended for  
22 use in the diagnosis, cure, mitigation, treatment, or prevention of  
23 disease in man," and "articles (other than food) intended to affect  
24 the structure or any function of the body of man." 21 U.S.C.  
25 § 321(g) (1) (B) and (C).

26           6. A "prescription drug" was any drug which, "because of its  
27 toxicity or other potentiality for harmful effect, or the method of  
28 its use, or the collateral measures necessary to its use, [was] not

1 safe for use except under the supervision of a practitioner licensed  
2 by law to administer such drug"; or any drug that was "limited by an  
3 approved application . . . to use under the professional supervision  
4 of a practitioner licensed by law to administer such drug." 21  
5 U.S.C. § 353(b)(1).

6 7. Under the FDCA, "label" was defined as "a display of  
7 written, printed, or graphic matter upon the immediate container of  
8 any article." 21 U.S.C. § 321(k). The term "labeling," in turn, was  
9 defined as "all labels and other written, printed, or graphic matter  
10 (1) upon any article or any of its containers or wrappers, or  
11 (2) accompanying such article." 21 U.S.C. § 321(m).

12 8. The FDCA prohibited the introduction, delivery for  
13 introduction, or the causing of the introduction or delivery for  
14 introduction into interstate commerce of any drug that was  
15 misbranded. 21 U.S.C. § 331(a).

16 9. Under the FDCA, a drug was deemed to be "misbranded" if,  
17 among other things, its labeling was false or misleading in any  
18 particular, 21 U.S.C. § 352(a), or if its labeling failed to bear  
19 adequate directions for use, 21 U.S.C. § 352(f)(1). "Adequate  
20 directions for use" meant directions under which a layperson could  
21 use a drug safely and for the purposes for which it was intended. 21  
22 C.F.R. § 201.5.

23 C. THE DRUGS

24 10. "Viagra" was a drug within the meaning of Title 21, United  
25 States Code, Section 321(g)(1), and a prescription drug within the  
26 meaning of Title 21, United States Code, Section 353(b)(1). Viagra  
27 was the trade name for Pfizer, Inc.'s FDA-approved erectile  
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1 dysfunction drug containing the active pharmaceutical ingredient  
2 Sildenafil.

3 11. "Cialis" was a drug within the meaning of Title 21, United  
4 States Code, Section 321(g)(1), and a prescription drug within the  
5 meaning of Title 21, United States Code, Section 353(b)(1). Cialis  
6 was the trade name for Eli Lilly & Company's FDA-approved erectile  
7 dysfunction drug containing the active pharmaceutical ingredient  
8 Tadalafil.

9 12. The FDA's approval of Viagra and Cialis was limited to use  
10 under the professional supervision of a practitioner licensed by law  
11 to administer such drug; therefore, Viagra and Cialis were  
12 "prescription" drugs under Title 21, United States Code, Section  
13 353(b)(1). Due to toxicity and other potentially harmful effects  
14 (e.g., life-threatening drops in blood pressure; loss of vision; loss  
15 of hearing; and prolonged, painful erections that result in permanent  
16 injury to the penis), drugs similar to Viagra and Cialis were not  
17 safe for use except under the supervision of a practitioner licensed  
18 by law to administer them, and they were thus prescription drugs as  
19 well.

20 13. These Introductory Allegations are incorporated into each  
21 count of this Indictment as though fully set forth therein.

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COUNT ONE

[18 U.S.C. § 371]

A. OBJECTS OF THE CONSPIRACY

Beginning on a date unknown to the Grand Jury, but at least as early as on or about December 29, 2015, and continuing to a date unknown to the Grand Jury, but at least on or about October 24, 2018, in Orange and Los Angeles Counties, within the Central District of California, and elsewhere, defendant LEE, together with others known and unknown to the Grand Jury, conspired with each other to knowingly and intentionally commit offenses against the United States, namely, fraudulently and knowingly importing and bringing into the United States, and causing to be imported and brought into the United States, certain merchandise contrary to law, in violation of Title 18, United States Code, Section 545; and introducing and causing 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), 333(a)(2).

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:

1. Defendant LEE would order wholesale shipments of bulk Tadalafil and Sildenafil from suppliers in China.

2. Defendant LEE's suppliers would fail to state the presence of Tadalafil and Sildenafil on the manifests for the shipments and instead state that the packages contained non-controlled substances or other merchandise.

1           3. Defendant LEE and other co-conspirators would receive the  
2 packages containing Tadalafil and Sildenafil from the Chinese  
3 suppliers at various business and residential properties under the  
4 control of defendant LEE or employees of defendant LEE.

5           4. Defendant LEE and other co-conspirators would repackage the  
6 wholesale quantities of Tadalafil and Sildenafil into smaller  
7 quantities and sell them in the form of a capsule as non-prescription  
8 herbal male sexual enhancement supplements.

9           5. Defendant LEE and other co-conspirators would sell the  
10 finished capsules to distributors across the United States in  
11 packages whose labeling stated that no prescription was necessary and  
12 did not disclose the presence of Tadalafil and Sildenafil.

13           6. Defendant LEE did not seek FDA approval to market these  
14 drugs; nor was defendant LEE licensed as a pharmacist in the State of  
15 California or otherwise authorized to prescribe or dispense  
16 prescription drugs.

17 C. OVERT ACTS

18           On or about the following dates, in furtherance of the  
19 conspiracy and to accomplish its objects, defendant LEE, and others  
20 known and unknown to the Grand Jury, committed various overt acts  
21 within the Central District of California, and elsewhere, including,  
22 but not limited to, the following:

23           Defendant LEE and a Co-Conspirator Agree to Mislabeled Shipping  
24           Manifests in Order to Pass U.S. Customs

25           Overt Act No. 1: On or about December 29, 2015, defendant LEE  
26 and Co-Conspirator #1 agreed in an email conversation that the  
27 product name contained on shipping manifests for packages shipped to  
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1 defendant LEE from Co-Conspirator #1 containing bulk Tadalafil and  
2 Sildenafil would be changed in order to pass U.S. customs undetected.

3 Overt Act No. 2: On or about March 14, 2016, defendant LEE  
4 and Co-Conspirator #1 agreed in an email conversation that the  
5 product name contained on shipping manifests for packages shipped to  
6 defendant LEE containing bulk Tadalafil and Sildenafil would be  
7 changed to "Granular Amino Molding Compound" in order to pass customs  
8 undetected.

9 Defendant LEE Establishes Corporations and Companies in Order to  
10 Manufacture and Sell Misbranded Drugs

11 Overt Act No. 3: On or about June 15, 2016, defendant LEE  
12 caused Hasim Distribution to be established as a corporation through  
13 which defendant LEE could manufacture and sell misbranded drugs.

14 Overt Act No. 4: On or about October 7, 2016, defendant LEE  
15 caused Rainbow Natural Production to be established as a corporation  
16 through which defendant LEE could manufacture and sell misbranded  
17 drugs.

18 Overt Act No. 5: On or about October 31, 2016, defendant LEE  
19 caused Dalee Supply to be established as a corporation through which  
20 defendant LEE could manufacture and sell misbranded drugs.

21 Overt Act No. 6: On or about January 11, 2017, defendant LEE  
22 caused Hasim Enterprise to be established as a company through which  
23 defendant LEE could manufacture and sell misbranded drugs.

24 Defendant LEE Imports Mislabeled Sildenafil and Tadalafil into  
25 the United States

26 Overt Act No. 7: In or about November 2016, defendant LEE  
27 caused one parcel containing approximately 21.4 kilograms of  
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1 unlabeled bulk Sildenafil to be imported from China to Gardena,  
2 California, which was manifested as a "Sample of Pentaerythritol."

3 Overt Act No. 8: In or about November 2016, defendant LEE  
4 caused one parcel containing approximately 25.10 kilograms of  
5 unlabeled bulk Tadalafil and approximately 21.55 kilograms of  
6 unlabeled bulk Sildenafil to be imported from China to Fullerton,  
7 California, which were manifested as "Acrylic Paint."

8 Overt Act No. 9: In or about November 2016, defendant LEE  
9 caused one parcel containing approximately 2.05 kilograms of  
10 unlabeled bulk Tadalafil to be imported from China to Buena Park,  
11 California, which was manifested as "Health Products."

12 Overt Act No. 10: In or about June 2017, defendant LEE caused  
13 one parcel containing approximately 1.84 kilograms of unlabeled bulk  
14 Tadalafil to be imported from China to Buena Park, California, which  
15 was manifested as "Glass Bottles."

16 Defendant LEE Ships Capsules Containing Sildenafil and Tadalafil  
17 to Distributors Outside of California

18 Overt Act No. 11: On or about July 27, 2016, defendant LEE  
19 shipped approximately 1,200 "Rhino 8 8000" capsules, containing the  
20 active pharmaceutical ingredients Tadalafil and Sildenafil, to a  
21 distributor in Beaumont, Texas.

22 Overt Act No. 12: On or about July 27, 2016, defendant LEE  
23 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the  
24 active pharmaceutical ingredient Sildenafil, to a distributor in  
25 Beaumont, Texas.

26 Overt Act No. 13: On or about July 28, 2016, defendant LEE  
27 shipped approximately 1,200 "Rhino 8 8000" capsules, containing the  
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1 active pharmaceutical ingredients Tadalafil and Sildenafil, to a  
2 distributor in Beaumont, Texas.

3 Overt Act No. 14: On or about July 28, 2016, defendant LEE  
4 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the  
5 active pharmaceutical ingredient Sildenafil, to a distributor in  
6 Beaumont, Texas.

7 Overt Act No. 15: On or about September 7, 2016, defendant LEE  
8 shipped approximately 2,400 "Rhino 69 9000" capsules, containing the  
9 active pharmaceutical ingredient Sildenafil, to a distributor in  
10 Beaumont, Texas.

11 Overt Act No. 16: On or about October 18, 2016, defendant LEE  
12 shipped approximately 1,000 "Rhino 69 9000" capsules, containing the  
13 active pharmaceutical ingredient Sildenafil, to a distributor in  
14 Baltimore, Maryland.

15 Overt Act No. 17: On or about November 28, 2016, defendant LEE  
16 shipped approximately 1,200 "Rhino 69 9000" capsules, containing the  
17 active pharmaceutical ingredient Sildenafil, to a distributor in  
18 Baltimore, Maryland.

19 Overt Act No. 18: On or about February 21, 2017, defendant LEE  
20 shipped approximately 1,000 "Rhino 69 9000" capsules, containing the  
21 active pharmaceutical ingredient Sildenafil, to a distributor in  
22 Baltimore, Maryland.

23 Defendant LEE Obtains Packaging and Labeling Material for  
24 Misbranded Drugs and Submits Labeling Material to the FDA that  
25 Fails to Disclose the Presence of Sildenafil

26 Overt Act No. 19: In or about March 2017, defendant LEE  
27 obtained approximately 295 cartons of packaging and labeling material  
28 to use to sell products such as "Black Panther," "libigrow," "Black

1 Stallion," and "Black Mamba," which were misbranded drugs that did  
2 not bear FDA-approved labeling, and were labeled as non-prescription  
3 herbal male sexual enhancement supplements.

4 Overt Act No. 20: On or about February 22, 2018, defendant LEE  
5 submitted a "Food Export Certification" to the FDA, along with a  
6 label for "Rhino 69 Platinum 9000," verifying that all the  
7 ingredients in "Rhino 69 Platinum 9000" were "approved by FDA and  
8 appear on the Generally Recognized as Safe List, and each product is  
9 intended for human consumption and is available for sale in the U.S.  
10 without restriction," when in fact "Rhino 69 Platinum 9000" contained  
11 the active pharmaceutical ingredient Sildenafil.

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## COUNTS TWO THROUGH FOUR

[18 U.S.C. §§ 545, 2]

On or about the following dates, in Orange and Los Angeles Counties, within the Central District of California, and elsewhere, defendant LEE fraudulently and knowingly imported and brought into the United States, and willfully caused to be imported and brought into the United States, merchandise, that is, unlabeled bulk Tadalafil and Sildenafil in the following quantities, contrary to law, by introducing into interstate commerce prescription drugs that were misbranded in that their labeling lacked adequate directions for use, contrary to Title 21, United States Code, Sections 331(a), 352(f)(1):

COUNT	DATE	MERCHANDISE	WEIGHT	DESTINATION
TWO	11/17/16	Sildenafil	21.4 kg	Gardena, California
THREE	11/14/16	Tadalafil	2.05 kg	Buena Park, California
FOUR	6/13/17	Tadalafil	1.84 kg	Buena Park, California

## COUNTS FIVE THROUGH TWELVE

[21 U.S.C. §§ 331(a), 333(a)(2)]

On or about the following dates, in Orange and Los Angeles Counties, within the Central District of California, defendant LEE introduced, and caused the introduction of, the following drugs into interstate commerce, with the intent to defraud and mislead, with the drugs being misbranded pursuant to Title 21, United States Code, Section 352(a)(1), because the drugs' labeling falsely and misleadingly stated "no prescription necessary," even though the drugs were prescription drugs that contained doses of Tadalafil or Sildenafil, or both, and because none of the labeling disclosed the presence of the ingredients Tadalafil or Sildenafil, or both, in the drugs:

COUNT	DATE	PRODUCT	QUANTITY	RECIPIENT'S LOCATION
FIVE	7/27/16	Rhino 8 8000	1,200	Beaumont, Texas
SIX	7/27/16	Rhino 69 9000	1,200	Beaumont, Texas
SEVEN	7/28/16	Rhino 8 8000	1,200	Beaumont, Texas
EIGHT	7/28/16	Rhino 69 9000	1,200	Beaumont, Texas
NINE	9/7/16	Rhino 69 9000	2,400	Beaumont, Texas
TEN	10/18/16	Rhino 69 9000	1,000	Baltimore, Maryland
ELEVEN	11/28/16	Rhino 69 9000	1,200	Baltimore, Maryland
TWELVE	2/21/17	Rhino 69 9000	1,000	Baltimore, Maryland

FORFEITURE ALLEGATION

[18 U.S.C. §§ 981(a)(1)(C), 982(a)(2)(B), and 28 U.S.C. § 2461(c)]

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3 1. Pursuant to Rule 32.2(a) of the Federal Rules of Criminal  
4 Procedure, notice is hereby given to defendant NAM HYUN LEE, also  
5 known as ("aka") "Daniel Lee," aka "Daniel Nam Lee," aka "Nam Lee"  
6 ("LEE"), that the United States will seek forfeiture as part of any  
7 sentence in accordance with Title 18, United States Code, Sections  
8 981(a)(1)(C) and 982(a)(2)(B), and Title 28, United States Code,  
9 Section 2461(c), in the event of the conviction of defendant LEE  
10 under any of Counts One through Four of this Indictment. If so  
11 convicted, defendant LEE shall forfeit to the United States the  
12 following property:

13 (a) All right, title, and interest in any and all  
14 property, real or personal, constituting, or derived from, any  
15 proceeds obtained, directly or indirectly, as a result of each such  
16 offense, including but not limited to the following real property  
17 located in the City of Fullerton, County of Orange, State of  
18 California, described as the property located at 1515 West Domingo  
19 Road, Fullerton, California, with Assessor's Parcel Number 287-071-  
20 28. Title to the real property is currently held in the names of  
21 defendant LEE's children: Lemuel Lee (40 percent), Yoon Ji Lee (30  
22 percent), and Yoon Jung Lee (30 percent), all of whom are siblings,  
23 all as tenants in common; and

24 (b) Any and all merchandise introduced into the United  
25 States, in violation of Title 18, United States Code, Section 545, or  
26 the value thereof.  
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1 (c) To the extent such property is not available for  
2 forfeiture, a sum of money equal to the total value of the property  
3 described in subparagraphs (a) and (b).

4 2. Pursuant to Title 21, United States Code, Section 853(p),  
5 as incorporated by Title 18, United States Code, Section 982(b), and  
6 Title 28, United States Code, Section 2461(c), defendant LEE shall  
7 forfeit substitute property, up to the total value of the property  
8 described in the preceding paragraph if, as the result of any act or  
9 omission of defendant LEE, the property described in the preceding  
10 paragraph, or any portion thereof: (a) cannot be located upon the  
11 exercise of due diligence; (b) has been transferred or sold to, or

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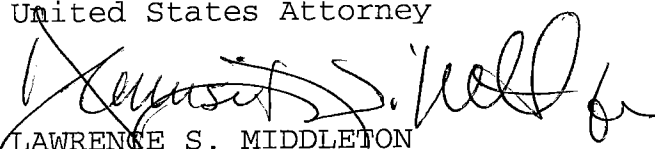
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1 deposited with, a third party; (c) has been placed beyond the  
2 jurisdiction of the Court; (d) has been substantially diminished in  
3 value; or (e) has been commingled with other property that cannot be  
4 divided without difficulty.

5 A TRUE BILL

6  
7  
8 Foreperson

9 NICOLA T. HANNA  
10 United States Attorney

11   
12 LAWRENCE S. MIDDLETON  
13 Assistant United States Attorney  
14 Chief, Criminal Division

15 DENNISE D. WILLETT  
16 Assistant United States Attorney  
17 Chief, Santa Ana Branch Office

18 DANIEL H. AHN  
19 Assistant United States Attorney  
20 Deputy Chief, Santa Ana Branch  
21 Office

22 JAKE D. NARE  
23 Assistant United States Attorney  
24 Santa Ana Branch Office  
25  
26  
27  
28