

# UNITED STATES DISTRICT COURT

for the

Southern District of Florida

United States of America

v.

JORGE MORENO and LUIS ANTHONY RIVERA

Case No.

15-29006-Torres

*Defendant(s)*

## CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of April - June 2015 in the county of Miami-Dade in the  
Southern District of Florida, the defendant(s) violated:

*Code Section*

21 U.S.C. § 331(t) and 333(a)(2)

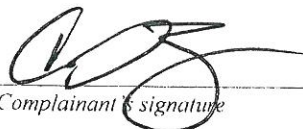
*Offense Description*

Jorge MORENO, and Luis Anthony RIVERA did fail to provide transaction history, transaction information, and transaction statements as required by 21 U.S.C. § 360eee-1(c) (1)(A)(iii) and in violation of 21 U.S.C. § 331(t) and 333(a)(2).

This criminal complaint is based on these facts:

SEE ATTACHED AFFIDAVIT.

☒ Continued on the attached sheet.

  
Complainant's signature

CESAR D ZAYAS, FDA-OCI  
Printed name and title

Sworn to before me and signed in my presence.


Date: 06/12/2015

City and state: Miami, Florida

  
Judge's signature

EDWIN G. TORRES, U.S. MAGISTRATE JUDGE  
Printed name and title

Steven M. Larimore, Clerk  
U.S. District Court  
Southern District of Florida

By   
Date: 06/12/15 Deputy Clerk

**AFFIDAVIT OF SPECIAL AGENT CESAR D. ZAYAS  
IN SUPPORT OF CRIMINAL COMPLAINT**

I, CESAR D. ZAYAS, being duly sworn, depose and say:

**A. INTRODUCTION**

1. I am a Special Agent with the Office of Criminal Investigations ("OCI"), United States Food and Drug Administration ("FDA"), Miami Field Office, located in Plantation, Florida. I have been employed as a Special Agent with FDA/OCI since July 2013.

2. As a Special Agent with FDA/OCI, I have participated in numerous investigations concerning criminal violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "FDCA"), and other federal criminal laws.

3. I am a law enforcement officer of the United States, in that I am empowered under the authority of the FDCA to conduct investigations and to make arrests.

4. In my capacity as an FDA/OCI Special Agent, I have received extensive training in, among other things, investigations of counterfeit drugs, drug misbranding, drug diversion, drug adulteration, and drug tampering.

5. Prior to my current employment, I was a Special Agent with Department of State Bureau of Diplomatic Security Service (DSS) for approximately (4) years. Prior to my employment with DSS, I was employed with the Department of State Bureau of Consular Affairs for approximately two (2) years.

6. Your affiant has executed and assisted with numerous search warrants and is familiar with the probable cause standard for the issuance of a federal search warrant.

7. The statements contained in this affidavit are based in part on information provided by Special Agents with the Food and Drug Administration, Office of Criminal Investigations ("FDA/OCI"), other law enforcement officers, inspection results, and my experience and background as a special agent. Except where indicated, all statements referred to below are set forth in substance and in part, rather than verbatim.

8. I have set forth herein only such information as I believe necessary to establish probable cause to believe that Luis A. RIVERA, and Jorge MORENO committed several violations of federal law, to wit, diversion of prescription drugs by acting as improper wholesale distributors of prescription drugs and, with intent to defraud and mislead, failing to provide transaction history, transaction information, and a transaction statement as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii).

**B. FEDERAL LAW GOVERNING PRESCRIPTION DRUG DISTRIBUTION**

9. On November 27, 2013, the Drug Supply Chain Security Act (DSCSA) was enacted to protect the integrity of the nation's drug distribution system. Effective January 1, 2015, the FDCA, as amended by the DSCSA, imposes several requirements on wholesale distributors of most prescription drugs, including certain product tracing requirements. Specifically, wholesale distributors of prescription drugs who did not purchase a prescription drug product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer must, prior to or at the time of each transaction, provide to the subsequent

purchaser a transaction history, transaction information, and transaction statement. 21 U.S.C. 360eee-1(c)(1)(A)(iii).<sup>1</sup>

10. Transaction history means a statement in paper or electronic form that includes the transaction information for each prior transaction going back to the manufacturer of the drug product. 21 U.S.C. § 360eee (25). Transaction information includes, among other things, the strength and dosage form of the drug product, the number of containers, the lot number of the drug product, the business name and address of the persons from whom and to whom ownership is being transferred. 21 U.S.C. § 360eee (26). Transaction statement means a statement in paper or electronic form that the entity transferring ownership of a drug product is in compliance with certain provisions of the DSCSA. 21 U.S.C. § 360eee (27).

11. The failure to provide the transaction statement, transaction history, and transaction information as required by 21 U.S.C. § 360eee-1(c)(1)(A)(iii) is a prohibited act under the FDCA.. See 21 U.S.C. § 331(t). If the offense is committed with intent to defraud or mislead, the offense is a felony punishable by up to three years in prison for each count,

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<sup>1</sup> On December 31, 2014, FDA issued a Compliance Policy Guidance that announced that FDA did not intend to take action against trading partners, including wholesale drug distributors, who did not prior to May 1, 2015 provide transaction history, transaction information, and transaction statement as required by the DSCSA.

## PROBABLE CAUSE

### C. CONTROLLED BUYS OF PRESCRIPTION DRUGS FROM TARGETS

12. Between on or April 6, 2015 and June 15, 2015, cooperating sources 1 and 2 ("CS 1 and CS 2") and Undercover Agent ("UCA") made a total of 3 separate purchases of alleged diverted prescription drugs from Luis Anthony RIVERA, which were delivered by Jorge MORENO (collectively, "TARGET SUBJECTS")

13. Agents confirmed with the State of Florida that TARGET SUBJECTS were not licensed with the State of Florida to distribute prescription drugs in the state. Furthermore, TARGET SUBJECTS failed to provide transaction history, transaction information, and transaction statements prior to or at the time of these transactions as required by the FDCA.

14. Prior to these transactions and/or during these transactions, CS 1 and CS 2, the UCA and TARGET SUBJECTS had recorded conversations in which TARGET SUBJECTS explained that they were willing to purchase and sell diverted and counterfeit prescription drugs. TARGET SUBJECTS explained that they could obtain large quantities of prescription drugs from various sources to be sold for a fraction of the legitimate wholesale acquisition cost ("WAC").

15. **On April 6, 2015**, at approximately 12:50pm, FDA agents monitored and recorded a meeting between CS 1, CS 2, Luis Anthony RIVERA and an Unindicted Co-conspirator ("UCC") which occurred at Rancho Luna Restaurant located at 45 NW 22nd Ave., Miami, Florida 33125. The purpose of this meeting was for RIVERA to introduce CS 1 to the UCC, whom RIVERA said owned a pharmacy and could provide CS 1 with diverted prescription drugs at 40 percent off of WAC.

16. At approximately 1:10pm, the UCC approached the table where RIVERA, CS 1 and CS 2 were sitting and provided CS 1 with a list of the medications that he/she had available to sell. The list included Abilify, Seroquel, Crestor, Restasis, Spiriva, Advair and other prescription drugs that are known to be commonly sold in drug diversion schemes.

17. UCC told CS 1 that he/she could provide these drugs immediately. UCC also indicated that sometimes orders could take up to 2 days. UCC also spoke about other associates who could provide these drugs and mentioned that these people owned pharmacies, just as UCC did.

18. CS 1 asked for 30 days credit to pay for these diverted drugs but UCC was not receptive to the request. UCC provided CS 1 with his/her phone number for CS 1 to contact him/her for whenever CS 1 was ready to conduct business.

19. Once the meeting concluded, agents observed UCC walk out of the Restaurant and walk inside a nearby pharmacy [the one UCC owned]. Luis RIVERA also offered to introduce CS 1 to another source that could get CS 1 product.

20. **On April 22, 2015** at approximately 12:00 pm, FDA agents monitored and recorded a meeting between CS 1 and RIVERA which occurred at Rancho Luna Restaurant located at 45 NW 22nd Ave., Miami, Florida 33125.

21. At approximately 12:08 pm, CS 1 arrived at the restaurant and met RIVERA who was already inside the restaurant to have a conversation.

22. At approximately 12:45 pm, CS 1 and RIVERA left the restaurant on foot and walked into UCC's pharmacy.

23. At approximately 12:47 pm, UCC met with CS 1 and RIVERA to discuss the purchase of prescription drugs from UCC's pharmacy.

24. At approximately 12:54 pm, CS 1 and RIVERA departed the pharmacy on foot and walked back over to the outside seating area of Rancho Luna Restaurant for further conversations and coffee.

25. At approximately 1:04 pm, an individual later identified by CS 1 in a debriefing as being Jorge MORENO arrived carrying a small black bag and a medium tan bag. CS 1, CS 2, and MORENO placed these bags in the trunk of CS 2's vehicle while RIVERA observed as a lookout. RIVERA later told UCA that his source for the prescription drugs on this occasion was not UCC's pharmacy but other sources, and that one of the reasons for this was that UCC did not like being asked for credit/extra time to pay and did not want to do business with CS 1. [See paragraph 28].

26. At approximately 1:14 pm, this meeting concluded and agents followed CS 1 to an agreed upon location to inventory and photograph the contents of these bags. Agents observed both bags contained prescription drugs that appeared to be diverted due to glue residue, missing labels, and labels with patient information on some bottles. After inventory it was calculated the value of these drugs according to WAC was approximately \$125,000.00

27. On **May 18, 2015** at approximately 12:30 pm, UCA, CS 1 and CS 2 met RIVERA at Las Vegas 2 Restaurant located at Plantation Marketplace, 7015 W Broward Blvd., Plantation, Florida 33317. This meeting was monitored by FDA agents. Agents observed RIVERA arrive at the restaurant driving a red Nissan bearing Florida license plate #BUMY46.

28. During this meet UCA provided \$20,000.00 in cash to RIVERA for the diverted prescription drugs delivered on **April 22, 2015**. During this meeting RIVERA identified his suppliers of his diverted prescription drugs as being an individual from Tampa and an unknown warehouse location. The participants also discussed the poor quality of the previously provided diverted prescription drugs with glue residue, missing labels and patients' information on a few bottles and RIVERA agreed to personally inspect any future deliveries of diverted prescription drugs purchased. RIVERA offered to sell additional diverted prescription drugs and wanted to deliver these drugs in 2 days' time that the same week.

29. **On May 20, 2015** at approximately 12:10 pm, UCA, and CS 2 met with Jorge MORENO Jr. at Las Vegas 2 Restaurant located at Plantation Marketplace, 7015 W Broward Blvd., Plantation, Florida 33317. This meeting was monitored by FDA agents. UCA and CS 2 arrived at the restaurant parking lot.

30. At approximately 12:15pm, MORENO arrived to meet with UCA and CS 2. MORENO gave UCA and CS 2 a box. UCA and CS 2 departed from the meet location. Agents then observed MORENO get into and depart the meet location driving a gray Isuzu pick-up truck bearing Florida license plate #DKWR65 registered to Jorge MORENO Jr., 3110 W. Abdella St., Tampa, Florida 33607. Upon inspection, agents determined the box provided by MORENO contained diverted prescription drugs do to the fact that there was glue residue on the bottles and partially ripped labels. These items were inventoried. After inventory it was calculated the value of these drugs according to WAC was approximately \$40,000.00.



31. **On May 26, 2015** at approximately 12:13 pm, UCA accompanied by CS 2 met with Luis Anthony RIVERA at Las Vegas 2 Restaurant located at Plantation Marketplace, 7015 W Broward Blvd., Plantation, Florida 33317. This meeting was monitored by FDA agents. At approximately 12:13 pm UCA arrived at the restaurant parking lot and CS 2 remained inside UCA's vehicle while UCA went inside the restaurant for the meeting with RIVERA.

32. At approximately 12:25 pm, RIVERA arrived in the parking lot of the restaurant driving a red Nissan bearing Florida license plate #BUMY46. UCA made contact with RIVERA inside the restaurant to discuss the purchase of diverted prescription drugs. RIVERA agreed to accept a \$25,000.00 bank wire transfer as payment for previously delivered diverted prescription drugs and provided a Regions bank account in the name of MAKENKO ENTERPRISE with routing number 062005690 and bank account number 0184127856.

33. RIVERA stated his "guy" was about one hour away from delivering diverted prescription drugs on this date to UCA. RIVERA stated his "guy" is the same guy from Tampa from previous deliveries of diverted prescription drugs and RIVERA does not put himself in the same place as the drugs when they are being delivered. RIVERA stated he has a source for counterfeit prescription drugs and could sell them to UCA. RIVERA also discussed with UCA the recent changes to the pedigree requirements for these diverted prescription drugs.

34. At approximately 1:03 pm, RIVERA and UCA exited the restaurant together. This meeting concluded at approximately 1:05 pm.

35. On May 26, 2015 at approximately 4:46 pm, UCA and CS 2 met with Jorge MORENO Jr. at the Hotel Indigo located at 7601 Miami Lakes Dr., Miami Lakes, Florida. This meeting was monitored by FDA. At approximately 4:44 pm, agents observed the red Nissan bearing Florida license plate #BUMY46 and the gray Isuzu pick-up truck bearing Florida license plate # DKWR65 parked in the front East parking lot of the hotel. At approximately 4:46 pm, agents observed MORENO walk out to his Isuzu pick-up truck and open the passenger side door.

36. At approximately 4:47 pm, UCA and CS 2 arrived at the hotel where from the main lobby entrance RIVERA waved to UCA and CS 2 to continue east on the parking lot to meet MORENO. MORENO was observed by agents placing a small box in the trunk of CS 2's vehicle. This meeting concluded at approximately 4:49 pm.

37. FDA agents later determined this box contained diverted prescription drugs due to the glue residue on the bottles consistent with the previous deliveries and the appearance of having previous labels. These items were inventoried. After inventory it was calculated the value of these drugs according to WAC was approximately \$34,000.

**D. CONCLUSION**

WHEREFORE, based on the foregoing, your affiant believes there is probable cause to believe that Luis Anthony RIVERA, and Jorge MORENO did, with intent to defraud and mislead, act as wholesale distributors of prescription drugs and fail to provide transaction history, transaction information, and transaction statements as required by 21 U.S.C. § 360eee-1(c) (1)(A)(iii) and in violation of 21 U.S.C. § 331(t) and 333(a)(2).

FURTHER YOUR AFFIANT SAYETH NOT

  
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CESAR D ZAYAS

Special Agent

United States Food and Drug Administration

Office of Criminal Investigations

SWORN AND SUBSCRIBED TO BEFORE ME  
ON THIS 12 DAY OF JUNE 2015 IN MIAMI, FL

  
\_\_\_\_\_  
HON. EDWIN G. TORRES

UNITED STATES MAGISTRATE JUDGE

