AO 91 (Rev. 11/11) Criminal Complaint (Rev. by USAO on 3/12/20)

ORIGINAL

# UNITED STATES DISTRICT COURT

for the

Central District of California

FILED
CLERK, U.S. DISTRICT COURT

APR 1, 2020

CENTRAL DISTRICT OF CALIFORNIA
BY: IB DEPUTY

United States of America

v.

FRANK RICHARD LUDLOW,

Defendant

Case No. 20MJ01469

## CRIMINAL COMPLAINT BY TELEPHONE OR OTHER RELIABLE ELECTRONIC MEANS

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 of March 18, 2020 in the county of Los Angeles in the Central District of California, the defendant violated:

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CLERK U.S. DISTRICT COURT
CENTRAL DIST. OF CALIF.
LOS ANGELES
BY

| *Code Section* | *Offense Description* |
|---|---|
| 21 U.S.C. §§ 331(a), 333(a)(2) | Introduction of Misbranded Drugs into Interstate Commerce |

This criminal complaint is based on these facts:

*Please see attached affidavit.*

☒ Continued on the attached sheet.

Virginia Keys
*Complainant's signature*

Virginia Keys, Special Agent
*Printed name and title*

Attested to by the applicant in accordance with the requirements of Fed. R. Crim. P. 4.1 by telephone.

Date: 4/1/2020

*Judge's signature*

City and state: Los Angeles, California

Hon. ALEXANDER F. MACKINNON,
U.S. Magistrate Judge
*Printed name and title*

ATTACHMENT TO COMPLAINT

Offense Description:

On or about March 18, 2020, in Los Angeles County, within the Central District of California, defendant FRANK RICHARD LUDLOW ("LUDLOW") introduced and willfully caused the introduction of 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, because, *inter alia*, the drugs' labeling falsely and misleadingly stated "Trinity COVID-19 SARS Antipathogenic Treatment," even though the drugs had not been approved by the FDA for any such purpose and the drugs had not been manufactured in an establishment duly registered with the FDA.

# AFFIDAVIT

I, Virginia Keys, being duly sworn, declare and state as follows:

## I. INTRODUCTION

1. I am a Special Agent with the Food and Drug Administration's Office of Criminal Investigations ("FDA-OCI") and have been so employed since February 2016. I am a graduate of the Criminal Investigator Training Program and the Special Agent Basic Training program at the Federal Law Enforcement Training Center in Glynco, Georgia, for IRS Criminal Investigation, and the Special Agent Training Program for FDA-OCI in Charleston, South Carolina. I hold a Bachelor of Arts Degree in Interdisciplinary Studies including Accounting and Business, and Communications. I also hold a Master of Criminal Justice Degree. I was a Special Agent for IRS Criminal Investigation for over 9 years, investigating criminal violations of the Internal Revenue Law (Title 26, United States Code), violations relative to money laundering and currency transactions (Title 18, United States Code), as well as Organized Crime and Drug Trafficking Organization investigations.

2. I have been a Special Agent for FDA-OCI for over four years and am currently assigned to the Kansas City Field Office, State of Utah Domicile. My duties and responsibilities include the investigation of criminal violations of the Federal Food, Drug, and Cosmetic Act ("FDCA," Title 21, United States Code, Sections 301-399f) and certain provisions of the Public Health

Service Act (Title 42, United States Code). As a Special Agent, I have had extensive training in, and conducted and participated in, criminal investigations domestically and internationally involving criminal drug offenses, smuggling, tampering, misbranding and adulteration, money laundering, currency violations and other financial crimes, and related offenses. These investigations include the execution of search and arrest warrants for counterfeit drugs, misbranded drugs, mail fraud, wire fraud, and drug tampering.

## II. PURPOSE OF AFFIDAVIT

3. This affidavit is made in support of a criminal complaint against, and arrest warrant for, FRANK RICHARD LUDLOW ("LUDLOW") for violations of 21 U.S.C § 331(a), 333(a)(2) (Introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead).

4. The facts set forth in this affidavit are based upon my personal observations, my training and experience, and information obtained from various law enforcement personnel and witnesses. This affidavit is intended to show merely that there is sufficient probable cause for the requested complaint and arrest warrant and does not purport to set forth all of my knowledge of or investigation into this matter. Unless specifically indicated otherwise, all conversations and statements described in this affidavit are related in substance and in part only.

## III. SUMMARY OF PROBABLE CAUSE

5. Beginning on or about March 1, 2020, in the midst of the global COVID-19 (Coronavirus) pandemic, LUDLOW repackaged preexisting "Trinity Remedy" kits as "Trinity COVID-19 SARS Antipathogenic Treatment" kits, even though the kits never had been approved by the FDA to treat COVID-19 or for any other use. LUDLOW smuggled the kits from the United Kingdom into the United States by shipping mislabeled parcels containing the kits to his distributors in California and Utah. LUDLOW's actions put consumers at risk by providing these unapproved drugs with insufficient labeling and directions for use.

## IV. FDCA REGULATORY FRAMEWORK

6. The FDA is an agency of the United States Government charged with the responsibility of protecting the American public by enforcing the FDCA, 21 U.S.C. §§ 301-399h, to ensure, among other things, that the drugs sold for human use are safe, and bear labeling containing true and accurate information.

### A. Drugs and Labelling

7. The FDCA defines a "drug," in relevant part, as (1) any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; (2) any article (other than food) intended to affect the structure or any function of the body; or (3) any article used as a component of either. 21 U.S.C. § 321(g).

8. The FDCA defines "new drug" as any drug the composition of which is not generally recognized by experts as

safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling. Id. § 321(p).

9. The FDCA provides that, with limited exceptions not relevant here, before a new drug can be shipped in interstate commerce, its sponsor (usually the manufacturer) first must obtain FDA approval of a New Drug Application ("NDA") for that drug. Id. § 355(a). The sponsor of a new drug is required to submit information in the NDA showing to the FDA's satisfaction that, among other things, its new drug is safe and effective for its intended uses. Id. § 355(b)(1); 21 C.F.R. § 314.50.

10. Under the FDCA, a "prescription drug" is any drug intended for use in humans that, because of its toxicity or potential for harmful effect, the method of its use, or the collateral measures necessary for its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or a drug which is limited by an approved application under 21 U.S.C. § 355 for use under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1).

11. The FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article," including food and drugs. Id. § 321(k). "Labeling" is a broader term, and is defined as "all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article." Id. § 321(m).

12. For the purposes of 21 U.S.C. § 360, the term "manufacture, preparation, propagation, compounding, or processing" includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user. 21 U.S.C. § 360(a)(1).

13. Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs in any establishment which he owns or operates in any State is required by the FDCA to immediately register with the Secretary of Health and Human Services, through the FDA, their name, all of their places of business, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address. Id. § 360(b)(1) and (c)(1). Such persons are also required to annually renew their registration. Id. § 360(b)(1).

14. Similarly, every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States must, upon first engaging in any such activity, immediately submit a registration to the FDA that includes the name and place of business of such person, all such establishments, the unique facility identifier of each such establishment, a point of contact e-mail address, the name of the United States agent of each such establishment, the name of

each importer of such drug in the United States that is known to the establishment, and the name of each person who imports or offers for import such drug to the United States for purposes of importation. Each such foreign establishment shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year. Id. § 360(i). At the time of initial registration, and biannually thereafter, both domestic and foreign drug manufacturers are also required to file a list of all the drugs being manufactured, prepared, propagated, compounded or processed by them for commercial distribution. Id. § 360(j).

**B. Misbranded Drugs**

15. The FDCA states that a drug is deemed misbranded:

a. If its labeling is false or misleading in any particular. Id. § 352(a)

b. If it is a drug in package form unless its labeling bears the name and place of business of the manufacturer, packer, or distributor, as well as an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Id. § 352(b). The statement of the place of business shall include the street address (unless listed in a current telephone directory), city, state, and zip code. 21 C.F.R. § 201.1(i).

c. If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered, or if it is not included in a list of drugs

manufactured by a facility registered with the FDA, as required by 21 U.S.C. § 360. 21 U.S.C. § 352(o).

d. If it is a prescription drug and at any time prior to dispensing, the label of the drug failed to bear, at a minimum, the symbol "Rx only." Id. § 353(b)(4)(A).

16. A drug is also misbranded unless its labeling bears (1) adequate directions for use; and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner or form as are necessary for the protection of users. Id. § 352(f). "Adequate directions for use" is defined as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. Directions under which the layperson can use a prescription drug safely cannot be written because such drugs can only be used safely, if at all, at the direction, and under the supervision, of a physician.

17. Dispensing a prescription drug without a valid prescription by a licensed practitioner is an act which causes the drug to be misbranded while held for sale. 21 U.S.C. § 353(b)(1).

18. The FDCA prohibits, among other things, the doing or causing of the introduction or delivery for introduction into interstate commerce of any drug that is misbranded. Id. § 331(a).

**C. Criminal Penalties**

19. The FDCA establishes criminal penalties for doing or causing any of the above-mentioned prohibited acts. Under 21 U.S.C. § 333(a)(1) and 18 U.S.C. § 3571, any individual who violates a provision of 21 U.S.C. § 331 shall be imprisoned for not more than one year and/or fined not more than $100,000.00 (i.e. a misdemeanor); for corporations, the fine is up to $200,000.00. This is true even if an act is committed without specific intent. United States v. Park, 421 U.S. 658 (1975). Pursuant to 21 U.S.C. § 333(a)(2) and 18 U.S.C. § 3571, if an individual commits a second violation of 21 U.S.C. § 331 after final conviction on the first charge, or commits a Section 331 violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years and/or fined not more than $250,000.00 or both (i.e. a felony); for a corporation, the maximum fine is $500,000.00.

## V. STATEMENT OF PROBABLE CAUSE

20. Based on my interviews with witnesses, including S.O., my conversations with other agents involved in this investigation, and my review of documents including investigative reports and financial records, I learned the following, among other things:

**A. Background**

21. S.O. first met LUDLOW on or about May 6, 2017, when LUDLOW traveled to the United States to visit S.O., who had severe medical issues and had heard of LUDLOW's miracle cure, the "Trinity Remedy." According to S.O., LUDLOW was not (and is

not) a doctor. During the visit, LUDLOW used a "Bio-Meridian device" to measure S.O.'s body frequencies. Based on the results, LUDLOW told S.O. she had a level-5 toxicity with one of the symptoms being feline leukemia. LUDLOW recommended that S.O. take his Trinity Remedy, which she did and felt better almost immediately.

22. According to S.O., the Trinity Remedy contained vitamin C, an enzyme mix, potassium thiocyanate, and hydrogen peroxide. LUDLOW and S.O. considered all of these ingredients to be natural and healthy. A consumer was supposed to add 18 ounces of water, say a prayer, drink half of the solution, take a probiotic along with bee pollen, and then ingest the remainder of the solution.

23. From 2017 until early March 2020, when S.O. started taking LUDLOW's remedy, "Trinity Mind, Body & Soul" had been printed on the labels of the treatment kits, the packaging of which were made of pink plastic.

24. S.O. and LUDLOW agreed that S.O. would pay LUDLOW approximately $50 per kit. From approximately May 2017 through March 2020, S.O. ordered between 300 to 400 kits from LUDLOW. According to S.O., she gave between 50 to 70 percent of the kits away to help people, but she sold the remainder for $125-$200 per kit.

25. S.O. did not order the kits online. Instead, she called LUDLOW and placed orders for the kits over the phone. S.O. paid LUDLOW through Western Union.

26. Western Union payment records show the following payments from S.O. to LUDLOW:

a. On or about October 21, 2017, S.O. paid $1,500 to LUDLOW (Tracking #8045383740);

b. On or December 18, 2018, S.O. paid $1,800 to LUDLOW (Tracking #2704518086);

c. On or about February 26, 2019, S.O. paid $1,800 to LUDLOW (Tracking #0149695979);

d. On or about May 13, 2019, S.O. paid $1,800 to LUDLOW (Tracking #1451166276);

e. On or about June 18, 2019, S.O. paid $1,800 to LUDLOW (Tracking #6100670497);

f. On or about November 25, 2019, S.O. paid $1,000 to LUDLOW (Tracking #4138270653);

g. On or about December 31, 2019, S.O. paid $1,000 to LUDLOW (Tracking #1874384912); and

h. On or about February 11, 2020, S.O. paid $1,000 to LUDLOW (Tracking #4957618207).

**B. LUDLOW's Marketing of the Kits as Treatment for Coronavirus**

27. In or about February or March 2020, LUDLOW texted a photograph to S.O. of the new label that he was putting on the Trinity Remedy kits. The new label stated "Trinity COVID-19 SARS Antipathogenic Treatment," but contained the same ingredients as the "Trinity Mind, Body & Soul" treatment kits that LUDLOW previously had shipped to S.O. S.O. was excited about the new label as she thought that people who were worried

about the Coronavirus pandemic would want to take the product and that it would help them. S.O. did not believe that the product would cure Coronavirus but rather that it would help people who have Coronavirus not become as ill as they otherwise would have been.

28. S.O. asked LUDLOW to send her as many "Trinity COVID-19 SARS Antipathogenic Treatment" kits as he could. LUDLOW agreed. LUDLOW shipped the kits from the United Kingdom to S.O.'s rental home in Ogden, Utah, and to the residence of S.O.'s boyfriend in Forestville, California. S.O. also received some additional "Trinity Mind, Body & Soul" treatment kits at her parents' home in Draper, Utah.

29. According to S.O., LUDLOW has not changed the ingredients or contents of the kits over the past several years. Instead, LUDLOW only recently changed the label of the kits, due to the Coronavirus pandemic.

**C. The Seized Shipments**

30. On or about March 18, 2020, I was notified by Homeland Security Investigations in Utah ("HSI-Utah") Special Agent Dan Ashment (SA Ashment) concerning a seized shipment of COVID-19 (Coronavirus) test kits. Based on my conversations with SA Ashment and my review of related reports, I learned the following:

a. Earlier that day, Customs and Border Protection ("CBP") at the Los Angeles International Mail Facility ("LA-IMF"), located in Los Angeles County, within the Central District of California, seized the shipment.

b. The shipment label description was "60 Water Treatment" with UPS Tracking number RN462702367GB, weight 1.765kg, value declared $120, and containing 60 pink plastic bags with various test samples. The package, when opened, appeared as follows:


c. The "treatment" kits inside the package were packaged as follows:

d. The shipper was listed as Frank Ludlow C/O Willow Cotthane, East Marden, Nr. Chicmester, West Sussex, P0189JE, U.K. and the Consignee was listed as "Sydney Osmum" at a specified address in Ogden, Utah.

e. One kit from the shipment was sent to the FDA Forensic Chemistry Center for testing; the results of the testing are pending.

31. On or about March 20, 2020, United States Postal Inspection Service Inspector Lance Howell told SA Ashment that he had received an additional inbound package originating in the United Kingdom addressed to S.O. and shipped via the LA-IMF to a USPS facility in Utah. I learned the following:

a. The package was addressed to S.O. at her parents' address in Draper, Utah.

b. The shipment label description was "21 Water Treatment" with the date "11-3-20 Frank R Ludlow" and sent through Royal Mail Priority Mail with International tracking number PRN: 0210-3E41-0396-D2BD.

c. The shipper was listed as Frank Ludlow c/o Willow Cottage, P018 9JE, UK.

d. The package contained 21 pink plastic bags labeled as "Trinity Mind, Body & Soul, 500ml Kit, Batch No 19/104, Use by 1/1/2021."

32. Based on my conversation with SA Ashment and my review of related reports, I know the following:

a. On or about March 20, 2020, SA Ashment conducted a recorded, telephonic interview of S.O. After SA Ashment

advised S.O. of her Miranda rights, she waived her rights and agreed to speak with him. SA Ashment told S.O. that lying to a federal agent was a felony.

b. S.O. said that the kits are vitamin packs and that they healed her past medical issues as well as her father's skin cancer. S.O. purchased approximately 300-400 of the kits from LUDLOW in the United Kingdom.

33. On or about March 30, 2020, I took possession of all the "Trinity Remedy" test kits from HSI (both the 59 "Trinity COVID-19 SARS Antipathogenic Treatment" kits and the 21 "Trinity Mind, Body & Soul" treatment kits).

34. On or about March 30, 2020, I interviewed S.O. After I advised her of her Miranda rights, she waived them. I also told her that lying to a federal agent is a violation of 18 U.S.C. § 1001.

a. S.O. voluntarily surrendered an additional 64 "Trinity COVID-19 SARS Antipathogenic Treatment" kits, 18 "Trinity Mind, Body & Soul" treatment kits, 43 "Trinity Detox" vials which she said contained Brandy and Holy Water, and one "Trinity Equestrian Kit" which she said contained the same ingredients as the COVID-19 and Mind, Body & Soul treatment kits but in a higher dosage.

b. S.O. confirmed that the package seized at LA-IMF (described above) was one that she had asked LUDLOW to send to her. S.O. also confirmed the package seized by HSI in Utah (described above) was one that she had ordered from LUDLOW.

### D. Lack of Regulatory Approval for LUDLOW's Coronavirus Treatments

35. Examples of cure, mitigation, treatment, and prevention claims found on LUDLOW's product label include: (1) the product name on the label is "Trinity COVID-19 SARS Antipathogenic Treatment;" and (2) the package insert states "Mixing instructions . . . Drink as soon as the solution is made as the Trinity molecule only has a short life."

36. There are no FDA-approved new drug applications in effect for "Trinity COVID-19 SARS Antipathogenic Treatment."

## VI. CONCLUSION

37. For all the reasons described above, there is probable cause to believe that LUDLOW violated 21 U.S.C §§ 331(a), 333(a)(2) (Introduction of a misbranded drug into interstate commerce with the intent to defraud and mislead).

/S/
Virginia Keys, Special Agent
Food and Drug Administration
Office of Criminal Investigations

Attested to by the applicant in accordance with the requirements of Fed. R. Crim. P. 4.1 by telephone on this 1st day of April, 2020

HONORABLE ALEXANDER F. MACKINNON
UNITED STATES MAGISTRATE JUDGE