

ORIGINAL

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

UNITED STATES OF AMERICA)	MAGIS. NO. 10-0267 LEK
)	
Plaintiff,)	DISTRICT OF COLORADO
)	10-MJ-01045-CBS
V.)	
)	
SHENGYANG ZHOU)	
a/k/a "Tom,")	
)	
Defendant.)	

FILED IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF HAWAII

MAR 24 2010

at _____ o'clock and _____ min. _____ M.
SUE BEITIA, CLERK

Before the Honorable Leslie E. Kobayashi, U.S. Magistrate Judge,
District of Hawaii, Honolulu, Hawaii.

The undersigned deponent being first duly sworn deposes and says:

The deponent is a Special Agent for U.S. Immigration and Customs Enforcement; that the deponent is informed and believes and, on the basis of such information and belief, alleges that on March 5, 2010, a Criminal Complaint was filed in the District of Colorado, and an arrest warrant issued, charging the above-named defendant, Shengyang Zhou with violating 18 United States Code, Sections 545, 2320(a) and 2, and Title 21 United States Code, Sections 331(d), 333(a)(2), 952(b), 960(a)(1) and 960(b)(4); introducing unapproved new drugs; trafficking in counterfeit goods; importing merchandise into the U.S. contrary to law; and importation of Schedule IV controlled substances.

The deponent is further informed that the judge in the District of Colorado recommended that no bail be set.

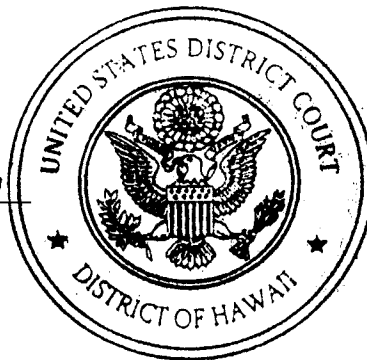
[Handwritten Signature]

LAURA DAI
SPECIAL AGENT
U.S. IMMIGRATION AND CUSTOMS

ENFORCEMENT

Subscribed and sworn to
before me, this 24th day
of March 2010.

[Handwritten Signature]
LESLIE E. KOBAYASHI
U.S. MAGISTRATE JUDGE



IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Criminal Case No. *10-mj-01045-0735*

UNITED STATES OF AMERICA,

Plaintiff,

v.

1. SHENGYANG ZHOU,
a/k/a "Tom,"

Defendant.

ORDER TO SEAL

The Court has for consideration the government's Motion to Seal wherein the government asks this Court to seal the criminal complaint and its supporting affidavit, and the arrest warrants in this case, as well as the government's Motion to Seal, and any order issued with regard to the motion. Upon consideration,

IT IS ORDERED that the government's Motion to Seal, this Order, and the criminal complaint and its supporting affidavit, and the arrest warrant are hereby sealed (except that copies may be provided to the U.S. Marshal and any other law enforcement agency assisting in the execution of the arrest warrant), until further order of this Court or until such time as the arrest

warrant is executed and the defendant's initial appearance on the criminal complaint in this case.

DONE AND ORDERED on this 5th day of March, 2010.


UNITED STATES MAGISTRATE JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

FILED
U.S. DISTRICT COURT
DISTRICT OF COLORADO
2010 MAR -4 PM 4:17
GREGORY C. LANGHAM
CLERK

Criminal Case No. *10-mj-01045-CBS*

UNITED STATES OF AMERICA,

Plaintiff,

BY _____ DEP. CLK

v.

1. SHENGYANG ZHOU,
a/k/a "Tom,"

Defendant.

MOTION TO SEAL

The United States of America, by and through the undersigned Assistant United States Attorney, hereby moves this Court for an order directing to be filed under seal this motion, any orders thereon, the criminal complaint and its supporting affidavit, and the arrest warrant issued thereon in this case (except for copies for the U.S. Marshal, and any other law enforcement agency assisting in the execution of the arrest warrant), until such time as the arrest warrant is executed and the defendant has his initial appearance on the criminal complaint in this case or until further order.

As grounds for the motion, the government states as follows:

It is believed that the defendant is currently residing in China and is unaware of the criminal complaint or that criminal

charges that are the subject of the complaint are imminent.

It is believed that public disclosure of the criminal complaint could alert the defendant and cause him to flee, relocate or take other actions to otherwise frustrate the execution of the arrest warrant.

Sealing the criminal complaint, supporting affidavit and arrest warrants issued thereon will help facilitate the orderly arrests of the defendant, and help ensure the safety of the law enforcement officers executing the arrest warrant, by allowing the arrest to take place without the advance knowledge of the defendant.

Further, the criminal investigation of the matters that give rise to the criminal complaint is still ongoing and is not public knowledge. There is reason to believe that the defendant is unaware that he is a target of this investigation or of the fact of the investigation. Public disclosure of the complaint could reveal to the defendant the fact and nature of the investigation and could jeopardize and impair the conduct of the investigation.

WHEREFORE, the United States respectfully requests that this Court issue an order sealing the criminal complaint and its supporting affidavit, and the arrest warrants in this case, this motion to Seal, and any order issued by this Court with regard to this motion (except for copies for the U.S. Marshal, and any other law enforcement agency assisting in the execution of the

arrest warrant), until further order of the Court or upon the execution of the arrest warrant and the defendant's initial appearance on the indictment in this case.

Respectfully submitted,

DAVID M. GAOUETTE
Acting United States Attorney

By: s/ Kenneth M. Harmon
KENNETH M. HARMON
Assistant United States Attorney
U.S. Attorney's Office
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Denver, Colorado 80202
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AO 442 (Rev 5/85) Warrant for Arrest

United States District Court

DISTRICT OF COLORADO

UNITED STATES OF AMERICA

V.

SHENGYANG ZHOU
a/k/a "Tom"

WARRANT FOR ARREST

CASE NUMBER 10-mj-01045-CBS

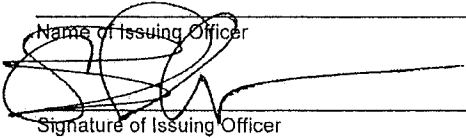
TO: The United States Marshal
and any Authorized United States Officer

YOU ARE HEREBY COMMANDED to arrest SHENGYANG ZHOU and bring him
forthwith to the nearest magistrate to answer a

Indictment Information Complaint Order of Court Violation Notice Probation Violation Petition

charging him with: introducing unapproved new drugs; trafficking in counterfeit goods; importing merchandise into the U.S. contrary to law; and importation of Schedule IV controlled substances – in violation of Title 18 U.S.C. Sections 545, 2320(a) and 2, and Title 21, United States Code, Sections 331(d), 333(a)(2), 952(b), 960(a)(1) and 960(b)(4)

Craig B. Shaffer, United States Magistrate Judge

Name of Issuing Officer

Signature of Issuing Officer

Title of Issuing Officer
Dennis Danilo on 3/15/10 at 9:40
Date and Location

(By) Deputy Clerk

Bail fixed at \$ _____ by _____
Name of Judicial Officer

RETURN		
This warrant was received and executed with the arrest of the above-named defendant at _____		
DATE RECEIVED	NAME AND TITLE OF ARRESTING OFFICER	SIGNATURE OF ARRESTING OFFICER
DATE OF ARREST		

THE FOLLOWING IS FURNISHED FOR INFORMATION ONLY:

DEFENDANT'S NAME: _____

ALIAS: _____

LAST KNOWN RESIDENCE: _____

LAST KNOWN EMPLOYMENT: _____

PLACE OF BIRTH: _____

DATE OF BIRTH: _____

SOCIAL SECURITY NUMBER: _____

HEIGHT: _____ WEIGHT: _____

SEX: _____ RACE: _____

HAIR: _____ EYES: _____

SCARS, TATTOOS, OTHER DISTINGUISHING MARKS: _____

FBI NUMBER: _____

COMPLETE DESCRIPTION OF AUTO: _____

INVESTIGATIVE AGENCY AND ADDRESS: _____

United States District Court

STATE AND DISTRICT OF COLORADO

UNITED STATES OF AMERICA

v.

CRIMINAL COMPLAINT

1. SHENGYANG ZHOU,
a/k/a "Tom"

CASE NUMBER: 10-mj-01045-CBS

I, the undersigned complainant being duly sworn, state the following is true and correct to the best of my knowledge and belief: On or about the dates indicated in Attachment A hereto, incorporated by reference, in the State and District of Colorado, and elsewhere, the defendant did:

Please See Attachment A attached hereto and incorporated by reference in violation of Title 18 United States Code, Sections 545, 2320(a) and 2, and Title 21, United States Code, Sections 331(d), 333(a)(2), 952(b), and 960(a)(1), (b)(4).

I further state that I am a Special Agent, U.S. Dept. Of Homeland Security, Immigration and Customs Enforcement and that this complaint is based on the following facts:

Please See Affidavit attached hereto as Attachment B.

Continued on the attached sheet and made a part hereof: Yes No

Trevor Melderop
Signature of Complainant -Trevor Melderop, Special Agent, U.S. Dept. Of Homeland Security, Immigration and Customs Enforcement

Sworn to before me, and subscribed in my presence

3/18/10 at 9:50 am at Denver Colorado
Date City and State

Craig B. Shaffer, United States Magistrate Judge
Name and Title of Judicial Officer

[Signature]
Signature of Judicial Officer

ATTACHMENT A

Specification No. 1

From on or about November 30, 2009 through on or about January 21, 2010, in the State and District of Colorado, and elsewhere, the defendant, with the intent to defraud and mislead, did introduce and deliver for introduction into interstate commerce, and did cause the introduction of and delivery for introduction into interstate commerce of, a new drug that had not been approved by application filed pursuant to Title 21, United States Code, Sections 355(b) or 355(j), which application was effective with respect to such drug, to wit, the following new drugs:

- 21,256 capsules of a substance labeled as "Superslim" containing the active pharmaceutical ingredient Sibutramine;
- 3,600 capsules of a substance labeled as "Meizitang" containing the active pharmaceutical ingredient Sibutramine;
- 6,000 capsules of a substance purporting to be Alli, purporting to contain the active pharmaceutical ingredient Orlistat, but actually containing the active pharmaceutical ingredient Sibutramine;

In violation of Title 21, United States Code, Sections 331(d) and 333(a)(2), and Title 18, United States Code, Section 2.

Specification No. 2

On or about January 20, 2010, in the State and District of Colorado, and elsewhere, the defendant, did intentionally traffic and attempt to traffic in goods, specifically, counterfeit copies of the pharmaceutical drug Alli, and did knowingly use on and in connection with such goods, counterfeit marks, to wit, spurious marks identical to and substantially indistinguishable from the marks used on the Alli packaging, which marks were in use and were registered for Alli by GlaxoSmithKline on the principal register of the United States Patent and Trademark Office, the use of which counterfeit marks was likely to cause confusion, to cause mistake, and to deceive.

In violation of Title 18, United States Code, Section 2320(a), and Title 18, United States Code, Section 2.

Specification No. 3

From on or about November 30, 2009 through on or about January 21, 2010, in the State and District of Colorado, and elsewhere, the defendant did fraudulently and knowingly import into the United States merchandise contrary to law, to wit, the following:

- 21,256 capsules of a substance labeled as "Superslim" containing the active pharmaceutical ingredient sibutramine;
- 3,600 capsules of a substance labeled as "Meizitang" containing the active pharmaceutical ingredient sibutramine;
- 6,000 capsules of a substance purporting to be Alli, purporting to contain the active pharmaceutical ingredient Orlistat, but actually containing the active pharmaceutical ingredient sibutramine;

In violation of Title 18, United States Code, Section 545 and Title 18, United States Code, Section 2.

Specification No. 4

From on or about November 30, 2009, through on or about January 21, 2010, in the State and District of Colorado, and elsewhere, the defendant did knowingly and intentionally import and attempt to import into the United States, from a place outside thereof, a Schedule IV non-narcotic controlled substance, that is, approximately 30,856 capsules containing detectable amounts of Sibutramine, the active pharmaceutical ingredient for the brand-name prescription drug Meridia,

In violation of Title 21, United States Code, Sections 952(b) and 960(a)(1), (b)(4), and Title 18, United States Code, Section 2.

Attachment B

Affidavit

I, Trevor Helderop, being first duly sworn, hereby depose and state as follows:

1. I am a Special Agent (SA) with the Department of Homeland Security (DHS), Immigration and Customs Enforcement (ICE) and have held that position for six years. As a Special Agent with DHS/ICE, I am responsible for conducting criminal investigations into violations of Titles 8, 18, 19 and 21 of the United States Code, as well as other federal criminal titles and statutes. In furtherance of my investigations, I have filed numerous affidavits with the United States District Court. In addition to my experiences as an ICE Special Agent I have, on numerous occasions, conducted interviews and interrogations resulting in both probable cause findings and criminal convictions in the United States District Court. I have a Bachelor of Arts degree in Criminal Justice. I have successfully completed the Special Agent Training Program at the Federal Law Enforcement Training Center, Glynco, Georgia. I am currently assigned to the Cyber Unit, wherein my duties and responsibilities include the investigation of criminal violations involving fraud and related activity in connection with electronic mail.

2. I am currently engaged in a joint investigation with the United States Food and Drug Administration, Office of Criminal Investigations (FDA/OCI), and the United States Postal Inspection Service (USPIS) concerning the unlawful sale and importation into the United States of counterfeit and unapproved new drugs that also constitute controlled substances. This investigation is concerning the illegal importation into the United States and unlawful trafficking of counterfeit, and

unapproved prescription pharmaceutical drugs from China. As a result of my work on this investigation, I have obtained a working knowledge concerning the trafficking and importation of pharmaceutical prescription drugs and the federal statutes and regulations governing this subject matter.

3. I submit this affidavit in support of a criminal complaint charging Shengyang ZHOU with committing certain federal criminal offenses, as set forth in the complaint, in connection with and arising from the importation of various unlawful pharmaceutical prescription drugs into the United States, as further set forth below. This affidavit is intended for the sole purpose of establishing probable cause for the complaint against Shengyang ZHOU and, as such, does not contain every fact known and/or information known to me concerning Shengyang ZHOU or the investigation involving him. The statements contained within this affidavit are based in part on the results of my participation in these investigations, in part on information that has been provided to me directly or indirectly by agents and investigators with other law enforcement agencies, on my experience and training as a special agent, and my discussions with other special agents, specialists, and officers who are familiar with these investigations.

Legal & Regulatory Background

4. ICE is the federal agency charged with defending this country's homeland by investigating criminal activity relating to Immigration and Customs violations. Part of ICE's responsibilities are to ensure that Customs-related laws are enforced in order to ensure products that are being imported into the United States are not being imported contrary to law.

5. The FDA is the federal agency responsible for administering federal statutes and regulations aimed at protecting the health and safety of United States citizens and residents by ensuring, among other things, that drugs are safe and effective for their intended uses before they may be offered and sold in the United States. One of the primary statutes that the FDA enforces - the provisions of which are implicated by the conduct that is the subject of this affidavit - is the federal Food, Drug and Cosmetic Act (FDCA) (Title 21, United States Code, Chapter 9), which is designed, among other things, to ensure that drugs sold for human use are safe and effective and bear labeling that contains true and accurate information.

6. Under the FDCA, it is a prohibited act - and a criminal offense - to introduce or deliver for introduction into interstate commerce a new drug that has not first been approved by the FDA for the uses intended for the drug. 21 U.S.C. §§ 331 (d), 333(a).

7. The FDCA defines a "drug" as (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). 21 U.S.C. § 321 (g) (1).

8. Under the FDCA, a "new drug" is any drug not generally recognized as safe and effective for use under the conditions prescribed, recommended or suggested

in its labeling. 21 U.S.C. § 321(p). Under the FDCA, unless there is in effect with the FDA an approved new drug application ("NDA"), an approved abbreviated new drug application ("ANDA") or a notice of claimed exemption for an investigational new drug ("IND"), a drug which comes within the FDCA's definition of "new drug" is deemed an unapproved new drug and cannot lawfully be introduced into interstate commerce. 21 U.S.C., Sections 355(a), 331 (d).

9. The FDA's approval of a new drug, pursuant to these applications, encompasses and addresses a number of matters. As part of approving the new drug, the FDA will consider and approve not just the drug's contents - its active pharmaceutical ingredients (API) and other aspects of its chemical composition - but also the contemplated dosages, the packaging of the drug, the labeling of the drug, and the drug's manufacturing methods and sources. For a new drug to be deemed approved within the meaning of the FDCA it must meet all of these parameters of approval. Accordingly, if, for example, the drug contains the approved API and chemical composition, but is introduced or delivered for introduction in interstate commerce without the approved packaging and labeling or from an unapproved manufacturing source, then the drug will be deemed an unapproved new drug under the FDCA and the act of its introduction or delivery for introduction into interstate commerce will be a prohibited act under the statute.

10. The FDCA, further defines a "prescription drug" as a drug which (A) because of its toxicity and other potential for harmful effects, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or (B) is limited

to such use by an approved NDA or an ANDA. 21 U.S.C. § 353 (b)(1). A prescription drug that is dispensed without a valid prescription by a licensed medical practitioner is deemed "misbranded" under the FDCA. 21 U.S.C. § 353 (b)(1).

11. Certain prescription pharmaceutical drugs are also classified as controlled substances under the Controlled Substances Act (CSA) (Title 21, United States Code, Sections 801-971) and are subject to regulation under that statute. A number of prescription pharmaceutical drugs which have been the subject of ongoing investigations by ICE and FDA/OCI, including the drugs which are the subject of this affidavit, are classified as Schedule IV non-narcotic controlled substances. I have learned that Schedule IV controlled substances, as defined by statute, include drugs determined to have accepted medical use in treatment in the United States and the abuse of which could lead to a limited physical dependence relative to drugs and controlled substances in other schedules (Title 21, United States Code, Section 812(b)(4)). I am aware that, like other controlled substances, prescription pharmaceutical drugs that are classified as Schedule IV controlled substances cannot generally be dispensed to an individual using the drug except pursuant to a written prescription issued by a licensed medical practitioner (Title 21, United States Code, Section 829). Additionally, under the CSA, these controlled substances cannot be distributed or generally handled in the course of being distributed other than by persons and entities who are registered with the U.S. Drug Enforcement Administration (DEA) (Title 21, United States Code, Section 822).

12. I am also aware that the importation into the United States of prescription pharmaceutical drugs, whether classified as controlled substances or not, is

subject to numerous United States Customs, DEA and FDA laws and regulations. Among other things, in order for a prescription drug to be lawfully imported into the United States, the importation of such drug must either be approved by the FDA or exempt from approval, and then the importation must be the subject of a specific Customs declaration. Under the CSA, a non-narcotic Schedule IV controlled substance cannot generally lawfully be imported into the United States unless the controlled substance is imported for medical, scientific or other legitimate uses and pursuant to notifications and declarations prescribed by regulation (Title 21, United States Code, Sections 952-953). I am aware that under these regulations, non-narcotic Schedule IV controlled substances can only lawfully be imported into the United States pursuant to prescribed import declarations completed by or through DEA registrants, and that the declaration must be furnished to the DEA prior to the importation and must accompany the imported drugs when entering the United States.

13. Title 18, United States Code, Section 545, makes it a crime for anyone to fraudulently or knowingly import or bring into the United States any merchandise contrary to law, or to receive, conceal, buy, sell, or in any manner facilitate the transportation, concealment, or sale of such merchandise after importation, knowing the same to have been imported or brought into the United States contrary to law. Accordingly, any importation of a prescription drug which does not meet these importation requirements constitutes an importation contrary to law, in violation of Title 18, United States Code, Section 545. Furthermore, any importation of a prescription drug which implicates a separate violation of the FDCA also constitutes an importation contrary to law, in violation of the same criminal statute.

14. Title 18 United States Code, Section 2320(a) prohibits intentionally trafficking or attempts to traffic in counterfeit goods and knowingly using a counterfeit mark on or in connection with such goods. Title 18 United States Code, Section 2320(e)(1)(A)(ii) defines the term "counterfeit mark" as a spurious mark that is identical with, or substantially indistinguishable from, a mark registered for those goods or services on the principal register in the United States Patent and Trademark Office in use, whether or not the defendant knew such mark was so registered.

III. BACKGROUND INFORMATION REGARDING FDA ALERTS

15. During the course of 2008, 2009, and 2010, the FDA issued a series of alerts on the FDA website concerning tainted weight loss pills and counterfeit drugs, relating to the matters involved in the investigation in which I am participating. One of the first related alerts, an alert which broadcast on or about December 22, 2008, indicated that the FDA was "alerting consumers nationwide not to purchase or consume more than 25 different products marketed for weight loss because they contain undeclared active pharmaceutical ingredients that may put consumers' health at risk". This alert listed more than twenty-five product names, including two of the products that are referenced in this affidavit, "Superslim" and "2 Day Diet". The alert further stated that "an FDA analysis found that the undeclared active pharmaceutical ingredients in some of these products, including Sibutramine (a controlled substance) and phenolphthalein (a solution used in chemical experiments and a suspected cancer causing agent)". The FDA alert also stated that "some of the amounts of active pharmaceutical ingredients far exceeded the FDA-recommended levels, putting

consumers' health at risk.” (As set forth below in this affidavit, many of the purported dietary supplement products that were seized and are the subject of this investigation were found to contain significant amounts of Sibutramine and Phenolphthalein.)

16. This December 22, 2008 FDA alert expressly stated that all of the products identified in the alert were "products [that] have not been approved by the FDA, are illegal and may be potentially harmful to unsuspecting consumers.” The FDA alert advised consumers who have used any of these products to stop taking them and consult their healthcare professional immediately. Furthermore, the FDA alert advised that the health risks posed by these products can be serious; for example, the alert stated that Sibutramine, which was found in many of the products, can cause high blood pressure, seizures, tachycardia, palpitations, heart attack or stroke. The FDA alert also made it known to its readers that Sibutramine can also interact with other medications that patients may be taking and increase their risk of adverse drug events.

17. On or about March 20, 2009, the FDA issued an alert on its website advising its readers that the list of tainted weight loss products containing undeclared active pharmaceutical ingredients had increased to seventy-two and included another product referenced in this affidavit, "Meizitang". On or about April 30, 2009, the FDA broadcast yet another alert, entitled "Questions and Answers about FDA's Initiative Against Contaminated Weight Loss Products," which provided the following information regarding Sibutramine:

"Sibutramine is a Schedule IV controlled substance and the active pharmaceutical ingredient in Meridia, an approved prescription drug to treat obesity. Some of the identified products recommend taking more than 3 times the recommended daily dosage of sibutramine. Because of this, even consumers without a history of health

problems that take these high doses of sibutramine may suffer serious adverse effects if they take these products, such as increased blood pressure, tachycardia, palpitations, and seizure. Populations who would be at increased risk of serious adverse health effects from consuming a standard dose of sibutramine include:

- Patients with a history of hypertension, especially those with uncontrolled or poorly controlled hypertension.
- Patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke.
- Patients with narrow angle glaucoma.
- Patients with a history of seizure.
- Patients predisposed to bleeding events and those taking concomitant medications known to affect hemostasis or platelet function.
- Patients with severe hepatic dysfunction.
- Patients concurrently taking the following medications: Sumatriptan, Dihydroergotamine, Dextromethorphan, Meperidine, Pentazocine, Fentanyl, Lithium, Tryptophan, MAO inhibitors.”

18. This same April 2009 FDA alert provided the following information regarding Phenolphthalein:

"Phenolphthalein was an ingredient in some Over-the-Counter laxative products until 1999 when the FDA reclassified the drug as “not generally recognized as safe and effective” after studies indicated that phenolphthalein presented a potential carcinogenic risk. Phenolphthalein has also been found to be genotoxic in that it can damage or cause mutations to DNA"

19. A recent FDA alert issued on or about January 26, 2010, entitled "...Counterfeit Alli Containing Sibutramine," warned the public about an additional product that is also referenced in this affidavit, a counterfeit version of Alli 60 mg capsules (120 count refill pack) which is being sold over the internet, particularly at online auction sites. FDA advised people who believe that they purchased the counterfeit Alli product not to use the drug. The FDA broadcast indicated that Alli is an FDA-approved over-the-counter weight loss drug that contains Orlistat as its active ingredient and that the counterfeit version of Alli does not contain Orlistat, but, instead

contains varying amounts of Sibutramine. The FDA broadcast advised the public that the "counterfeit product is illegal and unsafe". The FDA broadcast further advised the public that the "FDA laboratory tests on the counterfeit product show that people may be taking 3-times the usual daily dose (or twice the recommended maximum dose) of Sibutramine if they are following the dosing directions for Alli. Healthy people who take this much Sibutramine can experience anxiety, nausea, heart palpitations, tachycardia (a racing heart), insomnia, and small increases in blood pressure. This excessive amount of Sibutramine is dangerous to people who have a history of cardiovascular disease, and can lead to elevated blood pressure, stroke, or heart attack".

Background and Nature of the Investigation

20. Based on undercover purchases of pharmaceutical products being sold by ZHOU, and an undercover meeting that took place with ZHOU, I and other law enforcement agents identified Shengyang ZHOU, a Chinese national and Chinese citizen, as a trafficker, and importer into the United States, of counterfeit and unapproved purported controlled pharmaceutical drugs in violation of United States law.

21. As set forth below, ZHOU engaged in these illegal activities primarily through the operation of an internet website and internet postings placed on one or more business to business websites that solicited orders from customers in the United States and elsewhere for the purchase of commercial orders of products determined to be counterfeit and unapproved new drugs containing the schedule IV non-narcotic controlled substance Sibutramine which requires a prescription from medical practitioners for its use.

Details of the Investigation

22. On or about March 31, 2009, the Denver ICE office was notified that an express mail parcel, containing tracking number EB039492221CN, originating from China, had been intercepted by Customs and Border Protection (CBP) at the San Francisco, California air-mail facility on or about March 3, 2009. I was advised by CBP officers that, upon examination, the package contained 6,000 capsules of "Super Slim" and 120 capsules of "Meizitang." I was advised by CBP and the FDA that products identified under these names had previously been seized by CBP and analyzed by FDA laboratories and determined to contain Sibutramine, a Schedule IV non-narcotic controlled substance that is only approved for use and distribution in the United States as the patented drug Merida. I was advised that the parcel was addressed to a J.K. at the address of 580 Burbank St. Suite 130, Broomfield, Colorado.

23. On or about April 3, 2009, the ICE Denver office received custody of the seized parcel. I subsequently inspected the parcel further described as a large brown cardboard box, wrapped in plastic yellow tape with two white binding straps. Within the parcel were two hundred green boxes with Chinese and other foreign language markings and labeled, in part, "Super-Slim". Contained within each of these boxes were thirty foil wrapped unmarked green and white capsules, together with a leaflet providing purported directions for customer usage and identifying the ingredients of the capsules as various fruit and food components. The parcel also contained four green boxes, also bearing Chinese and other foreign language writing, identifying the product as "Meizitang." Within each of these boxes were thirty foil wrapped capsules. Accompanying the subject mail parcel, annexed to its exterior, were an EMS shipping

label and commercial invoice, declaring the contents as “dry fruit”.

24. A subsequent analysis performed on a representative sample of the capsules by the FDA's Forensic Chemistry Center indicated that both the Super-Slim product and the Meizitang product contained both Sibutramine and Phenolphthalein. The Super-Slim product contained an average of 24mg of Sibutramine per capsule and the Meizitang product contained on average of 10mg of Sibutramine per capsule. I learned from FDA/OCI SA Hermann that Meridia is the only FDA approved prescription drug that contains Sibutramine and that the Meridia is approved by the FDA in 5mg, 10mg, and 15mg strengths. SA Hermann further advised that no drug containing Phenolphthalein is currently approved for distribution and use in the United States by the FDA and that Phenolphthalein has not been approved for use in a drug by the FDA for at least the last several years.

25. On or about April 7, 2009, District of Colorado U.S. Magistrate Judge Michael E. Hegarty approved an application for a warrant (09-sw-05084-MEH) authorizing agents in this investigation to install a mobile tracking device and a GPS tracking device in the subject mail parcel containing the Super-Slim and Meizitang products, and to monitor the movements of the parcel once it was in the possession of its intended recipient, an individual identified in this affidavit as “J.K.”

26. On or about April 7, 2009, an individual identifying himself as J.K. arrived at a United States Post office in Broomfield, Colorado and took possession of the parcel and eventually took the parcel into a business complex located at 2150 W. 6th Avenue in Broomfield, Colorado. Agents subsequently contacted J.K. at his place of business and retrieved the subject mail parcel, its contents, and the tracking and

monitoring equipment. J.K. voluntarily agreed to answer questions regarding the importation and distribution of the tainted weight loss products.

27. During the interview, J.K. admitted to selling diet pills through a company called "Best2DayDiet," and stated that he had previously created a website identified as best2daydiet.com to promote the sale and distribution of these products to consumers throughout the United States as well as consumers located in other countries. J.K. acknowledged that he had reviewed one or more of the alerts issued by the FDA and had still continued to engage in the sale and distribution of the unapproved products. Later the same evening, District of Colorado U.S. Magistrate Judge Michael E. Hegarty approved an application for a subsequent search warrant (09-sw-05086) authorizing agents to search the space within the business belonging to J.K. which resulted in the seizure of, amongst other items, additional products listed on the FDA alerts that were subsequently tested by FDA's Forensic Chemistry Center which revealed the presence of Sibutramine.

28. Following the search of his business premises, J.K. agreed to cooperate with special agents of DHS/IE and FDA/OCI and U.S. Postal Inspectors concerning his sources of supply for the seized products. As part of his efforts to cooperate, J.K. acknowledged that he regularly purchased commercial quantities of both Super Slim and 2 Day Diet from foreign sources that he then resold through an internet website to retail customers in the United States. J.K. identified one of his sources of supply for Super Slim as "Tom," an individual further identified by agents as Shengyang ZHOU¹

¹ During an undercover meeting that took place in Bangkok, Thailand on or about February 23, 2010, discussed further below, two undercover agents in this case met with the individual who identified himself as "Tom" to J.K. and who had subsequent communications with one of the undercover agents. This individual showed a Chinese passport which contained a Thailand Visa that both were in the name of Shengyang ZHOU. The photograph

(hereafter referred to as "ZHOU"). J.K. told me and the other agents involved in this investigation that he did business with ZHOU (who he knew only as "Tom"), a Chinese based distributor, over the internet and through email communications.

29. On or about July 31, 2009, J.K. provided agents with consent to allow me and the other law enforcement agents involved in this investigation to access and take control over the email accounts that J.K. used to conduct his business, including the email account he used in communicating with ZHOU and specifically provided me and the other agents with permission to portray ourselves as him when using these email accounts. After assuming J.K.'s online presence, agents corroborated the information that was provided by J.K. regarding his suppliers. In particular, agents working with me in this investigation confirmed that J.K. had communicated with a person identifying himself as "Tom," who used the email address of sunshire2008@yahoo.com.cn (one of the email accounts that is the subject of this application), regarding the purchase of commercial quantities of purported diet pill products.

30. In August 2009, FDA/OCI SA Hermann, acting in an undercover capacity and posing as J.K., began to communicate with ZHOU who used the email address sunshire2008@yahoo.com.cn. On or about August 24, 2009, FDA/OCI SA Hermann, acting in an undercover capacity and posing as J.K., sent an email to sunshire2008@yahoo.com.cn inquiring as to whether or not the Super-Slim product was still available. In this email communication, SA Hermann asked for a price quote relating to the prospective purchase of 500 boxes of the Super-Slim product and asked

on the Chinese passport bearing the name Shengyang ZHOU matched that of the individual identifying himself as "Tom" during the undercover meeting.

if it could be successfully shipped into the United States. In a reply email that day, the user of the email account sunshire2008@yahoo.com.cn, who identified himself as "Tom," indicated that 500 boxes of the Super-Slim product could be purchased for \$3000. In the body of the email, the user identified as ZHOU advised that he could ship without any problems across the United States borders and would resend the order if there were problems with customs. ZHOU then stated that payment could be made by depositing money into one of the three US bank accounts that he listed. ZHOU indicated that the accounts were his; that they were in the name of Shengyang ZHOU; and that they were maintained by the financial institutions identified as "Bank of America, Chase Bank, and Citi Bank".

31. On or about August 26, 2009, FDA/OCI SA Hermann, using J.K.'s email account and posing as J.K., sent an email to ZHOU at email account sunshire2008@yahoo.com.cn indicating that during the last three months, two shipments containing the same types of products that J.K. had arranged to receive from other suppliers had been seized by Customs instead and that Customs had sent two letters to J.K. explaining that the products had been seized because they contained "banned substances and sibutramine". On or about the same day, ZHOU replied to this email message, stating that he would reship the products if any problems with shipment occurred.

32. On or about August 30, 2009, FDA/OCI SA Hermann, posing as J.K., sent an email to ZHOU at email account sunshire2008@yahoo.com.cn. This email forwarded an email which SA Hermann, posing as J.K.'s business partner, drafted and sent from an undercover email account to J.K.'s email account. The forwarded email

indicated that one of the partner's drug shipment had been seized by Customs and that an FDA alert was preventing their products from being imported into the United States. The forwarded email from J.K.'s 'partner' to J.K. pasted the following URL for this alert: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149547>. The referenced FDA alert listed, among other products, Super Slim as an "illegal" product that has not been approved by the FDA. The email to ZHOU indicated that, although J.K.'s partner had some concerns based on the alert and recent purported customs drug seizure, J.K. and his partner wanted to proceed with an order that had been discussed in prior email communications with ZHOU for 500 boxes of Super-Slim and that his partner wished to pay using Western Union.

33. On or about August 31, 2009, FDA/OCI SA Hermann received an email from email account sunshire2008@yahoo.com.cn, in which ZHOU stated that he could ship the Super-Slim products "without any problem from US customs..." In addition, ZHOU stated that a Western Union payment for the ordered products could be made by directing the money to Shengyang ZHOU, 192 West Renmin Road, Kunming, China, 650031, Mobile : 0086 13769177809. No money was sent at this time, and FDA/OCI SA Hermann, acting in an undercover capacity as J.K., emailed ZHOU that his partner had finally received his shipment of the Super-Slim from his other supplier but that they may be interested in placing an order with ZHOU in the future.

34. On or about November 13, 2009, FDA/OCI SA Hermann, acting as J.K., sent an email to ZHOU at email account sunshire2008@yahoo.com.cn, forwarding an email that SA Hermann drafted and sent to the J.K. email account which indicated that J.K.'s partner wanted to place an order for 500 boxes of Superslim. The forwarded

email indicated that the products should be mailed to an address in Littleton, Colorado, an undercover mailbox maintained by FDA-OCI.

35. On or about November 14, 2009, an email sent from ZHOU, using the email account sunshire@yahoo.com.cn, to the J.K. email account, indicated that ZHOU could sell J.K. and his partner 500 boxes of Superslim for \$2,500, with free shipping to the United States. ZHOU indicated in the email that half of the total amount should be sent using Western Union, with the remaining balance due upon receipt of the shipment. ZHOU also stated in the email that he would "resend or fully refund if the packages[SIC] had any problems". ZHOU directed that the money to be sent by Western Union should be directed to: Jing Xu, 192 West Renmin Road, Kunming, China, 65003, Mobile: 0086 13769177809.

36. On or about November 16, 2009, FDA/OCI SA Hermann sent an email to ZHOU at sunshire2008@yahoo.com.cn, in which he introduced himself as Rus Henderson, the business partner of J.K. SA Hermann, acting as Rus Henderson, advised ZHOU in this email communication that he (Henderson) intended on distributing the products that he was ordering from ZHOU through health food store chains in the United States and so perhaps would need very large quantities of Superslim in the future. SA Hermann, acting as Henderson, also asked in the email if ZHOU was the manufacturer of the Superslim products he was sending.

37. On or about November 16, 2009, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the email account that SA Hermann was using for "Rus Henderson." ZHOU stated in this email that he is "one of the biggest manufacturer in slimming industry," that he can "produce 100000 boxes per month",

and that he operates a website identified as www.2daydietsshopping.com. In the same email, ZHOU instructed Rus Henderson to send \$1,225 to Xu Jing via Western Union as the upfront one-half payment for the Superslim order.

38. I subsequently reviewed the website identified as www.2daydietsshopping.com and saw from its web pages that the site was offering for sale commercial quantities of a variety of diet pill products, including Superslim, 2 Day Diet, Meizitang, and Alli, all products that were the subject of the FDA alerts previously discussed in this affidavit and characterized by the alerts as illegal products that should not be sold or used in the United States. The www.2daydietsshopping.com website listed the following four email addresses that customers could use to contact the company in regards to placing orders for these and other products that were listed in these FDA broadcasts: sunshire2008@yahoo.com.cn, amusunshire@yahoo.com.cn, hjslim2008@yahoo.cn, and shengyangzhou88@yahoo.com. The website also stated that the company operated a branch in the United States associated with the address 2224 Sky Harbor Drive Plano, Texas 75025. Additionally, the website advised that payment could be made through Western Union to Shengyang ZHOU, 192 West Renmin Road, Kunming, China, 650031, Mobile : 0086 13769177809.

39. On or about November 17, 2009, FDA/OCI SA Hermann received information from FDA's Intelligence Branch indicating that the domain name www.2daydietsshopping.com is registered to an individual identified as Shengyang ZHOU, from Kunming, Yunnan, China.

40. That same date, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, and in

response to Henderson's question sent to ZHOU in an earlier email regarding how to describe the purpose for the Western Union payment if asked, advised Henderson to declare the money transfer as payment for "clothes or something else if Western Union ask". I subsequently reviewed this email and saw from the "From" field in its header information that the sender of the email was identified as "Shengyang ZHOU," leading me to believe and conclude that the ZHOU who was corresponding with SA Hermann was, in fact, Shengyang ZHOU.

41. On or about November 19, 2009, SA Hermann, acting in an undercover capacity, wired \$1,250, via Western Union, to Jing XU in Kunming China, as instructed by ZHOU, as partial payment for the 500 boxes of Superslim that had been ordered. SA Hermann, acting in an undercover capacity as Rus Henderson, then sent an email to ZHOU, at email account sunshire2008@yahoo.com.cn, advising that he had sent the requested \$1,250, via Western Union, to Jing XU as instructed by ZHOU.

42. On or about November 20, 2009, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, advising that he had sent out five (5) parcels to the Littleton, Colorado address provided by Henderson containing the 500 boxes of Super Slim that Henderson ordered. In the email, ZHOU provided the following tracking numbers as proof of shipment:

- 1) EE268617746CN
- 2) EE268617732CN
- 3) EE268617785CN
- 4) EE273375906CN
- 5) EE273375265CN

The tracking the numbers reflected that the parcels all originated from some place in China.

43. On December 4, 2009, FDA/OCI SA Hermann retrieved four large parcels (Tracking numbers: EE268617732CN, EE273375906CN, EE273375265CN, and EE268617785CN) from the undercover address located in Littleton, Colorado. The four parcels were sent from "Beijing jin tai yong hui, ltd, tya hua tai piaza, hai dian distrie, beijing, CHINA 100081," as partial shipment of the 500 boxes of Superslim that SA Hermann, posing as Rus Henderson, had ordered. The mailing labels on the four boxes, further described as an Express Mail Service ("EMS") shipping label, declared that their contents were gifts.² SA Hermann inspected the four boxes and saw that they collectively contained approximately 2,004 foil packets having markings labeling the product as "Super-Slim." Almost all of the foil packets each contained 6 capsules. There were approximately 12,022 capsules of Super-Slim capsules in all. SA Hermann thereafter used the tracking number for the fifth parcel and learned from a USPS database that that parcel had not been delivered because it had been misaddressed.

44. On or about December 4, 2009, acting in an undercover capacity as Rus Henderson, SA Hermann sent an email to ZHOU at email address sunshire2008@yahoo.com.cn advising him of the incorrectly addressed parcel and advising ZHOU that the parcel was not received with the others. On or about the same date, ZHOU, using email address sunshire2008@yahoo.com.cn, sent a response, via email, from email account sunshire2008@yahoo.com.cn indicating that he would remedy the situation involving the incorrectly addressed parcel by sending a replacement parcel. He also requested that the remaining balance be sent to Jing XU.

² I know from my training and experience as an DHS-ICE special agent that EMS shipping labels function as customs declarations that are reviewed by Customs and Border Protection Officers in connection with inspecting packages for importation into the United States.

In a subsequent email, ZHOU provided tracking number EE053367896CN, as proof of reshipment of the replacement parcel.

45. On or about December 8, 2009, SA Hermann wired the remaining \$1,250 for the 500 box Superslim order, via Western Union, to Jing XU in Kunming China, as instructed by ZHOU.

46. On or about December 14, 2009, FDA/OCI SA Hermann retrieved two parcels from an FDA undercover address located in Littleton, Colorado. One of the two parcels, which bore tracking number EE053367896CN, was sent by or at the direction of ZHOU as a replacement for the misaddressed parcel bearing tracking number EE268617746CN that was part of the initial order of 500 boxes of Super Slim placed on or about November 14, 2009. The second parcel that SA Hermann retrieved on this date from the FDA undercover address was the misaddressed parcel containing tracking number EE268617746CN.

47. SA Hermann subsequently sent samples from each of the parcels that had been shipped by ZHOU to FDA's Forensic Chemistry Center for analysis, and on or about January 13, 2010, FDA/OCI SA Hermann was advised by Doctor Samuel Gratz from FDA'S Forensic Chemistry Center that the representative samples of Superslim from all six parcels sent by ZHOU tested positive for both Sibutramine and Phenolphthalein. I was advised by SA Hermann that, based on these laboratory findings, the drug items sent in these parcels, in fact, constituted new drugs that had not been approved by the FDA for introduction and use in the United States, as the only FDA-approved drug permitted to contain the active pharmaceutical ingredient ("API") Sibutramine was the prescription drug known as Meridia and, as stated above, no drug

containing Phenolphthalein as its API is currently by the FDA approved for introduction and use in the United States.

48. On or about December 14, 2009, FDA/OCI SA Hermann, posing as Rus Henderson, sent an email to ZHOU at email address sunshire2008@yahoo.com.cn, advising that he received the parcel that was sent as the replacement parcel containing tracking number EE053367896CN. In the same email SA Hermann advised ZHOU that he had also received the misaddressed parcel, one of the five original parcels in connection with the 500 box order, but that this parcel did not contain any Superslim products and instead contained a letter from Customs indicating that the Superslim products were seized because they contained Sibutramine and considered to be FDA unapproved drugs.

49. On or about December 14, 2009, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, advising that he should not worry about the letter, that his other customers often have the same problem, and that he would reship a replacement parcel if any parcels were intercepted by Customs.

50. On or about January 5, 2010, FDA/OCI SA Hermann, posing as Rus Henderson, sent an email to ZHOU at email address sunshire2008@yahoo.com.cn, asking about the availability and pricing of commercial quantities of various products listed on ZHOU's www.2daydietsshopping.com website; SA Hermann specifically asked about purchasing 50 boxes of Alli, 200 boxes of Superslim, 100 boxes of Meizitang, and 100 boxes of 2 Day Diet. (I have been advised by SA Hermann that Alli is an FDA approved, over the counter drug manufactured by GlaxoSmithKline

used as an aid in weight loss. As discussed above, Alli contains the active pharmaceutical ingredient Orlistat. As further discussed above, Alli, together with Superslim, Meizitang and 2 Day Diet, were among the products that were the subjects of the FDA alerts described above; these alerts indicated that counterfeit versions of Alli being distributed over the internet, were considered by the FDA to be illegal and unapproved drugs.)

51. On or about January 5, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the email account associated with Rus Henderson, in which he indicated that the requested quantities of the products identified as Alli, 2 Day Diet, Meizitang, and Superslim were available at a total price of \$4,000.

52. On or about January 11, 2010, FDA/OCI SA Hermann, posing as Rus Henderson, sent an email to ZHOU at email address sunshire2008@yahoo.com.cn, advising ZHOU that he wished to place the order for 50 boxes of Alli, 200 boxes of Superslim, 100 boxes of Meizitang, and 100 boxes of 2 Day Diet for \$4,000 and indicated that he would wire the money to the Jing XU, the same person who received the money transfers in relation to the first order that was placed for 500 boxes of Superslim. Also on this date, SA Hermann, acting as Rus Henderson, sent \$2,000, via Western Union, to Jing XU, located in Kunming, China as the first of two payments in connection with this order.

53. On or about January 12, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, in which he stated that two parcels had been shipped out on the order. ZHOU indicated that the first parcel contained 100 boxes of 2 Day Diet and bore tracking number

EE017140982CN and that the second parcel contained 100 boxes of Superslim and bore tracking number EE275647805CN.

54. On or about January 13, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent another email to the Rus Henderson email account, indicating that a parcel containing 100 boxes of the product identified as Meizitang bearing tracking number EE275647624CN, had been shipped.

55. On or about January 14, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, in which he stated that a parcel containing 50 boxes of Alli which bore tracking number EE017110230CN, had been shipped.

56. On or about January 21, 2010, FDA/OCI SA Hermann and I retrieved three boxes from the FDA undercover address located in Littleton, Colorado, in relation to this second order placed with ZHOU. Through postal records, I learned that these parcels were delivered to the Littleton, Colorado address on January 20 and January 21, 2010. The first parcel bearing tracking number EE275647624CN contained approximately 3,600 units of the product identified as Meizitang; the second parcel bearing tracking number EE275647805CN contained approximately 3,186 capsules of the product identified as Super Slim; and the third parcel bearing tracking number EE017110230CN contained approximately 6,000 capsules of the product purporting to be Alli. Each of the parcels also contained product packaging for the respective products. The EMS shipping labels for these parcels either failed to describe the contents of the parcels or mis-declared the contents as "gifts."

57. SA Hermann sent a sample of the Alli product and packaging received in

connection with the undercover purchase to the GlaxoSmithKline (GSK) Pharmaceutical Company and requested that GSK compare the items with authentic Alli capsules and packaging. GSK indicated that its comparative analysis of these items confirmed that the purported Alli packaging bore markings that were substantially indistinguishable from the registered trademarks that GSK had on file with the U.S. Patent and Trademark Office for Alli and that GSK actively used in its marketing and sale of Alli. GSK accordingly concluded that the purported Alli products shipped by or at the direction of ZHOU were not authentic products manufactured by or at their direction. FDA's Forensic Chemistry Center (FCC) performed an analysis on a sample of the purported Alli product received in connection with the same undercover order and determined that the analyzed product contained approximately 9.29mg of Sibutramine.³

58. On or about January 25, 2010, FDA/OCI SA Hermann and I retrieved one parcel containing tracking number EE017140982CN from the FDA undercover address located in Littleton, Colorado in relation to the second order that was placed with ZHOU. According to ZHOU, this parcel, which originated from China, contained 100 bottles of the 2 Day Diet product. Samples from the parcel are being analyzed by FDA'S Forensic Chemistry Center.

59. On or about January 25, 2010, ZHOU, using email account

³ The directions contained on the purported Alli's product packaging reads in part as follows "...for overweight adults 18 years and older: take 1 capsule with each meal containing fat. Do not take more than 3 capsules daily..." If an individual followed the directions for this product they would ingest 3 capsules in one day and would in actuality by ingesting approximately 27.87mg of Sibutramine. As previously stated the highest FDA approved dose of Sibutramine is 15mg. FCC also performed an analysis on samples of the products identified on the packaging and labeling as Super Slim and Meizitang which were also received in connection with the undercover purchase and determined that these products also contained therapeutic amounts of Sibutramine. Further testing of these samples to determine the exact levels are currently being conducted.

sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, in which he stated that he had sent or caused to be sent the final parcel on the order, 100 boxes of Super Slim, and that the tracking number for this final parcel was EE053424752CN.

60. On or about January 25, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, requesting that final payment for this second order in the amount of \$2,000 be sent via Western Union since he (ZHOU) indicated that the parcel containing 100 boxes of Super Slim and bearing tracking number EE053424752CN had cleared customs.

61. On or about January 28, 2010, SA Hermann, acting as Rus Henderson, sent \$2,000, via Western Union, to Jing XU, located in Kunming, China as the second of two payments in connection with this order.

62. On February 1, 2010, SA Hermann and I retrieved the final parcel on the second order from ZHOU from the FDA undercover address located in Littleton, Colorado. According to ZHOU, this parcel, which originated from China, contained 100 boxes of the Super Slim product. Samples from the parcel are being analyzed by FDA's Forensic Chemistry Center.

63. Subsequent to FDA issuing the broadcasts relating to the counterfeit Alli products, the FDA/OCI Headquarters received numerous phone calls and webpage submissions from consumers who believed that they had purchased the counterfeit Alli. I was advised that on or about January 20, 2010, FDA/OCI SA Jason Simonian spoke with a person identified as Sandra Choudary over the telephone who stated that she is the aunt of Khalil Sarwar who sold the suspected counterfeit Alli product on eBay using

the eBay seller identification identified in part as "valueshere". Choudary advised SA Simonian that Sarwar purchased approximately one-hundred (100) bottles of Alli from the website www.2daydietsshopping.com, the same website that ZHOU identified as his in SA Hermann's undercover communications with him. Choudary further advised SA Simonian that Sarwar paid for the product by PayPal and by depositing cash into a Bank of America account in the name of Shengyang ZHOU.

64. I was advised by FDA/OCI SA Hermann that on or about February 3, 2010, he received a chart that was created by representatives working for the GSK Pharmaceutical Company that listed approximately five people who advised GSK that they believed that they had purchased the counterfeit Alli product from an eBay seller who used the Ebay seller identification containing the phrase "Valueshere". To date, samples of the purported Alli product were recovered from three of the five individuals by representatives working for GSK. These samples were subsequently provided to FDA'S Forensic Chemistry Center who tested these products which determined that they contained Sibutramine at levels ranging from 8.3mg per capsule to 9.3mg capsule.

65. I was advised by FDA/OCI SA Hermann that on or about January 25, 2010, FDA/OCI SA Marc Ruiz interviewed, at SA Hermann's request, Masis Mirzakhani, one of the individuals identified by SA Hermann as a person who had purchased the counterfeit Alli product from an eBay seller who used the Ebay seller identification containing the phrase "Valueshere". Mirzakhani had contacted FDA/OCI after learning of the FDA broadcast regarding the counterfeit Alli product. Mirzakhani advised SA Ruiz that he had been consuming the Alli product for approximately one year relative to his weight control and weight loss concerns without exhibiting any side-

effects and/or adverse reactions, typically purchasing the product from his local CVS drug store. According to SA Ruiz, on or about December 18, 2009, during an E-Bay search, Mirzakhani identified a source for the Alli product at a \$10.00 per bottle price reduction on eBay that was being sold by eBay seller identified in part by Mirzakhani as "valueshere". Mirzakhani advised SA Ruiz that he paid \$36.99 per bottle of Alli 60 mg/120 capsules, with a purchase of two bottles totaling \$73.98, using his PayPal account. Mirzakhani also advised that on or about December 27, 2009, he received the USPS, First Class parcel bearing tracking number 9101128882300940148717 without any declaration, shipper information and/or packaging invoice, containing two bottles of the Alli product.

66. Mirzakhani advised SA Ruiz that he proceeded to consume the suspect product approximately three (3) times per day during meals, consuming approximately sixty (60) capsules from approximately December 27, 2009 to January 20, 2010. Upon opening the bottle and handling the capsules prior to his consumption of the Alli product, Mirzakhani observed that the suspect capsules appeared to be larger or bulkier in comparison to previous capsules he had consumed, but could not compare them with his previous Alli product capsules because they had already been consumed. By December 30, 2009, Mirzakhani advised SA Ruiz that he started to feel ill and by January 1, 2010, Mirzakhani advised SA Ruiz that he started to exhibit a significant adverse reaction, including symptoms associated with heart palpitations, numbness within his left arm, severe anxiety, enormous eye pressure/headache, profuse sweating and chills. Mirzakhani added he felt like he was having a "heart attack-like" episode and thought at the time his life was in jeopardy. Mirzakhani voluntarily provided SA

Ruiz one sealed bottle of the purported Alli product and a partially filled bottle of the purported Alli product containing sixty-two (62) blue capsules. FDA'S Forensic Chemistry Center subsequently conducted an analysis on samples of the purported Alli product that was obtained from Mirzakhani and determined that the samples contained 8.9 mg and 9.1 mg of Sibutramine.

67. In an effort to identify the parties involved with this investigation, a commercial database record check was used to research the address of 2224 Sky Harbor Drive Plano, Texas 75025, which was listed on the www.2daydietsshopping.com web site. The database showed that an individual identified as Qing Ming Hu is residing at the residence. I also entered the same address into the Treasury Enforcement Communications System (TECS) database and found two records associated with the address. The first record indicated that on August 25, 2009, a mail parcel addressed to "Huong" at 2224 Sky Harbor Drive Plano, Texas was examined and seized by CBP officials in San Francisco, CA. The parcel was found to contain 2,200 capsules of a product called "2 Day Diet" which is a product that is listed as an illegal and unapproved product by the FDA on at least two of the FDA alerts broadcast on FDA'S website. The label on the package indicated that it was sent from Electronic Commerce Co. LTD in Beijing, China. The second record stated that on September 20, 2009, a mail parcel addressed to "Qing Ming Hu" at 2224 Sky Harbor Drive Plano, Texas was examined and seized by CBP officials in San Francisco, CA. The parcel was found to contain 5,910 capsules of "Super Slim" which, as previously stated, is also a product that is listed as an illegal and unapproved product by the FDA on at least two of the FDA alerts broadcast on FDA'S website. The label on the package indicated that it was

sent from Fuyong Logistics Center Xiashiweiv in Fuyong Town, Shenzhen City, Hong Kong.

68. On or about December 30, 2009, I accessed the TECS database and found two records for Shengyang ZHOU which is the name listed on the "From" field contained on the headers of the emails sent by ZHOU. Shengyang ZHOU was also the name provided in an email and on the website - www.2daydietsshopping.com - as a recipient for payments that were to be sent via Western Union in relation to orders for various types of purported diet products. The first record indicated that ZHOU entered the United States from China with a tourist visa otherwise known by the classification "B2" on July 6, 2009. The second record indicated that ZHOU flew back to China from the United States on July 20, 2009. On or about December 31, 2009, I accessed the United States Department of State Non-Immigrant Visa System and located a visa record for Shengyang ZHOU with a date of birth listed as June 17, 1979 and place of birth listed as Kunming, China. The record indicated that the subject was issued a B1/B2 Visa on June 17, 2009 with an expiration of June 15, 2010. This visa allows the subject to enter the United States as a tourist and to conduct business transactions. The record also listed ZHOU's employer as Yunnan Thompson Biologic Technology Corporation. ZHOU listed Qing Ming Hu as a point of contact within his application data.

69. On or about September 2, 2009, a preservation request letter for the email account of sunshire2008@yahoo.com.cn was issued to Yahoo, Inc. requesting that Yahoo, Inc. preserve records associated with the email account sunshire2008@yahoo.com.cn.

70. On or about November 30, 2009, I, having had reason to believe that the sunshire2008@yahoo.com.cn e-mail account was continuing to be used to facilitate the illegal importation of the products containing Sibutramine, filed a subsequent preservation letter with Yahoo, Inc. to preserve records contained within and associated to the sunshire2008@yahoo.com.cn email account.

71. On or about December 1, 2009, I, having had reason to believe that the amunshire@yahoo.com.cn and shengyangshou88@yahoo.com e-mail accounts were being used to facilitate the illegal importation of the products containing Sibutramine, filed a preservation letter with Yahoo, Inc. to preserve records contained within and associated to these email accounts.

72. On or about December 8, 2009, I, having had reason to believe that the hjslim2008@yahoo.cn e-mail account was being used to facilitate the illegal importation of the products containing Sibutramine, filed a preservation letter with Yahoo, Inc. to preserve records contained within and associated to this email account.

73. On or about December 8, 2009, a United States Customs Service Summons was issued to Yahoo, Inc. for general account information on Sunshire2008@yahoo.com.cn. On or about December 19, 2009, Yahoo, Inc. responded to the summons and provided information indicating that the account was active and had been created on September 6, 2007. The Internet Protocol (IP) address that was being used when the account was created is registered to a Chinese internet service provider. A review of the IP log provided by Yahoo, Inc. indicated that a majority of the time, the account was being accessed from China. From approximately July 7, 2009 to July 18, 2009, the timeframe in which Shengyang ZHOU was present in the United

States as a non-immigrant visitor, the IP address that was used to access the account came from within the United States to include Plano, Texas and California.

74. On or about December 8, 2009, a United States Customs Service Summons was issued to Yahoo, Inc. for general account information on amusunshire@yahoo.com.cn. On or about December 19, 2009, Yahoo, Inc. responded to the summons and provided information indicating that the account was active and had been created on December 8, 2006. The Internet Protocol (IP) address that was being used when the account was created is registered to a Chinese internet service provider. A review of the IP log provided by Yahoo, Inc. indicated that a majority of the time, the account was being accessed from China. From approximately July 7, 2009 to July 18, 2009, the timeframe in which Shengyang ZHOU was present in the United States as a non-immigrant visitor, the IP address that was used to access the account came from within the United States to include Plano, Texas.

75. On or about December 8, 2009, a United States Customs Service Summons was issued to Yahoo, Inc. for general account information on hjslim2008@yahoo.cn. On or about January 13, 2010, Yahoo, Inc. responded to the summons and provided information indicating that the account was active and had been created on January 29, 2008. The Internet Protocol (IP) address that was being used when the account was created is registered to a Chinese internet service provider. A review of the IP log provided by Yahoo, Inc. indicated that a majority of the time, the account was being accessed from China. From approximately July 7, 2009 to July 16, 2009, the timeframe in which Shengyang ZHOU was present in the United States as a non-immigrant visitor, the IP address that was used to access the account came from

within the United States to include Plano, Texas.

76. On or about December 8, 2009, a United States Customs Service Summons was issued to Yahoo, Inc. for general account information on shengyangzhou88@yahoo.com. On or about December 19, 2009, Yahoo, Inc. responded to the summons and provided information indicating that the account was active and had been created on July 10, 2009, which is when Shengyang ZHOU was present in the United States as a non-immigrant visitor. The Internet Protocol (IP) address that was being used when the account was created is registered to an internet service provider in Plano, Texas. A review of the IP log provided by Yahoo, Inc. indicated that a majority of the time, the account was being accessed from China.

77. I was advised by FDA/OCI SA Hermann that he had received information sent by Staff Coordinator Brian R. Rucker who is employed with the DEA'S Special Operations Division, Pharmaceutical and Chemical Internet Unit on February 3, 2010 that indicated neither Shengyang ZHOU or Jing XU are DEA registrants. I have since learned that none of the forms required for the lawful importation of Schedule IV non-narcotic substances were submitted in connection with the parcels found to contain Sibutramine that were mailed to the FDA undercover address in Littleton, Colorado.

Undercover Meeting

78. In connection with this investigation, the undercover agents arranged to meet with ZHOU in Thailand to further discuss details concerning future orders of Super Slim, 2 Day Diet and Alli. During the week of February 21, 2010, SA Hermann, posing as Rus Henderson, met with ZHOU two times in Bangkok, Thailand. USPIS PI

Michael Nix, posing as a prospective client, was present during the second meeting that occurred.

79. During the undercover meetings, ZHOU indicated that he is thirty years of age and not married. He further stated that he has been in this type of business for approximately five years. He stated that he has a Masters in business administration (MBA) but has never taken any science classes. He indicated that he is already a millionaire and boasted about owning an Audi Q7 which he claimed is worth about \$250,000.

80. ZHOU stated that he has a girlfriend who he identified as Jing XU. He confirmed that XU is the person who FDA/OCI SA Hermann had sent money to, via Western Union, in connection with the undercover purchases that he had made from ZHOU. ZHOU stated that in addition to using Jing XU, he uses names of his other workers as the intended recipients for money sent via Western Union. ZHOU acknowledged that 2daydietshopping.com and china-product-order.com were his websites. During the meetings, ZHOU acknowledged that he manufactures, amongst other products, Super Slim, 2 Day Diet, and Alli.

81. During the course of both meetings, ZHOU readily and repeatedly acknowledged that he was the manufacturer of counterfeit versions of Alli that were being shipped to the United States, including the counterfeit packages of Alli that were delivered to the Littleton, Colorado undercover address in January. He discussed specific aspects of his counterfeiting activities regarding this product. Among other things, ZHOU indicated that he did not put the lot number on the external packaging of the fake Alli product that he had previously manufactured. ZHOU acknowledged that

ALLI is an FDA approved product and that it is risky to produce. ZHOU indicated that he planned on producing an additional 5,000 boxes of the ALLI product in his next batch which will appear exactly the same as the authentic product. ZHOU indicated that the capsule that he used when manufacturing the previous batches of ALLI was slightly larger than the authentic ALLI capsule. ZHOU also indicated that the powder that he placed inside the counterfeit ALLI product did not look exactly like the contents of what is contained inside an authentic ALLI capsule. ZHOU stated that both of these issues can be easily remedied.

82. During the course of discussing potential future shipments to the undercover agents, ZHOU and the undercover agents discussed the current risks that counterfeit Alli that ZHOU was making could be detected and intercepted by authorities. ZHOU indicated, in this context, that he had recently suspended manufacturing counterfeit ALLI product because it had become "dangerous" under current circumstances. ZHOU acknowledged that there was a risk associated with manufacturing and distributing the ALLI product and that he could not saturate the market since ALLI is such a popular product. The undercover agents, during the course of the second meeting, showed ZHOU both one of the boxes of counterfeit Alli that ZHOU had mailed to the Littleton, Colorado address in January and an authentic Alli box that the agents had brought with them. The agents reviewed with ZHOU the various mistakes on the box of the counterfeit ALLI that ZHOU had sent to them. ZHOU acknowledged the mistakes and indicated that he would have to produce future counterfeit versions of the ALLI product so that it looked exactly the same as the authentic product so that no one will be able to distinguish between the two. ZHOU

stated that it would take him approximately three weeks to produce another batch of the fake ALLI product. ZHOU stated that he planned on correcting the mistakes that he made in connection with the previous fake ALLI products that he produced.

83. ZHOU stated that he recently purchased the equipment which will allow him to place the lot number on the external packaging of the fake ALLI product that he plans on manufacturing. ZHOU stated that he used an authentic ALLI product that he purchased while in Texas last year as his example. He specifically indicated that he purchased this authentic box of ALLI from a Wal-Mart store located in Texas for \$62.00. He admitted that he did not closely check the final copy of the ALLI product for mistakes. ZHOU claimed that he only noticed the mistakes within the last month and stated that it would take him approximately two weeks to remedy the mistakes associated with manufacturing additional fake ALLI products. He acknowledged that the legitimate manufacturer for ALLI is a large company. ZHOU stated that he is using Sibutramine as the main ingredient in the fake ALLI product that he manufactures which is the same ingredient that he uses when manufacturing SUPER SLIM and 2 DAY DIET. ZHOU stated that customers will not be able to distinguish between the authentic ALLI product and the product that he will manufacture; however, he also stated that although he would fix all of his mistakes regarding the fake ALLI product, the company may still be able to determine that the product is not genuine.

84. ZHOU stated that once he corrects the problems associated with the fake ALLI product he will be able to produce 3,000 boxes of the fake ALLI products per day. ZHOU also indicated that he planned on using the same or similar type of glue on his fake ALLI product that is used on the authentic ALLI product. ZHOU indicated

that he intends on producing a new batch of the fake ALLI product and will offer the undercover agent/postal inspector the opportunity to sell it; however, if for some reason they do not move forward with purchasing the fake ALLI from ZHOU, he will sell it to someone else.

85. ZHOU also stated that he had the idea of selling ALLI before he ever met with the undercover agents. ZHOU stated that nobody else in China can make this ALLI product but him since he possesses the unique technology and special equipment. Towards the end of the second meeting, ZHOU stated that he planned on manufacturing 10,000 more fake ALLI products which he intended on selling 5,000 to the undercover agent/inspector and 5,000 to a distributor based in the United Kingdom. ZHOU stated that he profits less than \$1.00 per average diet pill product; however, by selling the ALLI for \$10.00 he is able to profit \$5.00 per box. He stated that he does not want to lower the price from \$10.00 since manufacturing this product involves a dangerous risk.

86. During the both undercover encounters in Thailand, ZHOU also outlined his distribution network for all of his products that contained Sibutramine, including the counterfeit Alli that he was manufacturing. ZHOU stated that he also shipped some of the fake ALLI products to a distributor in the United Kingdom. He stated that he sold 1,000 boxes of the ALLI product to a seventy-three year old Pennsylvania based distributor who uses EBay to sell these products. FDA/OCI SA Hermann had identified a possible match to this person and is currently gathering additional evidence in connection with this Ebay seller. ZHOU stated that he has done business with this EBay distributor for approximately three years which mostly involved the product identified as Japan Weight Loss.

87. During the undercover meeting, ZHOU acknowledged that he recently sold the undercover agent fifty boxes of the fake ALLI product at a cost of \$15.00 per box. ZHOU stated that he has never had a parcel containing fake ALLI products intercepted by United States Customs and typically only has one out of every fifteen packages containing his other products intercepted by Customs. ZHOU indicated that all of his products contain Sibutramine and are nearly all the same.

88. ZHOU stated that he typically ships to Beijing, China from Kunming, China then often to the United States. ZHOU maintains a Citibank account, a Bank of America account and a Chase account in relation to this business.

89. ZHOU stated that he manufactures thirty or more diet products and stated, at one point, that he was aware that many of these products were listed on an FDA concerning products made in China that contained Sibutramine, and may be dangerous. ZHOU stated that he has two factories in China. He further stated that one is a factory and the other is a trading company. He described his factory as a three story building located in Kunming, China. He stated that he has twenty employees which he pays a salary of \$300 per month. He claimed that he makes all of the product listed on his website at this factory.

90. During the second of two undercover meetings that took place in Thailand, a call was placed to FDA/OCI SA Burke posing as a corrupt customs broker. The call was placed on speaker phone and SA Burke proceeded to agree to arrange for commercial quantities of fake ALLI to be shipped through air cargo to Colorado by

falsely declaring the fake ALLI as some type of food product. ZHOU indicated that he would be able to ship the products to a Beijing; China based freight forwarding company arranged by the corrupt customs broker for subsequent shipment to the United States. ZHOU indicated that this would not be difficult since he (ZHOU) already had some type of store located in Beijing, China.

91. During the meeting, SA Hermann placed an order with ZHOU for 100 boxes of 2 Day Diet (\$500), 100 boxes of Super Slim (\$500) and 1,000 boxes of ALLI (\$10,000) for a total cost of \$11,000. SA Hermann paid ZHOU \$5,500 as a down payment for these products.

Post Undercover Meeting Activity

92. On or about February 25, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, indicating that he had sent or caused to be sent a parcel bearing tracking number EE268710397CN and containing one-hundred boxes of 2 Day Diet to SA Hermann posing as Rus Henderson. A search conducted on March 3, 2010, of the United States Postal Service electronic tracking search function revealed that a parcel bearing this tracking number was received at the FDA/OCI undercover address located in Littleton, Colorado on March 3, 2010. ZHOU subsequently sent an email to the Rus Henderson email account on the same date and indicated that he had caused a parcel bearing UPS tracking number 1ZR85660340414429 and containing 100 boxes of SUPER SLIM to be sent from Texas to SA Hermann posing as Rus Henderson. According to the UPS website this parcel was received at the FDA/OCI undercover address located in Littleton, Colorado on March 1, 2010. Samples of the Super Slim and 2 Day Diet

product will be sent to the FDA'S Laboratory for analysis.

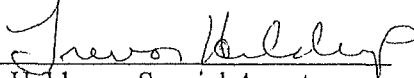
93. On or about March 1, 2010, ZHOU, using email account sunshire2008@yahoo.com.cn, sent an email to the Rus Henderson email account, indicating that he is booking his tickets for the meeting that is scheduled for March 24, 2010, that he has corrected the mistakes pertaining the fake ALLI product, that he will attempt to bring samples of the fake ALLI product with him to the meeting, and that he plans on producing 10,000 boxes of the fake ALLI product in this next batch. He sent a subsequent email to the Rus Henderson email account asking that the client portrayed by the undercover postal inspector purchase the entire 10,000 batch. He also stated in the email "Do not worry about the Alli this time. The Alli will be exactly same as the original".

Conclusion

94. Based on the foregoing, I submit that there is probable cause to believe that:

-- Shengyang ZHOU caused the introduction and delivery for introduction into interstate commerce of unapproved new drugs, in violation of Title 21, United States Code Sections 331(d); the importation of pharmaceutical drugs contrary to law, in violation of Title 18, United States Code, Section 545; the importation and distribution of scheduled IV, non-narcotic controlled substances, in violation of Title 21, United States Code, Section 952; and trafficking in counterfeit goods, in violation of Title 18, United States Code, Section 2320 in connection with the shipments received by ZHOU after the placement of the undercover orders and undercover meetings.

FURTHER AFFIANT SAYETH NAUGHT



Trevor Helderop, Special Agent
Immigration and Customs Enforcement/ICE

Sworn and Subscribed to before
me this day 5th of March 2010,
at Denver, Colorado



UNITED STATES MAGISTRATE JUDGE

g o Staffer, **United States Magistrate Judge**

(Rev. 04/05)

DATE: March 4, 2010

DEFENDANT: SHENGYANG ZHOU (a/k/a "Tom")

YOB: 1979

ADDRESS: Kunming, Yunnan, China

COMPLAINT FILED? YES NO

IF YES, PROVIDE MAGISTRATE CASE NUMBER: _____

IF NO, PROCEED TO "OFFENSE" SECTION

HAS DEFENDANT BEEN ARRESTED ON COMPLAINT? YES NO

IF NO, A NEW WARRANT IS REQUIRED

OFFENSE: Introduction and Delivery for Introduction
Of Unapproved New Drugs Into Interstate Commerce
21 U.S.C. §§331(d), 333(a)(2)

Trafficking In Counterfeit Goods
18 U.S.C. §2320(a)

Importation of Merchandise Contrary to Law
18 U.S.C. §545

Importation of Schedule IV Controlled Substances
21 U.S.C. §§ 952(b), 960(a)(1), 960(b)(4)

LOCATION OF OFFENSE: Jefferson and Douglas Counties, Colorado
And elsewhere

PENALTY: Introduction and Delivery for Introduction
Of Unapproved New Drugs Into Interstate Commerce
21 U.S.C. §§331(d), 333(a)(2)
NMT 3 years imprisonment, a \$250,000 fine, or both; and a \$100
Special Assessment Fee

Trafficking In Counterfeit Goods
18 U.S.C. §2330(a)
NMT 10 years imprisonment, a \$250,000 fine, or both; and a \$100
Special Assessment Fee

Importation of Merchandise Contrary to Law

18 U.S.C. §545

NMT 20 years imprisonment, a \$250,000 fine, or both; and a \$100 Special Assessment Fee

Importation of Schedule IV Controlled Substances

21 U.S.C. §§ 952(b), 960(a)(1), 960(b)(4)

NMT 5 years imprisonment; \$250,000 fine, or both;
\$100 Special Assessment

AGENT:

Trevor Helderop, Special Agent
U.S. Department of Homeland Security,
Immigration and Customs Enforcement
Denver, Colorado

Russell Hermann, Special Agent
U.S. Food and Drug Administration,
Office of Criminal Investigations
Denver, Colorado

Michael T. Nix, Postal Inspector
U.S. Postal Inspection Service
Denver, Colorado

AUTHORIZED BY: Kenneth M. Harmon
Assistant U.S. Attorney

ESTIMATED TIME OF TRIAL:

___ five days or less X over five days ___ other

THE GOVERNMENT

X will seek detention in this case ___ will **not** seek detention in this case

The statutory presumption of detention is **not** applicable to this defendant.

OCDETF CASE: ___ Yes X No