

SEALED

UNITED STATES DISTRICT COURT

for the

Western District of Virginia

JUN - 1 2017

JULIA C. DUDLEY, CLERK
BY: *A. Blaylock*
DEPUTY CLERK

United States of America)

v.)

Alok JAISWAL)

Case No. 1:17mj101

Defendant(s)

CRIMINAL COMPLAINT

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

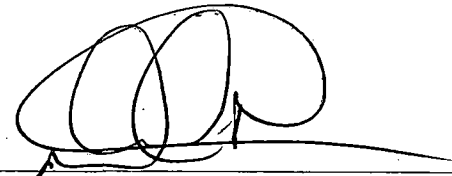
On or about the date(s) of Nov. 4, 2015 and Feb. 10, 2017 in the county of Washington in the Western District of Virginia, the defendant(s) violated:

<i>Code Section</i>	<i>Offense Description</i>
21 U.S.C. §§ 331(a) and 333(a)(2)	Introduction of a Misbranded Drug Into Interstate Commerce
18 USC § 545	Smuggling goods into the United States
21 USC § 841	Distribution of a Controlled Substance
18 USC § 371	Conspiracy to commit offense or to defraud United States

This criminal complaint is based on these facts:

See Attached Affidavit

Continued on the attached sheet.



Complainant's signature

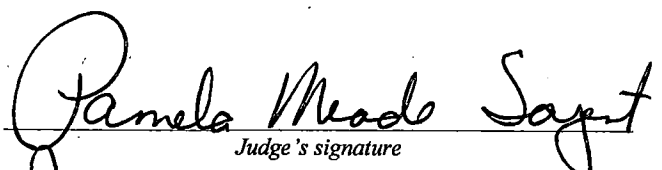
Darren Petri, Special Agent

Printed name and title

Sworn to before me and signed in my presence.

Date: 6/1/17

City and state: Abingdon, VA



Judge's signature

Pamela Meade Sargent USMTJ

Printed name and title

AFFIDAVIT

I, Darren Petri, Special Agent for the Food and Drug Administration, Office of Criminal Investigation (“FDA/OCI”), being duly sworn, depose and state as follows:

I am a Special Agent with the FDA/OCI, assigned to the Washington Metro Field Office. Prior to my current assignment, I was employed by the Department of Veterans Affairs, Office of Inspector General, Criminal Investigation Division, assigned to the Washington Field Office, Washington, D.C. I worked there from April 2006 to February 2013. Previously, I was employed by the FDA/OCI and worked there from March 2004 to April 2006. Prior to my employment with the FDA/OCI, I worked for the United States Army Criminal Investigation Command (“USACIDC”), Major Procurement Fraud Unit, Ft. Belvoir, Virginia, from September 2002 to March 2004, as a Special Agent investigating white collar fraud. Before working with the USACIDC, I was employed by the Harnett County Sheriff’s Office (“HCSO”), Harnett County, North Carolina, from August 2001 to September 2002, where I was assigned as a detective investigating economic crimes and general criminal offenses. Prior to my employment with the HCSO, I worked for the USACIDC, from August 1995 to August 2001, where I investigated economic crimes, general crimes, and drug crimes. During my 19 years of investigative experience, I have dealt with violations of the Uniform Code of Military Justice, the North Carolina General Statutes, and Titles 18 and 21 of the United States Code. I also have drafted and served a number of search warrants and arrest warrants authorized by local, state, and federal judges. In my current position with the FDA/OCI, I investigate violations of federal laws including the Federal Food, Drug, and Cosmetic Act (“FDCA”), Title 21, U.S. Code,

Sections 301 – 397, and Title 18 of the United States Code. Based on my training and experience, I am familiar with the rules and regulations governing the drug approval process, methods used to commit fraud against the U.S. Government, and documents and other records that frequently are evidence of such fraud.

During my time as a Special Agent, I have completed specialized training courses at the Department of Homeland Security's Federal Law Enforcement Training Center, the North Carolina Justice Academy, and the USACIDC training facilities. I also have participated in numerous investigations that have resulted in the seizure of evidence, including illegal drugs and documents.

The facts and information contained in this affidavit are based upon my training and experience, participation in investigations, personal knowledge, and observations during the course of this investigation, as well as the observations of other agents involved in this investigation. All observations not personally made by me were relayed to me by the individuals who made them or are based on my review of records, documents, and other physical evidence obtained during the course of this investigation.

This affidavit contains information necessary to support probable cause. It is not intended to include each and every fact and matter observed by me or known to the United States.

RELEVANT FEDERAL LAW

21 U.S.C. §§ 331(a) and 333(a)(2) – Introduction of a Misbranded Drug Into Interstate Commerce: The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

18 USC § 545 - Smuggling goods into the United States: Whoever fraudulently or knowingly imports or brings into the United States, any merchandise contrary to law, or receives, conceals, buys, sells, or in any manner facilitates 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.

21 USC § 841 – Distribution of a Controlled Substance: To manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance.

18 USC § 371 - Conspiracy to commit offense or to defraud United States: If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

INTRODUCTION

Based on the information set forth below, your affiant submits that there is probable cause to believe that between November 4, 2015 and February 10, 2017, in the Western District

of Virginia and elsewhere, Rahil MIR and Alok JAISWAL committed the offenses of Introduction of a Misbranded Drug Into Interstate Commerce, Smuggling Goods into the United States, Distribution of a Controlled Substance and Conspiracy, when MIR and JAISWAL knowingly and willingly sent controlled substances and misbranded Indian prescription medications, not approved by the U.S. Food and Drug Administration, to the U.S., and received payments through the use of bank accounts, credit cards, and Western Unions.

The drugs involved in this investigation are not U.S. approved versions of the drugs and, accordingly, have not been subjected to FDA regulatory scrutiny to ensure compliance with U.S. laws and quality control standards. They are also prescription drugs, which are more tightly regulated under federal law and by definition can only be safely used under the supervision of a licensed medical practitioner. 21 U.S.C. § 353(b). One of the federal requirements for all drugs is that they bear labeling that contains adequate directions for their use, 21 U.S.C. § 352(f)(1), which is defined by regulation 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. Since prescription drugs by definition cannot be used safely by a layperson, they must qualify for an exemption to this requirement in order to be introduced in interstate commerce. This exemption, set out in 21 C.F.R. § 201.100, requires all the conditions be met including: (1) they are in the possession of persons lawfully engaged in wholesaling, retailing, or dispensing prescription drugs; (2) they have directions sufficient for a medical practitioner to use the drugs safely (i.e., physician labeling); and (3) they bear a label with the statement "Rx only"; and (4) if they are drugs that would require premarket approval they t bear the FDA-approved labeling. None of the drugs in

this investigation meet the conditions of the exemption and they are therefore misbranded and it is a crime to introduce or receive them in interstate commerce.

By smuggling misbranded drugs into the United States and distributing them in the United States, as set forth below, the conspirators have attempted to defraud the United States by impeding, impairing, obstructing and defeating the lawful functions of the Food and Drug Administration ("FDA") of the Department of Health and Human Services in the regulation of drugs distributed in the United States.

DETAILS

During the course of this investigation, I, acting in an undercover capacity, conducted four different controlled purchases with MIR and JAISWAL on multiple dates (The dates reflected in the controlled purchases below are the dates that the drugs were received during the four controlled purchases). The four different controlled purchases were received on multiple dates during the time period of November 4, 2015 through February 10, 2017, in the Western District of Virginia. Prior to each transaction I communicated with MIR through the use of email and telephone. The evidence collected thus far also shows that MIR is the manager of the illegal pharmaceutical side of the company, known as Global Pharmacy (GP) and JAISWAL is the owner of the company as a whole. Recently, I have communicated with MIR and JAISWAL on several occasions. I have also met with MIR and JAISWAL in Mumbai, India, on March 23, 2017.

The controlled purchases are listed below. The names of the items purchased are the names used by GP.

DEALS:

Purchase 1:

- On November 4, 2015, (15) blister packs of 10 pills in each (250 pills) of Tadalafil tablets 20mgs and (15) blister packs of 10 pills in each (250 pills) of Sildigra tablets 100mgs. I paid \$990 for these products.

Purchase 2:

- On December 15, 2015, (300) Xanax tablets, 2mg, placed in blister packs with 10 tablets a piece and (298) White pills, reported to be Hydrocodone 10/325mg tablets. I paid \$1,100 of these products.

Purchase 3:

- On May 18, 2016, (1000) Xanax tablets, 2mg, placed in blister packs with 10 tablets a piece and (275) Hydrocodone 10/325mg tablets
- On May 20, 2016, (540) Hydrocodone 10/325mg tablets.
- On May 23, 2016, (275) Hydrocodone 10/325mg tablets.
- On May 24, 2016, (825) Hydrocodone 10/325mg tablets.
- On June 6, 2016, (275) Hydrocodone 10/325mg tablets placed in blister packs with 10 tablets a piece; (1000) Xanax tablets, 2mg, pills placed in blister packs with 10 tablets a piece; (60) Sildenafil Citrate and Tadalafil, 10mg, placed in blister packs with 6 tablets a piece; (50) Sildenafil softgel, 100mg, placed in blister packs with 10 tablets a piece; (50) Sildenafil Citrate, 50mg, placed in blister packs with 10 tablets a piece; (50) Tadalafil, 20mg, placed in blister packs with 10 tablets a piece; (50)

Tadalafil, 20mg, chewable, placed in blister packs with 10 tablets a piece; (50)

Sildenafil Citrate, 100mg, placed in blister packs with 10 tablets a piece; (50)

Sildenafil Citrate, 100mg, softgel, placed in blister packs with 10 tablets a piece; (50)

Tadalafil, 40mg, placed in blister packs with 10 tablets a piece; (52) Sildenafil and

Dapoxetine, 100mg, placed in blister packs with 10 tablets a piece; (50) Tadalafil,

20mg, softgel, placed in blister packs with 10 tablets a piece

- I paid a total of \$9,850 for these aforementioned products.

Purchase 4:

- On December 5, 2016, (500) Tadalafil, 40mg, Tadagra Strong-40, placed in blister packs with 10 tablets a piece.
- On December 16, 2016, (25) boxes of Eutropin (Human Growth Hormones/HGH) 4 IU.
- On February 10, 2017, (15) boxes of Eutropin 4 IU (HGH)
- I paid a total of \$5,850 for these products.

LAB Results:

On September 15, 2016, SA Petri received the laboratory results from the FDA/FCC, Cincinnati, OH, who tested multiple drugs from previous purchases with GP. The results of the laboratory were as follows:

Item#	Portion Analyzed	Drug Identified
1A	5 tablet composite	acetaminophen & codeine (Schedule III controlled substance, purchased on June 6, 2015)

1B	5 tablet composite	lorazepam (Schedule IV controlled substance, purchased on June 6, 2015)
1C	3 tablet composite	sildenafil & tadalafil (purchased on June 6, 2015)
1D	5 gel cap composite	sildenafil (purchased on June 6, 2015)
1E	5 tablet composite	sildenafil (purchased on June 6, 2015)
1F	5 tablet composite	tadalafil (purchased on June 6, 2015)
1G	5 tablet composite	tadalafil (purchased on June 6, 2015)
1H	5 tablet composite	sildenafil (purchased on June 6, 2015)
1I	5 tablet composite	sildenafil (purchased on June 6, 2015)
1J	5 tablet composite	tadalafil (purchased on June 6, 2015)
1K	5 tablet composite	sildenafil & dapoxetine (purchased on June 6, 2015)
1L	5 gel cap composite	tadalafil (purchased on June 6, 2015)
2A	5 tablet composite	alprazolam & diclofenac (Schedule IV controlled substance, purchased on December 15, 2015)
2B	1/2 tablet	acetaminophen & codeine (Schedule III controlled substance, purchased on December 15, 2015)
3A	5 tablet composite	tadalafil (purchased on November 4, 2015)
3B	5 tablet composite	sildenafil (purchased on November 4, 2015)
4A	5 tablet composite	acetaminophen & codeine (Schedule III controlled substance, purchased on May 20, 2016)
5A	5 tablet composite	lorazepam (Schedule IV controlled substance, purchased on May 18, 2016)

- 5B 5 tablet composite acetaminophen & codeine (Schedule III controlled substance, purchased on May 18, 2016)
- 6A 5 tablet composite acetaminophen & codeine (Schedule III controlled substance, purchased on May 24, 2016)
- 7A 5 tablet composite acetaminophen & codeine (Schedule III controlled substance, purchased on May 23, 2016)

The information provided with the drugs obtained from MIR indicated that the drugs were manufactured in India and were not the U.S. approved versions of the drugs.

CONVERSATIONS/MEETS:

On August 26, 2015, I talked with an individual who identified himself as Roger Smith, who at a later date identified himself as MIR. During the call MIR informed me that medications previously ordered were being delivered to the address provided. During a follow on conversation, MIR told me that the medications were not going to be sent because the name on the Western Union and the name provided to GP were different. MIR said that the distributor in Texas would not ship the medications with different names.

On September 8, 2015, I spoke with MIR, who was following up on our previous conversations. MIR said that since they are shipping all types of medications, to include controlled medications, they do not take the risk of using a well-known shipper to send their drugs. They instead send their drugs through a private shipper.

On October 20, 2015, I spoke to Sam, who I believe to be MIR, based on prior conversations and the recognition of his voice. MIR said that he had sent a shipment of 250 pills of Viagra and 250 pills of Cialis to the address that I provided. I told MIR that I sell the medications that I buy from MIR. MIR said that he was going to send a list of medications that his company sells, so that I would have a reference for the future.

On December 2, 2015, I spoke to MIR several times about the purchase of different medications. I made a purchase from GP by ordering (300) Hydrocodone 10/325mg and (300) Xanax 2mg for \$1100 from MIR. I used my UC credit card to make the transaction. During the conversation, MIR also said that the company has two warehouses, one in Delhi, India and the other in Mumbai, India. He explained that they only sell to customers in Canada and the U.S. There are approximately 100 employees in the sales department and MIR is manager within that department. MIR said that the company will disguise the purchases of medications through the credit card transaction, so that the credit card company will not know that the purchase is for medications. MIR explained that if the credit card company knew that it was for prescription medications, they would not process the charge.

On December 2, 2015, I spoke to an employee from Your Herbal Care, who referred to himself as Michael (NFI) from the shipping department. Michael was calling to confirm the order for the medications. Michael said that Your Herbal Care was the processing company for the order from Global Pharmacy.

On December 2, 2015, I received from Global Pharmacy (info.globalpharmacy@gmail.com) an email order confirmation showing that the following order was processed: (300) Hydrocodone 10/325mg and (300) Xanax 2mg for \$1100. The receipt also showed that the merchant processor was Your Herbal Care TSYS, San Francisco, CA.

On December 14, 2015, I received an email notification that the medications I ordered from GP had arrived in Abingdon, VA. I queried the USPS website and searched the tracking number ED730929014IN and determined that the package had been sent out on December 9, 2015, from Delhi Foreign Parcels, India. The package entered into the U.S. on December 12, 2015 and came through Jamaica, NY.

On December 16, 2015, I spoke to MIR about the medications that were sent to me. MIR said the Hydrocodone pills that were sent were copy pills (generics). He said that the pills are made in Texas. I told MIR that I sell the medications that I receive from MIR. MIR told me that GP will credit back the \$1,100 to the credit card. MIR wanted me to send \$1,100 through Western Union for the medications. MIR explained that they only sell controlled medications through Western Union and use their merchant account for the ED (erectile dysfunction) medications. MIR explained the merchant account used to process the transaction was the only merchant account they have and they do not want to lose the ability to use it by selling controlled substances through it. MIR said it is wrong to sell controlled medications, so they cannot do it through the same account as the ED medications. MIR said if I am ever asked about my prescription for the medications, GP has a prescription on file for him. MIR provided the name Sandeep JAISWAL for the Western Union transaction.

On December 21, 2015, I confirmed that the UC credit card had been credited the \$1,100 for the previous transaction. I received \$1,100 in UC funds to send through Western Union to MIR for the medications he previously sent to me. I then sent \$1,100 via Western Union, tracking number #642-671-6151, to MIR through the use of the name Sandeep JAISWAL, Mumbai, India. I spoke to MIR and provided the confirmation number of the transaction. I also confirmed the identity of MIR as Rahil MIR.

On March 17, 2016, I spoke to MIR about increasing the volume of medications being purchased. MIR advised they sell user quantity of medications to individuals and also bulk amounts for resale. MIR mentioned that GP has one business in Texas that they sell large quantities of medications to. I requested that MIR either provide the Texas customer or provide the customer with my information for the purposes of referral. MIR provided three items of information me: (1) quotes for several medications for bulk rates, (2) a list of all the medications provided by GP, and (3) a list of bestselling ED medications.

On March 24 and 25, 2016, I spoke to MIR about further business dealings with GP. During the discussion, I discussed increasing the volume of medications being purchased and MIR providing a referral for business references. MIR told me the Texas business refused to allow MIR to share their information with me because they said they were afraid I was with law enforcement.

On March 25, 2016, I spoke to (Person 1), who was referred to me by MIR as a customer who regularly purchases large quantities of medications from GP. (Person 1) explained that he purchases large amounts of muscle relaxing medications and Viagra from GP. (Person 1) uses the muscle relaxing medication but sells the Viagra to others in the Seattle, WA area.

On April 5, 2016, I emailed with MIR (info.globalpharmacy@gmail.com) who provided a quote of medications, detailed company information and banking information. The final quote was Hydrocodone 30/325, 2,200 pills at \$6050, and Xanax 2mg, 2,000 pills at \$3800, totaling \$9,850.00. The company information was as follows: KNM Global Services Pvt.Ltd; B wing office number 107-108 Kailash Mansarovar Opposite Garden Court behind Maxus Mall Bhayander West, Thane 401101, Maharashtra. Company telephone number 022-69999959 and company Fax number 022-69999959. The company banking information was NKGSB Co-operative Bank Limited, Bhayander West; Address, NKGSB Bank Maxus Mall Temba Road Bhayander West District Thane 401101 Maharashtra; Account number 063110400000002; IFSC Code NKGSS0000063; MICR Code 400086039, and Contact number 022-28141277.

On April 11, 2016, I spoke to MIR several times over the telephone, at which time I determined that one of the company owners/directors of the company is Alok Kailash Nath JAISWAL. I did a query of JAISWAL and determined the following information: Directors of KNM Global Services Private Limited are Alok Kailash Nath JAISWAL and (Person 2).

On April 26 and 27, 2016, I spoke to MIR about the transaction of funds from my UC bank account to MIR's account. I explained the funds were returned a second time due to

insufficient information on the receiving account. I requested the other bank account that MIR previously mentioned in conversation to send the money for the medications. MIR related that he would send the account information via email. MIR also mentioned that the company in Canada (Company 1), which MIR previously provided a sample invoice for was sending money through the first bank account provided to me.

On April 26, 27, and 28, 2016, I emailed with MIR to obtain the bank account information for the company. MIR provided the account information for KNM Global Services as follows: company name: KNM Global Services Pvt.Ltd; company address: B wing Office No.107-108 Kailash Mansarovar, Opposite Garden Court, behind Maxus Mall Bhayander West. Thane 401101, state: Maharashtra; company telephone number: 022-69999959; and company fax number: 022-69999959. Account details: KNM Global Services Pvt.Ltd (ALOK K JIASWAL); bank name: Kotak Mahindra Bank Ltd; branch name: Mira Bhayander Road; bank address: Kotak Mahindra Bank Ltd,E-wing, Poonam Shrushti Building, Latif Park,Mira Road E, Thane 401107; district number: 401107; account number: 3811597035; IFSC code: KKBK0000649; MICR code: 400485051; SWIFT code: KKBKINBB; and contact number: 022 2812 0740.

On April 26, 27, and 28, 2016, I emailed with MIR, during which I provided MIR with two addresses to send the medications. MIR requested I provide him with the two addresses because the medications were prescription/controlled medications and they would likely be stopped by U.S. Customs if they were sent in larger quantities to the same address.

On June 15, 2016, I spoke to MIR over the telephone about future business with one another. MIR explained that GP had another division within their business, other than the sale of legal and illegal pharmaceuticals. The other division to their business deals with computer software, which is called KNM Global Services. They dial customers in the U.S. to generate business. Over the course of a day, they call 5,000 phone numbers and of those numbers around 50 people answer their phone. Of the 50 people who answer their phone, only 30 people are interested in purchasing medications and around 10 people actually buy. GP will process the medication transaction with the customers over the phone with a credit card. GP only ships to the U.S. and Canada.

On June 21, 2016, I organized a conference call, which included an Indian Confidential Informant (CI); me; Officer Nate Moore, Kentucky State Police and MIR, during which time they discussed many business aspects. MIR explained that when an order comes in from a customer, GP contacts the distributor/supplier for the medication. The manufacturer and the distributor are two different entities. MIR has received complaints from customers who take too many of the erectile dysfunction (ED) drugs, who are exhibiting symptoms of headaches. GP has no customers in India. GP has only one shipper/distributor in Mumbai, who has stopped shipping to Canada, but continues to ship to the U.S. The shipper is given the order that is taken through GP employees over the phone. The shipper receives these orders through email from GP. The shipper will then process the order and send out the medications to the customers in the U.S. MIR has been to the shipper's warehouse on several occasions, which is the largest distributor in Mumbai. The controlled medications are coming from one place in Delhi and the

ED medications are coming from the supplier in Mumbai. Note: The CI was only used during this call to help further establish rapport with MIR.

On March 13, 2017, I spoke to MIR about the anticipated travel to India for a business meeting. MIR said that the owner of the company JAISWAL would also be attending the meeting. They also planned to bring one of the distributors of the prescription medications that ship out of the Mumbai, India area. They have used the distributor for the last 7 to 8 years. MIR explained their process: Once they have received the orders from the customer, they send that order to the distributors. The distributors will then ship the medications out to the customers. The distributors may use other people to send the medications, MIR is unaware who sends out the medications for the distributors. MIR and his employees send the request to the distributors via email. I provided MIR with the address of the Seventh Sky, whose address is on the packages received, Ground Floor, Godown, Cama House, Mint Road, Fort, Mumbai-400001. MIR explained that the address of the company Seventh Sky is the address of the warehouse they use in Mumbai.

On March 23, 2017, SA Eric Flagg, FDA/OCI, and I went to Mumbai, India and met with MIR and JAISWAL in the lobby of a hotel to discuss future business partnering. SA Flagg and I escorted MIR and JAISWAL to the meeting room and began the controlled meet. A few noteworthy conversations that took place between MIR, JAISWAL, SA Flagg and I were as follows: MIR and JAISWAL said that they have been in business for about six years. In India, they provide medications, specifically antibiotics, to around 70 to 80 hospitals and around 150 pharmacies. Their customer base in the U.S. is around 400 a month and they sell about \$200 to

\$300 worth of medication to each customer. Overall they have an email collection of U.S. customers of around 65,000, which 75% are ED medications. They currently use the merchant account through VMS Herbal Care, who charges them 10% for each transaction. The shipping process consists of them receiving orders from the customer directly. MIR and JAISWAL then send an email to the applicable agent/distributor. They have three distributors, one in Mumbai, India, who deals in the ED medications; one in New Delhi, India, who deals with the controlled medications; and one in Chadigarh, India, who deals with the HGH.

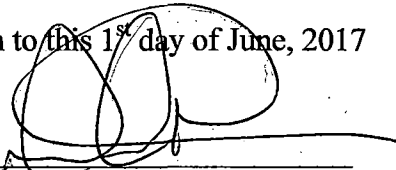
On April 25, 2017, I spoke with MIR about the meeting that took place in India on March 23, 2017. MIR also said that he has Fentanyl, but he did not want to send it to me because the quality is not good. MIR continued to say that another reason he could not send Fentanyl was that all controlled substances out of India have been stopped, but they will continue in a couple of months. MIR and I also discussed the merchant account/payment gateway for GP.

On April 27, 2017, I spoke with MIR, at which time he said that he and JAISWAL would like to come to the U.S. for a meeting. I further discussed with MIR some of the details that would occur during the meetings, when they came to the U.S. MIR said he would send copies of his and JAISWAL's passports to my UC email account. On May 2, 2017, I received from MIR copies of his and JAISWAL's, passports. MIR sent the passports in anticipation of them coming to the US in July 2017 for what he believes will be a meeting.

CONCLUSION

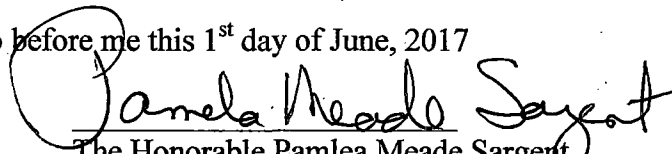
Your affiant believes there is probable cause to believe between November 4, 2015 and February 10, 2017, in the Western District of Virginia, MIR and JAISWAL committed the offenses of Introduction of a Misbranded Drug Into Interstate Commerce, Distribution of a Controlled Substance, Smuggling Goods into the United States, and Conspiracy, when they knowingly and willingly sent controlled substances and misbranded Indian prescription medications, not approved by the U.S. Food and Drug Administration, to the U.S., and received payments through the use of bank accounts, credit cards, and Western Unions.

Signed and sworn to this 1st day of June, 2017



Darren C. Petri
Special Agent

Subscribed and sworn to before me this 1st day of June, 2017



The Honorable Pamela Meade Sargent
United States Magistrate Judge