

Comment : Hi I would like to report sale of anabolic steroids. Check out this website (b) (4), (b) (7)(B) They do not require a valid prescription for prescription drugs, based on an in-person examination. They sale of unapproved drugs, including counterfeit, expired, misbranded or falsified drugs. They dispensing of prescription drugs without a valid pharmacy license in the relevant jurisdiction. (b) (5), (b) (7)(E) 01/03/2017 06:16:40

Comment : A seller on (b) (7) called (b) (4), (b) (7)(B) is selling counterfeit coils for e-cigarettes (b) (4), (b) (7)(B) I believe I don't need to inform the danger of using this kind of "fake" products. I've bought two itens and I still have those itens with me. Please, get in touch if need something. I'm willing to help. Thank you. 01/05/2017 13:46:02

Comment : January 5, 2017 Office of Criminal Investigations Food and Drug Administration 7500 Standish Place Rockville, MD 20855 RE: Suspected Tampering To Whom It May Concern, We have been in contact with the regional office and have spoken to (b) (7)(F) regarding this incident. I am contacting you on behalf of (b) (7)(B), (b) (4) to report a loss and potential tampering of (b) (4) 2mg/ml 1ml oral dose syringes and of (b) (4) morphine 10mg/0.5ml 0.5ml oral dose syringes. I have attached a copy of the DEA 106 Form for your review. Our hospital license number is (b) (4), (b) (7)(P) The suspicious behavior, which led to this investigation, was first reported on August 23, 2016 by (b) (6), (b) (7) . During her shift at the (b) (7)(B), (b) (4) , on August 21-22, 2016, (b) (6), (b) (7)(P) noticed odd behavior from (b) (6), (b) (7)(C) around the various (b) (4) stations and other nurse's (b) (4) (b) (6), (b) (7)(C) ran a (b) (4) user activity report from the machines which showed several canceled withdrawals for morphine 10mg/0.5ml oral dose syringes by (b) (6), (b) (7) She reported this to the Director of Nursing – (b) (4), (b) (7)(B) Human Resources Manager. That day, Hospital Administration, Nursing Management, Pharmacy Management, Risk Management, and Human Resources worked to compile medication use data and quarantined all morphine 10mg/0.5ml oral dose syringes from the (b) (4) machines on campus. On the evening of August 23, 2016 (b) (6), (b) (7) was interviewed, relieved of duties, and placed on administrative leave pending a comprehensive investigation. At this point, pharmacy technician (b) (6), (b) (7)(C), (b) (7)(C) voiced concerns of tampering and diversion of (b) (4) 2mg/ml oral dose syringes. These were then also quarantined at that time. A subsequent investigation and staff interviews were conducted. The investigation utilized (b) (4) reports, (b) (4) reports, and (b) (4) software to identify staff members with suspect behaviors. It revealed that (b) (6), (b) (7) had potentially diverted approximately (b) (4) doses of morphine 10mg/0.5ml oral dose syringes, with suspicious activity escalating from October 1, 2015 through August 23, 2016. Samples from the confiscated morphine doses were sent to an external lab (b) (4) for diversion testing of potency. The (b) (4) results showed that (b) (4) morphine oral syringes had extremely low potency (b) (4), (b) (7)(B) Other staff interviews uncovered nursing practices in documentation and wasting that needed improvement. Nursing leadership is addressing medication use practices with the staff. Staff interviews and reports from (b) (4) and (b) (4) have not been able to identify a specific potential diverter of the (b) (4) syringes secondary to its storage in an open bin in the locked (b) (4) refrigerator. Samples from the confiscated (b) (4) doses were sent to an external lab (b) (4)) for diversion testing of potency. The (b) (4) results showed that (b) (4) oral syringes had extremely low potency (b) (4) Diversion Specialist, (b) (6), (b) (7)(C), (b) (7)(D) was contracted to assist us in, completing the investigation, conducting a gap analysis, and reviewing our policies and procedures. She was onsite from Nov 28 through Dec 2, 2016. Some of her recommendations for improvement are included in our corrective action plan described and listed below. Her final report is pending completion. During her stay she educated our (b) (4) /Diversion team regarding additional avenues for reporting potential tampering to the FDA through the Office of Criminal Investigation. (b) (4), (b) (7)(B) Diversion Corrective Actions Corrective action Responsible party Date completed Evaluation of effectiveness (b) (4), (b) (6), (b) (7)(C), (b) (7)(B), (b) (7)(D)

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C), (b) (7)(D)

Pharm.D. Medication Safety Coordinator

Manager/PIC of (b) (4), (b) (7)(B)

Pharm.D. Director of Pharmacy Services (b) (4), (b) (7)(B)

(b) (5), (b) (7)(E)

Comment : Counterfeit versions of the (b) (4), (b) (7)(B) medical device have been found on sale on (b) (4), (b) (7)(B) and on (b) (4), (b) (7)(B) by (b) (4), (b) (7)(B) 01/06/2017 11:17:41
 These are the (b) (4), (b) (7)(B) " pouches in the 2g and 15g sizes. Samples of both of these products were purchased via (b) (4), (b) (7)(B) on December 15th 2016.
 They are not the same product as the real (b) (4), (b) (7)(B) product in dark green packaging manufactured by (b) (4), (b) (7)(B) (establishment registration number (b) (4), (b) (7)(B) the packaging, labelling and hemostatic product are all significantly different. It is assumed that the counterfeit product is not an effective hemostatic agent and would be ineffective at treating severe bleeding as indicated. The counterfeit product labelling also does not provide the information required to use the product safely and effectively. No specific laboratory tests have been performed on the products. Samples of both the 2g and 15g product sizes were purchased from (b) (4), (b) (7)(B) . The packaging of the counterfeit product is different from the real (b) (4), (b) (7)(B) product; the pouch material is different and the counterfeit product has a low quality paper label attached which only contains the product name, indications for use, product size and, on the 15g version, the (b) (4), (b) (7)(B) logo with a barcode which links to the (b) (4), (b) (7)(B) website. The real (b) (4), (b) (7)(B) product is packaged in a foil pouch with labelling printed directly on the pouch material with a green background and all of the correct information, including the name and address of the manufacturer (b) (4), (b) (7)(B) directions for use and warnings etc. The counterfeit product is also described as a powder but the real product is described as granules. With the counterfeit product, the substance inside the pouch is a gritty powder substance with an unpleasant smell. The real (b) (4), (b) (7)(B) product is more of a flake/granule format with essentially no smell.

Comment : (b) (4), (b) (7)(B) Updated 1 second ago DOMAIN INFORMATION Domain (b) (4), (b) (7)(B) Registrar: (b) (4), (b) (7)(B) Registration Date: (b) (4) Expiration 01/08/2017 22:53:23
 Date (b) (4) Updated Date (b) (4) Status:ok Name Servers: (b) (4), (b) (7)(B) Basically this Steroids company is selling steroids in (b) (4) and my cousin took their products and got hurt. They now refuse to acknowledge it is their products fault and am contacting you in the hope that you can get this company to check their products thoroughly. (b) (5), (b) (7)(E)

Comment : I would like to report A Rouge Pharmacy operating in the US. They sell anabolic steroids to North America customers. All drugs are manufactured underground. 01/11/2017 08:25:05
 This company goes by 2 different domains (b) (4), (b) (7)(B) Registrar of these domains is (b) (4), (b) (7)(B) E-mail: (b) (4), (b) (7)(B) I contacted them and asked to suspend these domains but they refused. I believe that Registrar is supporting sale of illegal drugs. Please shut down these sites. (b) (5), (b) (7)(E)

Comment : (b) (6), (b) (7)(C) is a RN, and owner of (b) (4), (b) (7)(B) The business is reportedly near bankruptcy and (b) (6), can no longer get a vendor to supply her with product. An Office Assistant reported physically seeing (b) (6), (b) (7)(C) inject a patient with (b) (4), (b) (7)(B) and charge them for (b) (7), (b) (6), then asked the Office Assistant to falsify the patients medical record. The Office Assistant is willing to tell you these things first hand. She is (b) (6), (b) (7)(C), (b) (7)(D) . She can be reached at (b) (6), (b) (7)(C), (b) (7)(D)

(b) (4)
(b) (4)

Comment : (b) (4), (b) (7)(B) . Sold me an (b) (4), (b) (7)(B) , that was recalled by the manufacturer and the FDA. The company did NOT advertise nor tell me that it was recalled prior to my purchase. He will not return my phone calls or emails. There have been 3 deaths and over 19K inaccurate test results using this device. His LLC ID NUMBER (b) (4), (b) (7)(B) His name is (b) (6), (b) (7)(C) . If you need me to fax or scan my receipt from this company let me know. He should not be selling dangerously recalled medical devices.

Comment : I am concerned that claims made by (b) (4), (b) (7)(B) about its (b) (4), device being FDA cleared are false. The same claim is made by distributors marketing the device to doctors' offices under other names (b) (4), (b) (7)(B) device by (b) (4), (b) (7)(B) part of (b) (4), (b) (7)(B) I am not able to find FDA clearance for this device in your database. I hope I am wrong, but if I am right, please help prevent more healthcare professionals from being misled about this device. I may be reached at (b) (6), (b) (7)(C), (b) (7)(D) . Thank you.

Comment : (b) (4), (b) (7)(B) owner (b) (6), (b) (7)(C) is operating under (b) (6), (b) (7)(C) license (still up on the wall in a frame) no other employee has one) She has not worked there since 11/15/2016. Please be advised this facility is selling medical devices like tubing - urinary bags and nebulizers without a prescription. I would like this to remain anonymous. Thank you.

Comment : I would like to report Criminal Activity.(b) (4), (b) (7)(B) is a rouge pharmacy selling anabolic steroids, pain killers and many unregulated drugs. They deliver illegal drugs to the U.S.A. citizens. Their drugs are dirty and dangerous. Please follow it up and bust criminals. (b) (6), (b) (7)(C), (b) (7)(D) (b) (5), (b) (7)(E) 02/01/2017 05:57:36

Comment : Hello, I want to report the domain (b) (4), (b) (7)(B) They sell illegal drugs online. Thank you! (b) (5), (b) (7)(E) 02/01/2017 08:47:22

Comment : HI, I am (b) (7)(F), and I work for the (b) (7)(F). I was recently informed that a clerk by the name of (b) (6), (b) (7)(C), and another clerk (b) (6), (b) (7)(D) (unknown last) are selling cigarettes to minors. However, they are not just selling to any minors, these are minors they know and one of them has gotten into a disagreement and came to me to tell me this information. I would like some contact from someone so I can discuss the information with them. I can be reached at (b) (7)(F) and my email is above. Thank You, (b) (7)(F) (b) (5), (b) (7)(E) 02/07/2017 16:34:51

Comment : Hello, my name is (b) (6), (b) (7)(C), (b) My son bought chemical products on these sites. Now he's in the hospital. Let me show you these sites: (b) (4), (b) (7)(B) 02/09/2017 05:52:52

So I turned to the registrars and hosters these domains (b) (4), (b) (7)(B). I was told that they were not responsible for the content and operation of sites that they service. And they will not block domains. To show how this works, I've created a few emails and sent inquiries to buy banned products requested delivery in the United States. The products that I ordered: (b) (4), (b) (7)(B) These products are listed in the «List of Controlled Substances by DEA Drug». That is why, the sellers written on parcels other names do not match the content. Please open the emails to see correspondence and orders information. (b) (4), (b) (7)(B)

Please let me know if you require any further information. Thank you! (b) (5), (b) (7)(E)

Comment : (b) (4), (b) (7)(B) This company is selling (b) (4) machines on (b) (4), (b) (7)(B) without requiring a prescription. The sold me a (b) (4), (b) (7)(B). I did not realize the consequences that I would not receive support for manufacturer updates to the software. (b) (4) machines are also supposed to be set up by the provider prior to delivery. The machine is not performing well and I am struggling to get a refund. 02/10/2017 18:12:41

Comment : (b) (6), (b) (7)(C) , owner of (b) (4), (b) (7)(B) , has for the past two years been importing large quantities of pharmaceutical oncology products from (b) (4) and selling them to two major buyers within the medical business within the United States. Over the past two years he has been behind the importation of cancer drugs worth in excess of \$2.8M without declaring anything to the IRS and of course without having any licenses. However (b) (6), (b) (7)(C) has been extremely careful as he has not personally been linked in anyway with the actual importation but has always used other people so that he cannot be linked but of course he has received the funds for his illegal activities. Bank account name: (b) (4), (b) (7)(B) (a (b) (4), (b) (6), bank Bank account number: (b) (4), (b) (6), (b) (7)(C) Company name: (b) (4), (b) (7)(B) email address: (b) (6), (b) (7)(C) Company website: (b) (4), (b) (7)(B) Company Number: (b) (4), (b) (7)(B) Names of persons buying the oncology products: (b) (6), (b) (7)(C)

Phone: (b) (6), (b) (7)(C) How (b) (6), (b) (7)(C) imports drugs illegally: Orders are shipped from (b) (4) as genuine cancer drugs but to persons who have no license, they are then shipped to the United States in parcels which have cool boxes hidden inside and are not marked as oncology drugs but as samples. They are addressed to (b) (6), (b) (7)(C) who also uses another name of (b) (6), (b) (7)(C) . Parcels are sent to (b) (6), (b) (7)(C) via the United States Postal Service and are therefore not subject to a full inspection but are sometimes stopped and if found to contain pharmaceutical drugs are then returned to the sender and then resent. Once they arrive with (b) (6), (b) (7)(C) he then delivers direct to the buyers. Once the buyers have the shipments they then pay (b) (6), (b) (7)(C) directly. (b) (6), (b) (7)(C) is now having cancer drugs shipped from (b) (4) The company that ships most of the products is called (b) (4), (b) (7)

Comment : For the past several weeks, there have been ads placed in the (b) (4), (b) (7)(B) to purchase boxes of insulin pens (b) (4), (b) (7)(B) and others). The selling price is usually \$50. Obviously there is no prescription involved. As a pharmacist, I am alarmed and concerned that this situation is even permitted by (b) (4), (b) (7) The amount of insulin in 5 pens is very capable of serious harm and even death. Hopefully your agency has the resources to address this concern. Thank you. (b) (6), (b) (7)(C), (b) (7)(D)

Comment : Discovered \$70,000 to \$100,000 worth of peanuts, during an (b) (5), (b) (7)(E) at a private rural residence. Pictures of peanuts and shipping labels available. Please contact Investigator (b) (7)(F)

Comment : Two separate medical practices in (b) (4), (b) (7)(B) have been confirmed by (b) (4), (b) (7)(B) to be purchasing injectable cosmeceuticals from non-U.S. sources. Both are injecting non-U.S. produced botulinum toxin. (b) (6), (b) (7)(C) is also injecting many other cosmeceuticals produced outside of the U.S. This is an illegal practice which puts patients at risk. Not surprisingly, both businesses claim on their websites and elsewhere that their products are actually U.S. manufactured. (b) (6), (b) (7)(C)

(b) (5), (b) (7)(E)

Comment : (b) (4), (b) (7)(B) dear fda rep. this mail order drug company altered my insulin injection drug without my consent , 03/03/2017 14:47:57
or price approval, they sent it out and charged my credit card, and are not willing to let me return it . I deserved a notification that they refused to provide. they kept my
card number on file so I would not be aware of price increase.please tell me I have a right to fair treatment and notification of price increases before they charge me thank
you (b) (6), (b) (7)(C), (b) (7)(D) (b) (5), (b) (7)(E)

Comment : I suspect the website (b) (4), (b) (7)(B) may be conspiring with illegal (b) (4), (b) 03/03/2017 18:45:43
in order to protect their online activities. I have messaged (b) (4), (b) (7)(B) about this issue. (7)(B)

Comment : This site (b) (4), (b) (7)(B) is selling devices with dubious to provably-impossible claims involving medical benefits such as (b) (4), (b) (7)(B) 03/05/2017 21:05:32

Comment : (b) (4), (b) (7) sells portable hyperbaric chambers which are Class II Medical Devices requiring a prescription. They are only FDA approved for (b) (4), (b) (7)(B) 03/06/2017 01:34:51
(B) . However, (b) (4), (b) (7) and its distributors promote and even suggest FDA approval for conditions such as autism. (b) (4), (b) (7)(B)
(B)

Comment : (b) (6), (b) (7)(C) has for a number of years been illegally importing (without a license) Hematology and Oncology drugs. Its known that over two years he 03/08/2017 09:06:43
has imported at purchase value \$2.8million worth of drugs for a number of doctors who then sell the drugs to their patience. Further details: Bank account details (b) (4), (b)
Buyers - (b) (6), (b) (7)(C) (6), (b) (7)
(C), (b) (7)
No tax has been paid of his earnings.

Comment : Dear Sir/Madam, Our office received a complaint about an allegation of illegal activity related to counterfeit drugs from overseas. Please see below the 03/08/2017 09:30:27
description from the complainant: BUSINESS NAME: (b) (4), (b) (7)(B) BUSINESS TYPE:
DOMESTIC BUSINESS CORPORATION BUSINESS START DATE: (b) (4) CORPORATE OFFICERS: (b) (6), (b) (7)(C) INDIVIDUALS: WHAT HAPPENED?: This business
is using other business address without any permission. Also, They have been switching owners name to avoid tax. They Sell illegal counterfeit drugs from overseas. Peter
Kwan Helen Kwan are a married couple. The reside at: (b) (6), (b) (7)(C) .They usually have unboxed goods inside their home. Usually in the evenings
they couple will process the goods. By changing the expiration dates on the packing, package the products individually.Their goods come in raw materials where the boxes,
wrapping, bottling are all shipped separately. Inside their home is where they do the illegal work. Their products are (b) (4), (b) (7)(B)
. They make all cash income and never report their revenue.

Comment : Fake erection pills, called (b) (4), (b) (7)(B) Thank you (b) (5), (b) (7)(E) 03/09/2017 04:16:50

Comment : Fake erection pills, (b) (4), (b) (7)(B)

03/09/2017 04:40:41

Thank you (b) (5), (b) (7)(E)

Comment : Fake erection pills, (b) (4), (b) (7) and others on (b) (4), (b) (7)(B)

03/09/2017 04:45:27

(b) (5), (b) (7)(E)

Comment : Fake erection pills, (b) (4), (b) (7)(B) and others on (b) (4), (b) (7)(B)

03/09/2017 04:47:12

Thank you (b) (5), (b) (7)(E)

Comment : Fake erection pills, (b) (4), (b) (7)(B)

03/09/2017 04:49:12

Thank you (b) (5), (b) (7)(E)

Comment : I recently had my pain medication (b) (4), (b) (7) tampered with, and a portion was stolen from each of the two bottles en route to me. With my illnesses I could not use any portion of what was left. Instead of being treated as the victim of this crime, I was treated like the criminal by the insurance company, and the physician (who said she had to report me for 'losing' my medication!). I have probably taken the (b) (4), (b) (7)(B) for more than a decade (long before it became a controlled prescription), and this was the first time anything has happened like this. I had reported it right away to (b) (4), (b) (7)(B)

03/21/2017 17:39:53

It was also reported to the local police who came out to take a statement and took the bottles and envelope back to be checked for fingerprints (none came back as a match, but the driver was questioned and of course claimed ignorance). It was then passed to a detective, that with no other evidence really has nowhere to go unless someone makes a confession. No one would send a clean prescription, so I had to get a prescription from my doctor for another pain medication. There is also a very disturbing twist that the last two times this medication was sent, it came from another insurance company instead of my own. Now obviously I didn't send the script in, only a doctor's office can do that, and the doctor's office says it wasn't them, my insurance company says it wasn't them, and the insurance company who sent these poorly protected pills is just plain hostile when I call them. So there's the other question, how did that company get hold of my prescription? I have to wonder if it's a scam of some sort and I really want someone to own up to what has been done. If my actual insurance company has sent this, it would have been in a very hard to tamper with mailer, unmarked, and each bottle is machine sealed for safety (sent through USPS). This other company doesn't seal the bottles and sent it in a regular bubble envelope that was split open right down the side. Is there someone who can help me with this mess? I'm a disabled Mom with a limited income and now my doctor doesn't even want my prescriptions faxed in (which is much cheaper for me because they do 3 months at a time, and sometimes they are even free....huge help when every dollar counts). Thanks so much for your time (and for getting through this long winded explanation. (b) (5), (b) (7)(E)

Comment : (b) (4), (b) (7)(B)
(b) (5), (b) (7)(E)

Selling unapproved drugs this fellow (b) (6), (b) (7)(C) is openly promoting his steroids and peptides and pharmacy drugs website

03/29/2017 19:09:29

Comment : A product complaint (b) (4) was received on 3/27/17 in regards to suspected tampering of (b) (4), (b) (7)(B)

03/30/2017 14:33:34

It was reported by a clinical pharmacist from (b) (4), (b) (7)(B) that the product seemed cloudy and contained small pieces of floating debris. Reporter believes some of the product was taken by a nurse and replaced with tap water. (b) (4), (b) (7)(B) was packaged on (b) (4) The lot was released on (b) (4) totaling (b) (4) units. The product began distribution on (b) (4) units remain in inventory. The packaging batch record from (b) (4), (b) (7)(B)

was reviewed. One deviation (b) (4)

(b)
(4)

This is the first product complaint received

from (b) (4), (b) (7)(B) . In addition, this is the first product complaint received from (b) (4), (b) (7)(B) . A complaint history search was completed. It was determined that this is the first complaint received for the lot in question. Contact information for the complainant is: (b) (6), (b) (7)(C), (b) (7)(D)

My Contact Information is: (b) (6), (b) (7)(C), (b) (7)(D)

Comment : I manage the (b) (4), (b) (7)(B)

. Recently, as part of a tobacco inspection of (b) (6), (b) (7)(C)

03/31/2017 11:35:40

we came across evidence the store is selling single pills of (b) (4), (b) (7)(B) were in a plastic bag marked (b) (4), (b) (7)(B) along with some unknown foreign language. The pills them self are identical to (b) (4), (b) (7)(B) pills, even having (b) (4), (b) (7)(B) imprinted on one side and (b) (4), (b) (7)(B) on the opposite side. I have pictures if needed and can be reached at (b) (6), (b) (7)(C), (b) (7)(D) Thank you (b) (6), (b) (7)(C), (b) (7)(D)

Comment : SUMMARY- QC Testing manipulation in Active Pharmaceutical Ingredient of Cancer drug^{(b) (4), (b) (7)(B)}
Please look into it ASAP. All relevant details below- Company - ^{(b) (4), (b) (7)(B)}

to pass lots that have failed- NO DATA INTEGRITY.
^{(b) (4)}

04/04/2017 07:02:17

is a highly marketed product used in cancer treatments please look into it. ^{(b) (4), (b) (7)(B)} . However the management decided to proceed without taking any action. Since this
have been previously investigated for similar allegations ^{(b) (5), (b) (7)(E)}

Comment : ^{(b) (4), (b) (7)(B)} is claiming the FDA has approved ^{(b) (4), (b) (7)(B)} for the treatment of autism. ^{(b) (4), (b) (7)(B)}

04/07/2017 01:45:34

Comment : This firm is blatantly selling umbilical cord stem cells to physicians in the US for use in treating patients. ^{(b) (4), (b) (7)(B)} They claim their product is
FDA registered (but not FDA approved) website inspected and makes reference to FDA regulations. Does not guarantee results of therapy. ^{(b) (5), (b) (7)(E)}

04/12/2017 09:35:13

Comment : Dear Sir / Madam, I am not sure I am contacting the right department, however since I have nowhere else to turn to I had to refer to you. Please note there are
fake pills on ^{(b) (4), (b) (7)} claiming to be FDA approved while they are not. The item numbers are ^{(b) (4), (b) (7)(B)}

04/13/2017 16:29:02

All items also use an ARTG number from different products and they use same names of the same product, while the product is completed and its
functions are completely different from the claims of the sellers. Not sure if it is a coincidence but all items are either from ^{(b) (4), (b) (7)(B)} , using exactly same
wording. Thanks

Comment : My wife requested a free product samples from (b) (4), (b) (7)(B) Doing so signed her up for a 15 day trial period after which a 30 supply would be shipped. The samples never arrived. My wife cancelled the order at the 12 day point, has a receipt of the cancellation, yet at the 15 day point (after the order was placed) was charged \$103 and \$109 for the 30 day supplies of the two products. The two products are (b) (4), (b) (7)(B)

04/13/2017 23:10:38

Aside from the deceptive practices of (b) (4), (b) (7)(B) , the website and product literature list claims like (b) (4), (b) (7)(B) which as described in FDA Import Alert (b) (4), (b) (7)(B) places this product as a new drug as opposed to a cosmetic. I searched the FDA NDA database and did not find either product listed. The company is based at (b) (4), (b) (7)(B) however I find no listing for the company in the (b) (6), (b) (7) Secretary of State Business Listing. Please do not hesitate to contact me should you have any questions. Sincerely, (b) (6), (b) (7)(C), (b) (7)(D)

Comment : (b) (6), (b) (7) has been selling a Chinese product named (b) (4), (b) (7) . It is a Chinese medicine. (b) (6), (b) (7) has been selling the product to people in (b) (4), (b) (7)(B) ... She sells it the product by (b) (4), (b) (7)(B) . (b) (6), (b) (7) ID is (b) (6), (b) (7) . She sells the product as medicine to someone who has pain of the body. She post the Ad in (b) (4), (b) (7)(B) . She bought lots of (b) (4), (b) (7)(B) from someone in China, and she uses USPS or UPS to mail the product to the U.S, her address. Also or she pays someone who travels to China and bring the product to her (b) (6), (b) (7) also sells it to people in (b) (6), (b) (7)(C) and she is collecting money by (b) (4), (b) (7)(B) without paying any tax.

04/17/2017 18:17:30

Comment : This website (b) (4), (b) (7)(B) takes orders there for products (b) (4), (b) (7)(B) which the website promotes for conditions that cause the products to be drugs under section 201(g)(1)(B) and/or section 201(g)(1)(C) of the Act [21 U.S.C. § 321(g)(1)(B) and/or § 321(g)(1)(C)]. The claims on your website establish that the products are intended for use in the cure, mitigation, treatment or prevention of disease and/or articles intended to affect the structure or any function of the human body, rendering them drugs under the Act. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

04/18/2017 02:52:26

Comment : Hello, I am a family physician in (b) (6), (b) (7)(C) . A patient I saw today here reported to me that he has getting Testosterone, Hcg, and several other anabolic steroids from a place called the (b) (4), (b) (7)(B) . The testosterone would be legal, if he had baseline low testosterone, which he did not. Its also controlled but the patient received it in the mail from a compounding pharmacy the place uses. The other substances are likely not legal. The place claimed to the patient to be legitimate and did a phone consult and labs. However, I find it very concerning and am sure its not on the level. The patient has lingering side effects from the meds including low testosterone now that is not recovering as well as possible adrenal insufficiency. There seems to be a few places giving out steroids or hormones under the guise of being legal. There is another in (b) (4), (b) (7)(B) run by a (b) (6), (b) (7)(C) you may want to look into as well.

04/21/2017 14:09:13

Comment : the lady on (b) (4), (b) (7)(B) is continuously selling contact lenses on (b) (4), (b) (7)(B) without a dr visit or prescription (b) (6), (b) (7)(C), (b) (7)(D) April 22 at 12:52pm (b) (4), (b) (7)(B) contact lenses \$60 (b) (4), (b) (7)(B) 1.25 contacts. 38 lenses

04/24/2017 08:47:38

Comment : (b) (4), (b) (7)(B) representatives in the U.S. are marketing their (b) (4), (b) (7)(B) for unapproved dosing regimens, claiming it can be used twice weekly for severe FVIII hemophilia patients when in fact it is only approved for 3 times per week or every other day. They do not have it in writing, but are verbally marketing this way at trade shows and patient events. (b) (5), (b) (7)(E)

04/27/2017 09:57:58

Comment : My name is (b) (6), (b) (7)(C), (b) (7) . I am making a whistle blower claim. I was employed by (b) (4), (b) (7)(B) as a (b) (6), (b) (7)(C) I was officially fired by (b) (4), (b) (7)(B) in retaliation for my uncovering and internally reporting to my superiors of the existence of false data reporting to the FDA. Specifically, in or about 2014 through 2015, my former employer (b) (4), (b) (7)(B) bio-staticians were knowingly reviewing unblinded oncology pharmaceutical data, which compromised (b) (4), (b) (7)(B) scientific research, in the development, approval and marketing of (b) (4), (b) (7)(B) oncological pharmaceuticals for interstate commerce. In 2016 I reported to my superiors that the unblinding of oncology pharmaceutical (b) (4) studies were occurring, which constituted a significant study conduct error, constituting risk to patients' health and general welfare, which if properly disclosed by former employer (b) (4), (b) (7)(B) . to the FDA, would cause (b) (4), (b) (7)(B) (b) (4) had (b) (4), (b) (7)(B) disclosed its study misconduct. I was terminated in retaliation for discovering and reporting the unblinded oncology pharmaceutical (b) (4) study misconduct. Please contact me at the above-captioned email and/or directly by telephone at (b) (6), (b) (7)(C), (b) (7)(D) (b) (4), (b) (7)(B) My attorney representing me in said (b) (6), (b) (7)(C) . Please contact both my attorney and I to acknowledge receipt of this whistle blower reporting and in order for me to email you detailed information and documentation which substantiates my whistle blowing claim against (b) (4), (b) (7)(B) Thank you for your anticipated courtesies and prompt attention in this regard. Sincerely, (b) (6), (b) (7)(C), (b) (7)(D)

04/28/2017 09:32:16

Comment : I want to report anonymously, there is a shop suspected of operating unqualified health care products,all of there dietary supplement are produced from illegal factory and all of the products ingredients and content is doesn't match the actual products,If use these dietary supplement everyday for a long term it is not good for the body maybe even damage the body health. Most of the customer in the store is come from China they are all the tourists.These unhealthy products price in the store is more than 3 times higher than other dietary supplement,people wants the heathy body but the high prices is not proportional to the heathy benefits.Chinese tourists believe that they can buy good heathy food or dietary supplement in anywhere stores in the USA,These store called (b) (4), (b) (7) is deceived them also deceived the US heathy care market.I think this is a criminal behavior. Here is the information of the store Manager (b) (6), (b) (7)(C) Name: (b) (4), (b) (7)(B) Address: (b) (4), (b) (7)(B) Phone: (b) (4), (b) (7)(B) Open hours: Monday-Sunday 8:00-12:00 (b) (5), (b) (7)(E)

05/02/2017 01:38:09

Comment : There is currently a group of individuals, (b) (6), (b) (7)(C) individuals who illegally possess biometric devices that go through persons (symbaticos)/personal information. This group of individuals are using cyber criteria and the DNA of that persons to embed themselves And their children in that medical equipment for the purpose of eluding their health problem, STDS mainly but not limited to AIDS, as well as substances. This activity causes that "person/symbatico" to unwelcomely experience the symptoms of their health problems, itching, odor, etc.. This activity and equipment is also being used as a weapon against the persons that this equipment goes through, not only through the symptoms of their health, but also independently as a weapon. These illegal possessors of this equipment use this equipment and the health of that individual as a replacement for medicine, consequently worsening their illness without the knowledge of medical professionals. This group of people not only participate in these activities themselves, but also recruit others in the community, forcing the problems of 50-100 on five or six individuals. They are also using this equipment to participate in biohazardous activities, affecting people all over the globe. (b) (5), (b) (7)(E)

05/02/2017 02:44:23

Comment : (b) (4), (b) (7)(B) 05/04/2017 17:06:36

Comment : (b) (4), (b) (7)(B) continues to sell (b) (4), (b) (7)(B) claiming that it is non-toxic, in direct violation of US Law. 05/06/2017 14:36:57

Comment : this (b) (4), seller is selling fake (b) (4), (b) (7)(B) (b) (4), (b) (7)(B) (b) (5), (b) (7)(E) 05/10/2017 01:32:59

Comment : Two convicted felons by the name of (b) (6), (b) (7)(C) are illegal making supplements out of a storage shed in (b) (6), (b) (7)(C) Specifically, they have made a preworkout called (b) (4), (b) (7)(B) ' for a company called (b) (4), (b) (7)(B) owned by (b) (6), (b) (7)(C) and a male enhancement pill called (b) (4), (b) (7)(B) ' distributed by (b) (4), (b) (7)(B) out of Austin, TX. They are also fraudulently making a similar product called (b) (4), (b) (6), (b) (7)(C) (b) (7)(B) within the last couple of years). The have conspired to distribute both of these products through gas stations and supplement stores throughout Texas. Both of these products had me reporting high blood pressure on two separate occasions. It is said that (b) (6), (b) (7)(C) is (b) (6), (b) (7)(C) according to (b) (4), (b) (7)(B) and website posts. They are very violent and scary and have made veiled threats towards me and my family so I've chosen to stay both quiet and anonymous. (b) (6), (b) (7)(C) also works for a company called (b) (6), (b) (7)(C) in violation of a (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) . He represents (b) (4), (b) (7)(B) all over the State by securing accounts under the threat of lawsuit. EVERYONE IN THIS INDUSTRY KNOWS AND FEARS (b) (6), (b) (7)(C) . I've recently been made aware that (b) (6), (b) (7)(C) so the likelihood of the government taking action is slim. PLEASE HELP. (b) (5), (b) (7)(E)

Comment : (b) (4), (b) (7)(B) , a website which appears to be located in the UK, is selling prescription-only veterinary medicine without a prescription and shipping such medicine into the U.S. Please contact me for further information. Thank you, (b) (6), (b) (7)(C), (b) (7)(D)

Comment : (b) (4), (b) (7)(B) has shipped products (b) (4), (b) (7)(B) and materials for long term implantables) with knowledge of adulteration. (b) (4), (b) (7)(B) as well as several 5-gallon pails of material for long term implantables with the spouts replaced because the original spouts dissolved into the material. Spouts were replaced and material was sold with the adulterated material. (b) (4), (b) (7)(B) was knowingly sent out with "dark particulates" to customers. The customers rejected the material and returned several lots. This was all done with the "approval" of upper management (including (b) (6), (b) (7)(C)). The management of (b) (4), (b) (7)(B) completely lacks ethics and morality for its consumers. (b) (5), (b) (7)(E)

Comment : Please contact me. I have detailed information on a criminal drug rep trying to sell chemotherapy. I recorded my conversation with the rep as well. Thank-you. (b) (6), (b) (7)(C), (b) (7)(D) (b) (5), (b) (7)(E)

Comment : This (b) (4), (b) (7)(B) page is marketing (b) (4), (b) (7)(B) as a drug/illicit substance. (b) (4), (b) (7)(B) The person involved is (b) (4), (b) (7)(B) I will make a follow up call on Monday to your Washington DC field office. This person has been telling many that what he sells is equal in nature to morphine but a safe high. The (b) (4), (b) (7)(B) industry is scary enough in compliance without far more illegal issues like this gentlemen involved not even bothering to even attempt to follow FDA compliance and selling (b) (4), (b) (7)(B) as the next new drug. (b) (6), (b) (7)(C), (b) (7)(D) . His (b) (4), (b) (7)(B) is showing what was an advertisement for (b) (4), (b) (7)(B) and there is a major concern if he is selling that it may kill someone. (b) (4), (b) (7)(B) is what was involved in (b) (5), (b) (7)(E)

Comment : My name is (b) (6), and I work for (b) (4), (b) (7)(B)

I don't want to leave my phone number on here I did leave an email. On 05/28/17 (b) (6), (b) (7) texted me and asked me if I would change labels for him because I was going to work for him on Memorial day. I asked him why do I need to change labels for him and he said because they will say raw and that he changes them every time that he works that's why we have a folder there with all the labels. Now when I first started they told me that sometimes when milks are delivered they label them wrong and I just need to change the label. I know how busy they get at the farm so it all seemed reasonable sometimes we would get stuff labeled wrong and sometimes we would get stuff with no labels on them at all and it didn't happen much and it wasn't every delivery. Soon I wasn't working on delivery days anymore and I never thought about it until he told me he does it every delivery and he didn't even get the order yet something just didn't sound right so I told him no. I said I'm not doing that and that if we were selling raw milk in the store all that needed to be changed at the farm. He clarified that it wasn't the milk that it was the probiotics and toddy coffee that say raw. Those are things that come in mislabeled at times but with the order not being received I didn't understand why he would ask so I said no if we are not supposed to be selling something at the store I'm not changing it to look like we can. I told him I don't get paid enough to be taking risks like that. Saying that I do have to tell you that I did ask for a raise and was told that a raise was not possible yet. I can say I'm fine with that now but at first I really needed the money so I wasn't but after realizing that I needed to go back to school or look for another job anyways I didn't worry about the raise anymore. When I went home I talked to my dad and told him what happened and he said that didn't sound right either. On Thursday 6/1/17 I get a call and (b) (6), (b) (7) says he talked to his partner and he can't give me a raise and that if I want to quit he understood or I could go part time and that (b) (6), (b) (7) could take on more responsibility at the store. I asked him if I could think about it and he said yes I already knew I wasn't getting a raise because he told me that earlier but I didn't know if I wanted to look for a another job or part time so I could study. Later that day I told him I would like to go part time so I could start taking classes again and (b) (6), (b) (7) said OK (b) (6), (b) (7) later comes in and has product for the store and tells me to take off an expiration date and make the date for 2 weeks later. He said he made it for 2 weeks early so he could check it later. He has told me to do this before because it was labeled wrong and the products were clearly still good but I did not feel comfortable with it this time so I said no. He got very upset told me I was wrong and he didn't have time to explain it to me. He told me to mark the kefir as a loss to some other store I don't even remember the store. He said I wasn't happy there and to just make Sunday my last day and then left. I have to admit I got really upset at this point and start thinking about what I am going to be doing about income I have a lot of bills my dad just retired and he has to help my grandmother out I cant afford to be out of a job. I started calling unemployment and the department or labor laws I talked to someone at the unemployment office and they said I can't do anything until I am actually fired and that I need to call them back then. About an hour after (b) (6), (b) (7) left I'm not to sure on the time (b) (6), (b) (7) came in and I thought she had talked to (b) (6), (b) (7) and was making sure I didn't leave or steal anything. So I was still upset so I just said I guess you talked to (b) (6), (b) (7) and he told you I got fired. She said no I'm just coming in to look at inventory and asked me why I got fired I tell her the story and she says no wait let me talk to someone. She comes back and says (b) (6), (b) (7)(C) the other owner wants to talk to me. (b) (6), (b) (7) tells me he wants me to close the store and come to the head office to talk to me I tell them what happened. It was clear to me that they didn't know I was fired or anything else. They said that I wasn't fired and that they were going to get more involved with the store and farm and make sure that everything was was going to be taken care of. He asked me about inventory but I haven't noticed anything wrong with that and I am starting to feel like that is going to be a register inventory thing and once they learn how to use that they will be able to find out what ever they need. I am making this report because my dad has talked to a friend and after talking to her she expressed that I needed to make this report. I told the head office I was making this report and that I would be sending them a copy. (b) (6), (b) (7)(C) (b) (5), (b) (7)(E)

06/05/2017 17:47:33

Comment : reported before selling contact lenses without a prescription (b) (4), (b) (7)(B)

(b) (5), (b) (7)(E)

06/07/2017 13:13:47

Comment : Hi, Please investigate and suspend the following domain:(b) (4), (b) (7)(B)
drugs. Their shipping page clearly shows that they don't deny being involved in illegal actions (b) (4), (b) (7)(B)

It is an online pharmacy selling prescription drugs/illegal

06/08/2017 10:28:28

In payment terms(b) (4), (b) (7)(B) something a legitimate company would request. Company claims to be online for several years yet website has only been registered a few months ago. Additionally, they are listed in (b) (4), (b) (7)(B) database of fraudulent websites here:(b) (4), (b) (7)(B)

They list(b) (4), (b) (7)(B)

as method of payment - not

(b) (5), (b) (7)(E)

Comment : I'm reporting this group unlawful immigration people, they are well organized and trained to manufacture, transport, import and resell large amount unlicensed non- prescription drugs, also they perform uric acid injection and (b) (4), (b) (7)(B) injection (b) (4), (b) (7)(B)) for cash income. They also have been doing advertising over social media smart phone Apps. They have been doing this illegal stuffs since 2015. Each injection and cosmetic surgery cost to their costumers from \$1000 - \$5000, and only cash deal. (b) (4), (b) (7)(B) We do not have their real name and real phone number at this moment. All their contacts are been done over a smart phone App. (b) (4), (b) (7) Below is the main contact from this group info for your reference: Name: Unknown Phone: Unknown (b) (4), (b) (7)(B) ID : (b) (4), (b) (7)(B) Surgery Office Address: (b) (4), (b) (7)(B) also below address: (b) (4), (b) (7)(B) (b) (5), (b) (7)(E)

06/12/2017 12:42:45

Comment : (b) (4), (b) (7)(B) I selling poisonous drugs regulated by the government. (b) (5), (b) (7)(E)

06/14/2017 02:04:37

Comment : I am a former employee of (b) (4), (b) (7)(B) . A homeopathic pharmaceutical manufacture. I would like to report that they have been using illegal silver in their products for years without listing them on the label. Only recently after being audited by the FDA did they stop using the silver in their formulas. (b) (6), (b) (7)(C) had a number of employees including managers (b) (6), (b) (7)(C) stay after hours during their audit to strip labels and hide evidence that they were using this non approved homeopathic ingredient.

06/14/2017 12:56:18

Comment : (b) (4), (b) (7) is a company that is using a (b) (4), (b) (7)(B) to treat Amblyopia. They do not have FDA approval however, they claim to be "FDA Cleared". They are making a claim to treat Amblyopia without any apparent clinical data or FDA approval. (b) (4), (b) (7)(B)

06/16/2017 17:51:45

Comment : (b) (4), (b) (7)(B) is a company that is using a video technology to treat Amblyopia. They do not have FDA approval. They are making a claim to treat Amblyopia without any apparent clinical data or FDA approval. (b) (4), (b) (7)(B)

06/16/2017 17:53:07

Comment : The API and OSD drugs manufacturing sites of (b) (4), (b) (7)(B) . Has lots of malpractices related to the manufacturing quality record integrity. The drugs are manufactured and the records are generated later on. This can be found in the records during the period of 2013 - 2015. The ground water which is being used for these manufacturing is also of not good quality. The ground water is contaminated with the chemicals. The facility at (b) (4), (b) (7)(B) also has (b) (4), (b) (7)(B) manufacturing facility in a different company name, which belongs to the group only. They have buried loads of chemicals waste below ground which has contaminated ground water, the same is the case in API manufacturing facility. How this must be affecting the quality of drugs being manufactured is for you to find out and ascertain. I only thought to provide your organization a lead into it. 06/20/2017 02:45:04

Comment : This company (b) (4), (b) (7)(B) is selling medical devices that are not registered AND are hurting people. They sell a device called (b) (4), (b) (7)(B) It is similar to the old (b) (4), (b) (7)(B) devices that were shut down by FDA. These people claim this device can cure anything including cancer as you can see on their websites I listed below: My name is (b) (6), (b) (7)(C), (b) (7)(D) and I am the owner and operator of (b) (6), (b) (7)(C), (b) (7)(D) Products. (b) (6), (b) (7)(C), (b) (7)(D) 06/20/2017 09:08:08

< He is the true owner/operator (b) (6), (b) (7)(C) works for him (AKA) (b) (6), (b) (7)(C) I hope you can do something about this quickly as mentioned above people are getting hurt I bought one get a shock that sent me to the floor!! I sent my unit back to (b) (6), (b) (7)(C) and never heard from him again as he doesn't take my calls. My unit cost me over (b) (4) (b) (6), (b) (7)(C), (b) (7)(D) . Thank you.

Comment : The warehouse i work for had a coworker remove labels off of a carton of (b) (4), (b) (7)(B) food additive and replace it with a label off of a completely different kind of additive. I have proof of this. (b) (5), (b) (7)(E) 06/20/2017 10:24:10

Comment : I just discovered that it appears one can purchase a (b) (4), (b) (7)(B) machine from (b) (4), (b) (7)(B) without a prescription? Although, I am already a (b) (4), (b) (7)(B) user and obtained mine from (b) (6), (b) (7) it seems that one can simply go onto this site and make a purchase without having the prescription. 06/21/2017 21:26:56

Comment : We are a (b) (4), (b) (7)(B) . We were approached last week by a company called (b) (4), (b) (7)(B) via (b) (4), (b) (7)(B) offering (b) (4), (b) (7)(B) at a very good price. In review of their license they submitted to us for review and authentication, it does not entitle them to distribute pharmaceuticals, and looks similar to (b) (4), (b) (7)(B) I have spoken to both (b) (4), (b) (7)(B) . Neither have heard of this company nor the address they claim to be working from stated on the license. The emails offering products have come from come from (b) (6), (b) (7)(C) , claiming to work for: (b) (4), (b) (7)(B) Please Note (b) (4), (b) (7)(B) are a legitimate company which we already work with and have informed them a person or persons are claiming to work for them. We have also reviewed (b) (4), (b) (7)(B) website, that also offer scheduled controlled substances, including other restricted drugs (b) (4), (b) (7)(B) I am happy to pass all information and communications, including the supposed license they hold in the state of (b) (4) . Please feel free to contact me at (b) (6), (b) (7)(C), (b) (7)(D) or call (b) (6), (b) (7)(C), (b) (7)(D) . Thank you (b) (5), (b) (7)(E) 06/22/2017 10:54:32

Comment : A patient advocacy forum saw someone recently offer this comment (b) (4), (b) (7)(B)

06/28/2017 07:47:58

looked at the site (b) (4), (b) (7)(B) and was amazed to see they have a US number and seem to intimate from their website that their product is available in the US. Pretty sure its not approved by FDA. Seems their 'data' pretty sketchy too. I suspect they are marketing this unapproved drug into FDA territory. Good luck (b) (5), (b) (7)(E)

Comment : (b) (4), (b) (7)(B) the address: (b) (4), (b) (7)(B) This company is the source of most of Misbranded Drugs that were Labeld as (b) (4), (b) (7)(B) However these supplements actually contained an unregulated drug - an (b) (4) - which pose a serious health risk. some examples of his products (b) (4), (b) (7)(B)

06/29/2017 23:34:45

Comment : Nutritional Supplement manufacturer/Distributor making anti-cancer health claims: (b) (4), (b) (7)(B)

06/30/2017 13:29:14

Comment : No variance operator, outdoor laser show, beams entering through windows of buildings at unsafe distances and levels. As beams entering airspace. This is getting ready to happen in the next hour or so at the (b) (4), (b) (7)(B) for an event called (b) (4), (b) (7)(B)

07/01/2017 19:01:44

Comment : Illegal outdoor laser operation at (b) (4), (b) (7)(B)

07/01/2017 19:14:21

Comment : (b) (4), (b) (7)(B) after opening (b) (4), (b) (7)(B) cigarette pack noticed some filters have slit puncture through middle of them and one short thick white hair attached to filter paper. (b) (5), (b) (7)(E) 07/04/2017 20:59:59

Comment : I suspect the office of (b) (6), (b) (7)(C) is illegally importing (b) (4), (b) (7)(B) 07/05/2017 20:23:01

Comment : (b) (4), (b) (7)(B) has recently submitted a supplemental NDA for a combination of (b) (4), (b) (7)(B) . There should be black box warning of urinary retention. In addition, this combination is already being given to the specific population off label of needed. The only reason it is submitted is so that marketing can start promoting it to a wider patient population thereby leading to misleading prescription. This combination is not superior over (b) (4), (b) (7)(B) which indicates that it is a very poor combination and should be used only for a specific group of people under a physician's guidance. These drugs are not together in the same formulation. They are separate tablets and (b) (4), (b) (7)(B) It is not appropriate to approve this only for marketing and sales divisions and their desperation to talk about it. Let the doctors do what is right for the patients. There is no strong data for the approval of this combination. 07/05/2017 22:51:39

Comment : (b) (6), (b) (7)(C) (b) (4), (b) (7)(B) posted the following on a (b) (4), (b) (7)(B) (b) (4), (b) (7)(B) 07/06/2017 16:47:21
The product she is selling is (b) (4), (b) (7)(B) , a rx birth control pill that I found to be discontinued (b) (4), (b) (7)(B) . I researched the drug online and found that it was killing women, most likely the reason it is discontinued in the United States. The post can be located if you type her name on (b) (4), (b) (7)(B) but instead of clicking on her name, you let the public posts show up after searching her name. You can then click "view more" and see the post. The original page on which she posted it no longer shows the post (b) (4), (b) (7)(B) . Also, if necessary, I have a screen shot of the post. (b) (6), (b) (7)(C) and immediately moved into this address, (b) (6), (b) (7)(C) is suspected that she was not authorized to be in the United States, although it hasn't been confirmed. The concern is that someone will get a hold of this drug (a teen perhaps who doesn't want their parents to know they need birth control), and that it could have detrimental affects on the purchaser since it is no longer sold in the United States. (b) (6), (b) (7)(C) is also not a licensed pharmacist and should not be selling rx drugs online. I hope this is the correct place to report the activity. Additionally, she recently reduced the sale to \$20 a piece.

Comment : I have received an email that looks like illegal drug sales via the Internet. A copy of this email is located at the following URL: (b) (4), (b) (7)(B) 07/07/2017 21:10:10

Comment : Dear Sir, (b) (4), (b) (7)(B)

has obtained evidence indicating that a distributor in (b) (4), (b) (7)(B) has distributed counterfeit (b) (4), (b) (7) products. The products are (b) (4), (b) (7)(B)

07/11/2017 17:49:12

In the first instance, the catalog number and lot number falsely represent (b) (4), (b) (7) numbers. In the second two instances, the catalog numbers and lot numbers are not (b) (4), (b) (7)(B), however the labeling and certificates contain (b) (4), (b) (7) logos and include counterfeit (b) (4), (b) (7) QA signatures. We can provide additional background information regarding the counterfeit items upon request, including photographs. To our knowledge, none of these counterfeit items have been distributed in the United States. We are writing to ask whether FDA requires more notification than this, and also to inquire whether our responsibility extends to notification of the (b) (4), (b) (7) authorities. If so, we request information on how best to make such a notification. My contact information appears below. Regards, (b) (6), (b) (7), (C), (b) (7)(D)

Comment : Hello, I ordered two supplements off of (b) (4), (b) (7) that appeared to have banned and hidden, illegal ingredients. I obtained this information from the FDA's list of tainted products. These products should have been taken off the market but appear to be in circulation still. These products are (b) (4), (b) (7)(B)

They are listed here:

07/11/2017 21:44:03

provide more information if necessary.

I can

Comment : I have been recently involved with a product remediation for a major medical device manufacturer (b) (4), (b) (7)(B) as an independent clinician. I was hired through a third party recruiter in (b) (6), (b) (7)(C) I was brought in as the product expert as I had formerly worked for this division of (b) (4), (b) (7)(B) as the Sales Training Manager and I possess intimate knowledge of the product line and its functionality, as well as how it relates to harms to patients. During the remediation, I began to notice significant infractions, most specifically FDA regulatory violations regarding the writing of harms. None of the legacy files from which data was being transferred actually had harms populated. It was my job to do so in the new files. Two clinicians currently on the project are currently falsifying information to these files in order to decrease the company's liability both financially and legally. They have both put this information in writing and I have copies of those emails. The clinicians in question are (b) (6), (b) (7)(C) and (b) (6), (b) (7)(C) . Both clinicians are 1099 independent contractors of (b) (4), (b) (7)(B) As soon as I began to uncover their infractions and incompetencies, I was terminated. Prior to my termination, I was involved in hiring a new clinician to complement my skill set. Her name is (b) (6), (b) (7)(C) and she is an expert in FDA regulations with regard to medical device. (b) (6) is still currently employed, but is also beginning to experience the same resistance to her inquiries that I did. She has been deliberately been excluded from the re-writing of protocol by the two previous clinicians, as well as one of the Usability engineers, (b) (6), (b) (7)(C) . The three of them have been excluding (b) (6) as it would expose their cover-up. I am fully willing to cooperate with the FDA in further investigation needs, and (b) (6), (b) (7)(C) is available onsite to help as well. She has continued to gather information for me, and has forwarded over 30 emails to her personal email in order to document these continuous infractions. It is clear that (b) (6), (b) (7)(C) are completely unaware of the gravity of their offenses. There are other issues of which I would have to show you documentation. Please contact me as soon as possible. (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) (b) (6), (b) (7)(C) It is critical that the FDA get back to the (b) (4), (b) (7)(B) plant asap to further investigate. I have file names and numbers for harms that are falsified, along with their severity of harm and inappropriately written sequence of events. The Director of Regulatory for the (b) (4), (b) (7)(B) division is (b) (6), (b) (7)(C) , and the manager assigned to run this consulting group is (b) (6), (b) (7)(C) . These infractions and abuses, as well as consistent verbal abuse upon being exposed, is and has been consistently reported to (b) (6), (b) (7)(C) , as well as (b) (6), (b) (7)(C) , with no intervention. Their solution was to terminate their only product expert to stop the exposure to the continuous cover ups and illegal activity. Please contact me as soon as possible for further information. Kind Regards, (b) (6), (b) (7)(C), (b) (7)(D)

07/12/2017 15:01:35

Comment : (b) (6), (b) (7)(C) Purchased in excess of 200,00.00 dollars worth of neurotoxin and fillers from (b) (4), (b) (7)(B) Dispensing controlled substances without an authorized provider in house. Dispensing expired medications.

07/13/2017 11:45:55

Comment : (b) (4), (b) (7)(B) The advertising leading to this, as well as the content are clearly fraudulent, in spite of any fine-print disclaimer (e.g. Location-based clause saying "(b) (4), (b) (7)(B) Please, please, make an example out of these guys. (b) (6), (b) (7)(C), (b) (7)(D)

07/14/2017 20:10:48

Comment : (b) (4), (b) (7)(B) is illegally selling non fda approved systems in the realm of radiography/fluoroscopy. They are using quotes from their (b) (4), (b) (7)(B) platform to be a "placeholder" for their in development product, the (b) (4), (b) (7)(B) (b) (6), (b) (7)(C), the leaders of the business at (b) (4), are teaching the salesforce to do this. The company developed "special language" for their quotes that the reps are using to pro actively sell and book orders as (b) (4), (b) (7)(B) (product they have approval for) but they are for (b) (4), (b) (7)(B). The plan is to convert the orders in the backlog to (b) (4), (b) (7)(B) from the (b) (4), (b) (7)(B). They also are setting the price for the (b) (4), (b) (7)(B) to equal the projected price of the (b) (4), (b) (7)(B). This is illegal. They are preselling a non FDA approved product and taking orders for it. They are telling customers that the system will convert to (b) (4), (b) (7)(B). This has happened at (b) (4), the sales rep there is (b) (6), (b) (7)(C) who did this. He told the customer they came up with a very creative way to (b) (4), (b) (7)(B) for them. They are currently working on orders like this in (b) (4). They have many orders places on the West Coast like this as well.

07/19/2017 06:54:23

Comment : I listen to (b) (4), (b) (7)(B) they are running ads that I think are a disgrace & a sham & should not be allowed. It's (b) (4), (b) (7)(B). And they are running testimonials from people supposedly helped with Everything from MS to diabetes to Digestive disorders. And other serious illnesses that I can't recall at the moment. I think they get around the law by not actually making any claims themselves .Talk about the old cure all snake oil salesman. The thing that bugs me is the fact that these ads may stop getting someone from getting the real treatment that they need. I'm sure that they aren't the only ones running these ads. Somebody needs to stop them !

7/19/2017 9:59