



Buyer Beware - The Risks and Dangers of Purchasing Drugs Online



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Office of Criminal Investigations



Objectives

- Understand the mission of and activities of the Office of Criminal Investigations.
- Educate consumers about the true nature of many online pharmacy operations.
- Detail recent criminal investigations and enforcement actions involving illegal online pharmacies.
- Understand how FDA is leveraging global law enforcement partnerships in the fight against counterfeit drugs.
- Advise consumers on what to do if they suspect they have received a counterfeit or substandard drug.

Office of Criminal Investigations

- Established in March 1992
 - Increased criminal violations U.S. Food, Drug and Cosmetic Act.
- Approximately 200 Special Agents
- Average Federal Law Enforcement Experience 12-1/2 years
- Training
 - Primary Criminal Investigator Training
 - OCI Special Agent Training Program
 - FDA Food and Drug Law Course
- Select Continuing Education Programs:
 - Cybercrime Investigations
 - Computer Forensics
 - Financial / Asset Forfeiture Investigation
 - Polygraph

General Areas of Enforcement

- Counterfeit/unapproved drugs, vaccines, medical devices, tobacco.
- Pharmaceutical or medical device cargo theft.
- Prescription Drug Marketing Act violations.
- Illegal diversion of pharmaceuticals and other regulated products.
- Product tampering & product substitution crimes.
- Health fraud.
 - Treatments/cures/devices
- Application and clinical investigator fraud.
- Safety/integrity of the nation's blood supply.
- Adulteration and/or misbranding of food.
- Internet facilitated crimes involving FDA regulated products.
- Illegal importation of FDA regulated products.
- Off-label promotion of drugs and devices.

Enforcement Statistics

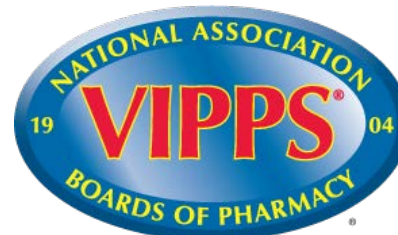
- From 2009-2012, OCI Investigations resulted in :
 - 1,259 Arrests
 - 1,274 Convictions
 - \$10.6 Billion in Fines and Restitution

Internet Pharmacies

- Pharmacies regulated by the states.
- Federal statutes involving drug distribution in interstate commerce:
 - Ryan Haight Online Pharmacy Consumer Protection Act of 2008.
 - Food, Drug and Cosmetic Act.
 - Fraud and smuggling statutes

Internet Pharmacies

- NABP: January 2013 report shows 97% of 10,000+ Web sites analyzed operate out of compliance with U.S. pharmacy laws.
 - V.I.P.P.S. Program
 - .PHARMACY gTLD Proposal
- Center for Safe Internet Pharmacies



International Collaboration

- Permanent Forum on International Pharmaceutical Crime
- Interpol





Office of Criminal Investigation Case Example

Counterfeit Alli[®] Investigation

Initial Complaint

- Reported to FDA-OCI on January 12, 2010
- Contained Sibutramine
- eBay, Amazon and other online sellers



Alli Counterfeit Summary of Initial Investigation

Voluntary Report of Suspected Counterfeit to
FDA Office of Criminal Investigation
January 12, 2010



Alli® Counterfeit Complaint



Authentic Alli Sample



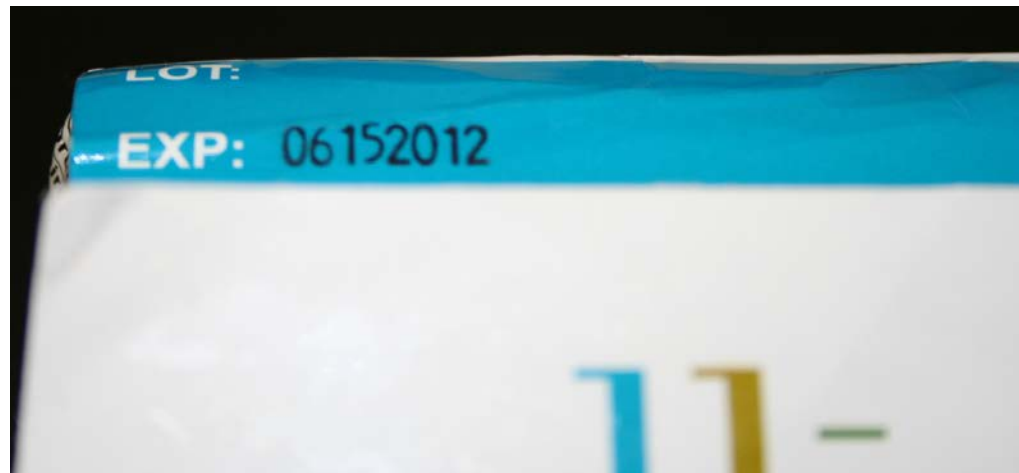
Counterfeit Alli Sample



Alli[®] Counterfeit - Carton

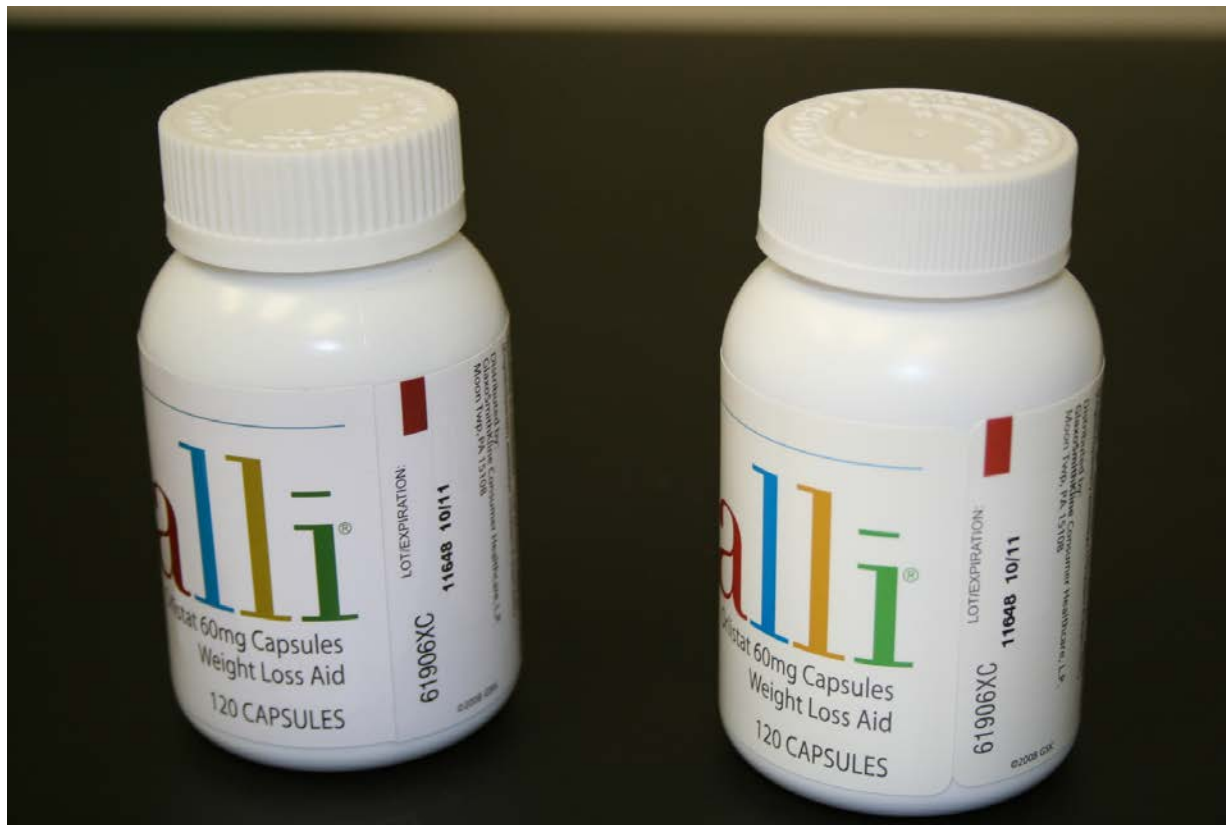


Authentic Alli Sample



Counterfeit Alli Sample

Alli® Counterfeit – Comparison of Bottle



Counterfeit Alli Sample

Authentic Alli Sample

Alli[®] Counterfeit – Seal



Authentic Alli Sample

Counterfeit Alli Sample

Alli® Counterfeit - Capsule



Counterfeit Alli Sample

Authentic Alli Sample

Alli® Counterfeit Complaint – Capsule Content



Authentic Alli Sample



Counterfeit Alli Sample

Public Communication

FDA NEWS RELEASE

For Immediate Release: January 18, 2010

Media Inquiries: Tom Gasparoli, 301-796-4737, thomas.gasparoli@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA Warns Consumers about Counterfeit Alli

The counterfeit products contain controlled substance sibutramine

The U.S. Food and Drug Administration is today warning consumers about a counterfeit

UPDATED Public Health Alert: Counterfeit Alli containing sibutramine

1/23/2010

The U.S. Food and Drug Administration (FDA) is updating its warning to the public about a counterfeit of Alli 60 mg capsules (120 count refill pack) being sold over the internet, particularly at online e-

Public Response

- Flood of consumer complaints
- One consumer suffered a mild stroke after ingesting the counterfeit Alli®.
- Many others experienced adverse reactions consistent with Sibutramine.
- Victims interviewed by OCI

Industry Action

- Cooperation with eBay, Amazon and other B2C websites.
- GSK Security



Criminal Investigation

- OCI Investigation identified Chinese Source of Supply
- Identification of “Tom” via internet communication.
- Undercover Operation
- International Cooperation

Criminal Investigation

- Shengyang Zhou, of Kunming, Yunnan, China
- Arrested March 23, 2010
- Guilty: trafficking and attempting to traffic in counterfeit goods.
 - 87 months (over 7 years) in federal prison
 - restitution totaling \$504,815.39

*Chinese man sentenced in weight-loss
drug scam*



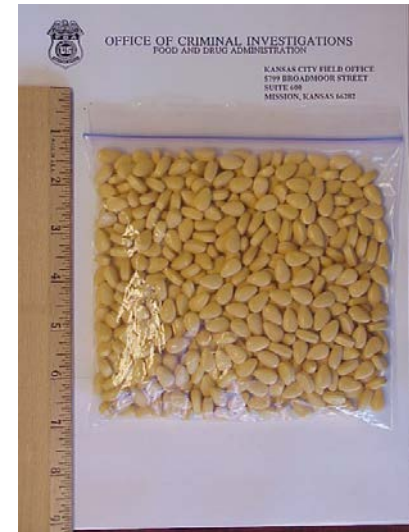
Office of Criminal Investigations Case Example

Newpharm.net



Customs and Border Protection Seizures

- Referral to OCI
- Joint Investigation with ICE and the U.S. Postal Inspection Service



Criminal Investigation

- Identification of U.S. drop shippers
- Identification of websites



Criminal Investigation

- Drug Supplier located in China
- Website Operators located in Israel
- Customer Service located in the Philippines
- Banking/Money Laundering in Cyprus and Seychelles.

Joint Investigation with Hong Kong Customs and Excise

- Drug Supplier
- Arrest of Jian Qiang Xu
- Prosecution in China



Joint Investigation with Israeli Police

- Website Operators
 - Moshe Dahan:
 - Probation in Israel
 - \$50,000 forfeiture
 - Benny Carmi:
 - 10 months in prison in U.S
 - \$85,000 forfeiture





Office of Criminal Investigations Case Example

Allmedspharmacy.net

Website Hosted in the U.S.

- Variety of suspected counterfeit, unapproved, misbranded and controlled substances.
- “seizure” guarantee.
- Drugs sourced from Pakistan.

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Welcome to AllMedsPharmacy.net

Your Reliable Source for Prescription Drugs Without Prescription

Promotions				Valid until: 11/15/2007	
Brand name	Type	Dosage	Quantity	Price	
Darvocet	Generic	32.5 - 325mg	100 Tabs	USD 129.00 USD 119.00	Buy
Dormicum	Brand	7.5mg	30 Tabs	USD 59.00 USD 54.00	Buy
Mogadon	Brand	5mg	50 Tabs	USD 85.00 USD 79.00	Buy
Xanax	Generic	1mg	30 Tabs	USD 69.00 USD 62.00	Buy

All Meds Pharmacy is an International Online Pharmacy. Our International Pharmacy offers a large selection of brand and generic prescription drugs. All prescription drugs can be obtained in our online pharmacy **Without Prescription** although we do recommend you consult a physician before placing your order.

All Meds Pharmacy has **NO Consultation Fees, No Membership Fees** or any other hidden fees. There are no appointments or embarrassments at our online international pharmacy.

All the prescription drugs offered in our International Pharmacy are obtained directly from licensed pharmaceutical manufacturers and international distributors. Therefore, we guarantee the highest quality of the prescription drugs at the lowest price.

Order Processing:
Orders are reviewed by a Risk Assessment Team. Normally orders are reviewed and approved within 24h (except weekends and holidays). If required, a team member will call you.

Shipping:
Once the order is approved, it will be shipped by our Logistics Team. We ship to most countries. We ship from Pakistan.

Orders are shipped by International airmail. With airmail, delivery is generally 10-14 days. We allow a delivery time of max. 30 days.

Our Benefits:

- Save up to 80% on Medical Bills

Top Sellers

- Anxiety**
- Ativan
- Xanax
- Arthritis**
- Celebrex
- Cholesterol**
- Lipitor
- Epilepsy**
- Klonopin
- Gastro-Intestinal**
- Nexium
- Insomnia**
- Dormicum
- Mogadon
- Restoril
- Ambien
- Muscle relaxant**
- Soma
- Other**
- Zyban
- Pain relief**
- Darvocet
- Celebrex
- Ultram
- Weight loss**
- Meridia
- Acomplia
- Phentermine**
- Anti-depression**
- Paxil
- Zoloft
- Prozac
- Men's Health**
- Cialis
- Levitra
- Propecia
- Viagra

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Brand name
Generic Name
Therapy

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V W X Y Z

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OFFLINE

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Criminal Investigation

- Confirmed counterfeit, unapproved, misbranded and controlled substances.
- Identification of website operator Manuel Calvelo in Costa Rica
- Undercover Investigation
- International Cooperation
 - Costa Rica Judicial Investigation Agency (OIJ),
 - Interpol

Extradition and Conviction

- Smuggling charges dropped
- November 2010 – Extradited from Costa Rica
- February 2011 – Pleaded guilty
 - Drug counterfeiting and distribution of a controlled substance
- May 2011 – Sentenced to 4 years in federal prison



BeSafeRx: Know Your Online Pharmacy

www.fda.gov/besaferrx



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Resources for You

- Information for Consumers (Drugs)
- Buying & Using Medicine Safely
- Buying Medicines Over the Internet
- BeSafeRx: Know Your Online Pharmacy**

Resources for You

- About BeSafeRx
- For Campaign Supporters
- For Health Professionals
- Campaign Materials
- For the Media

BeSafeRx: Know Your Online Pharmacy



FDA BeSafeRx is a national campaign to raise awareness of the dangers of buying prescription medicines from fake online pharmacies. This campaign provides the resources to help consumers:

Know the Risks

Learn the dangers of buying from a fake online pharmacy.



Know the Signs

Identify the signs of a fake online pharmacy.



Know Your Online Pharmacy

Find a safe online pharmacy.



For further information, contact us at 1-888-463-6332 or druginfo@fda.hhs.gov.

Know Your Online Pharmacy
(featuring Gary Coody, FDA's National Health Fraud Coordinator)



Questions?