Adulteration of Herbal Medicinal Products with Active Pharmaceutical Ingredients: Global Trends

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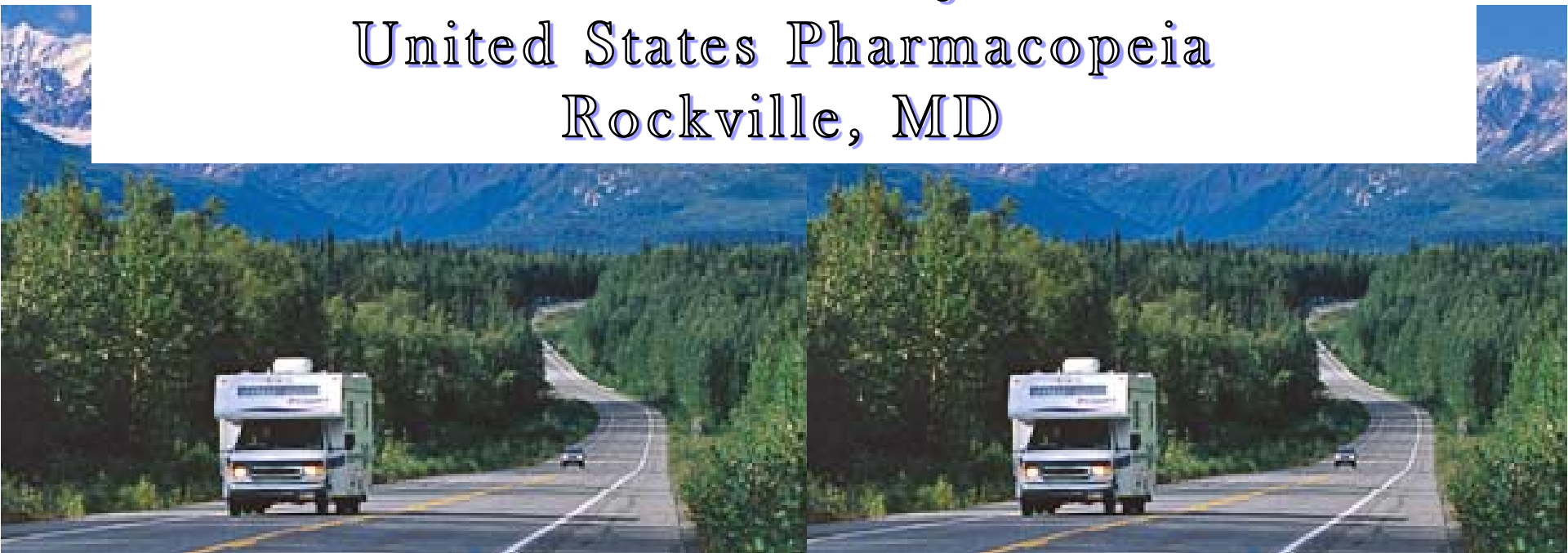
United States Pharmacopeia
Rockville, MD




Welcome to USP

USP's Mission

- To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.

Disclaimer

- All comments are my personal observations on the subject and do not represent USP view

Brief Outline of my Presentation

Background information on adulteration

Growing trend of intentional adulteration

Recent examples of Intentional adulteration domestically and internationally

Efforts being made by USP and other Organizations to keep adulterated products from entering the market

Adulteration

- Intentional adulteration is define as the fraudulent, substitution or addition of a substance in a product for the purpose of increasing the apparent value of the product or reducing the cost of its production, i.e., for economic gain.

- Simple definition:

  Reducing the purity of an article by the addition of a foreign or inferior substance

Adulteration in the 1st Century CE – per Dioscorides

Dioscorides noted that frankincense (*Boswellia sacra*, Burseraceae) when burned was easily flammable, and the smoke was clear with a pleasant fragrance.

Dioscorides' *Materia Medica* provides **40 adulteration examples**, 30 including **methods of detection**:

Table 1 Adulteration of glycerin with DEG

Year	Location	Details regarding adulteration	Total deaths
1937	USA	Elixir of sulfanilamide: DEG used in formulation of this drug product	107
1969	South Africa	Sedative formulated with DEG	7
1985	Italy	Found in wines from grapes grown in Austria Recall ensued. The US FDA tested 1,000 imported wines and found 58 with DEG	No known deaths
1986	India	Industrial-grade glycerin substituted for medicinal grade: contaminated with DEG	14
1990	Nigeria	Acetaminophen pediatric syrup—compounded	40
1990–1992	Bangladesh	Acetaminophen pediatric syrup—compounded	339
1995–1996	Haiti	Acetaminophen cough syrup	85
2006	Panama	Cough/antiallergy syrup	46
2007	USA	Toothpaste from China labeled to contain sorbitol actually contained up to 5% DEG	No known deaths

DEG, diethylene glycol; FDA, Food and Drug Administration.

Between June and September 1990, 47 children died at Jos University Teaching Hospital, Nigeria from ingestion of paracetamol syrup adulterated with diethylene glycol

Annals of Tropical Paediatrics (1992) 12, 235–238

Diethylene glycol poisoning in Nigerian children

H. O. OKUONGHAE, I. S. IGHOGBOJA, J. O. LAWSON & E. J. C. NWANA*

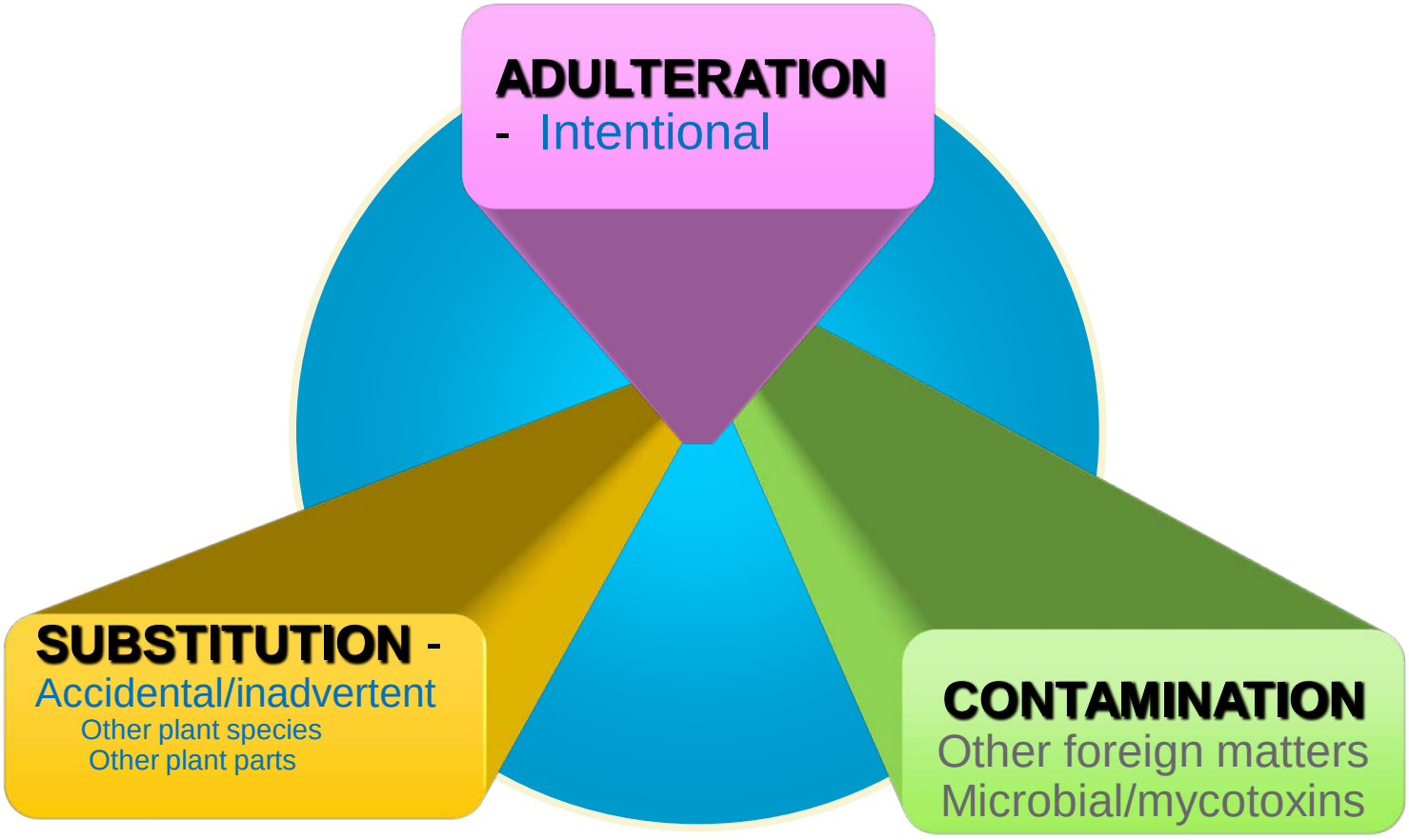
*Departments of Paediatrics and *Pathomorphology, Jos University Teaching Hospital, Jos, Nigeria*

(Received 4 September 1991)

Summary Between June and September 1990, 47 children died at Jos University Teaching Hospital, Nigeria from ingestion of paracetamol syrup adulterated with diethylene glycol. Most of the children presented with anuria, fever, vomiting, diarrhoea and convulsions. Signs on admission were tachycardia, acidotic breathing, pallor, oedema and hepatomegaly. Laboratory findings included hyperkalaemia, acidosis, elevated creatinine level and hypoglycaemia. Management consisted of correction of dehydration and acidosis plus administration of antibiotics when indicated. None of the children had dialysis. All died within 2 weeks of admission. Proper government supervision of pharmaceutical companies and their agencies is urgently needed in order to prevent any future occurrence of such tragic deaths.

Jos

ADULTERATION
Affects Botanical products quality

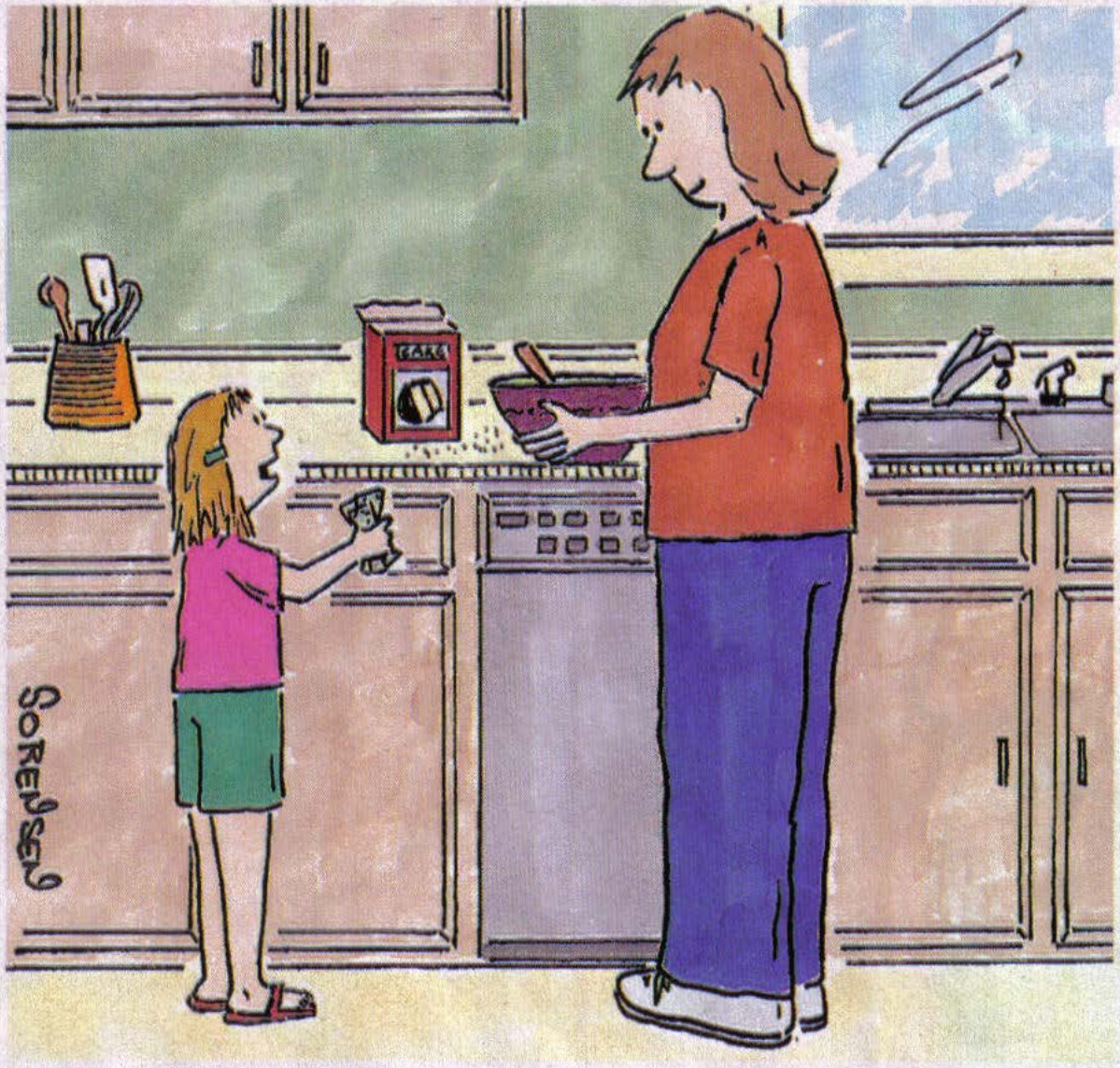


Adulteration

- Can potentially lead to
  - Unsafe products and herbs
  - Treatment failure
  - Serious side effects to death
- "Manufacturers, distributors, importers and others in the supply chain of dietary supplements are responsible for ensuring that their products comply with the statutes and regulations FDA enforces."
  - FDA Letter to Dietary Supplement Manufacturers, Dec. 2010.

High Risk Categories of HMPs

- Sports Supplements (major)
- Weight Loss Supplements (major)
- Men's Virility (ED) Supplements (major)
- Blood Sugar Support Supplements (growing)
- Mood/Well Being Supplements (re-emerging)
- Sleep Aid Supplements (re-emerging)
- Cardiovascular Support Supplements
- Nootropics (cognitive support) Supplements



"After an hour of trying to sell lemonade, we put in more water and less lemon, called it flavored water, and made tons more money!"

"avoid"

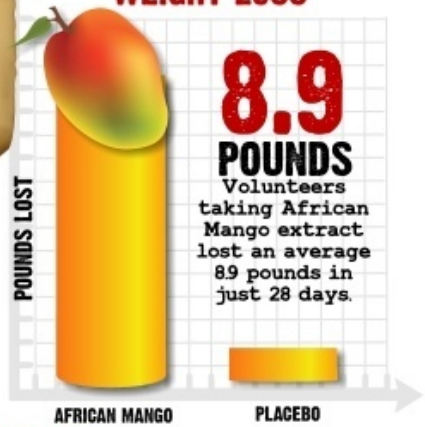
Drinks and dietary supplements containing aloe vera are increasingly popping up at online retailers and in health food stores boasting of the plant's "powerful healing properties," including claims that it "balances stomach acidity," detoxifies, or promotes "overall well-being." But carefully conducted studies by the U.S. government found clear-cut evidence that aloe vera extracts caused intestinal cancers in male and female laboratory rats. For that reason, the nonprofit Center for Science in the Public Interest is giving aloe vera an "avoid" rating in its Chemical Cuisine guide to food additives.

Government Tests Point to Cancer in Rats
August 21, 2013

THE CLINICALLY TESTED HEALTH BENEFITS OF AFRICAN MANGO

www.PureAfricanMango.com

EFFECT OF AFRICAN MANGO ON WEIGHT LOSS



8.9 POUNDS

Volunteers taking African Mango extract lost an average 8.9 pounds in just 28 days.

STRENGTHENS HEALTH MEASURES

In tests, African Mango extract reduced total cholesterol by 39%, triglycerides by 44.9%, and bad LDL cholesterol by 45.6% in 28 days.

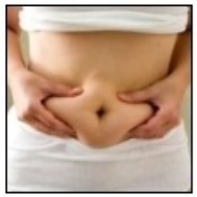
Subjects taking African Mango extract lost over 8 pounds and 2 inches in just 28 days.

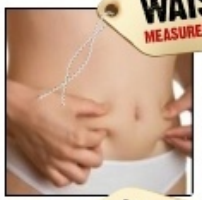
INHIBITS FAT STORAGE

Helps Reduce the Fattening Effects of Food

Research shows African Mango acts as a "super soluble fiber," helping delay gastric emptying, thereby reducing the fattening effects of certain foods.

REDUCES WAIST MEASUREMENT





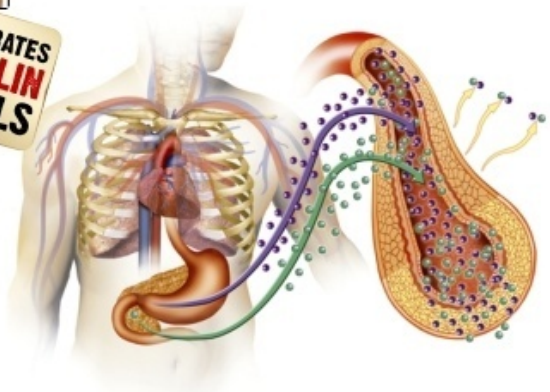
Subjects Lost Over 2 Inches from Their Waist in 28 Days

Men and women supplementing with African Mango extract (1.05 grams), 30 minutes before meals, three times daily, lost an average of over 2 inches from their waistlines within just 28 days.

MODERATES INSULIN LEVELS

May Reduce the Elevation of Blood Sugar

When taken 30 minutes before meals, the soluble fiber of African Mango supports a more gradual absorption of dietary sugar. This effect can reduce the elevation of blood sugar levels that is typical after a meal, which may lead to enhanced insulin sensitivity and fat loss.



Source: Lipids Health Dis. 2005 May 25;4:12. Copyright 2011 www.PureAfricanMango.com

The Frequency and Characteristics of Dietary Supplement Recalls in the United States

Table. Characteristics of Class I Drug Recalls of Dietary Supplements, 2004 to 2012

Characteristic	Supplements, No. (%)
Drug products recalled, Total No.	237 (100)
Recalls by year, No.	
2012	16 (7)
2011	30 (13)
2010	117 (49)
2009	47 (20)
2008	8 (3)
2007	12 (5)
2006	0
2005	5 (2)
2004	2 (1)
Type of dietary supplement	
Weight loss	64 (27)
Bodybuilding	73 (31)
Sexual enhancement	95 (40)
Other	5 (2)
Manufacturing region	
United States	175 (74)
Outside the United States	57 (24)
Not recorded	5 (2)
Reason for recall	
Unapproved ingredient/unapproved drug	237 (100)
Lots recalled	
1	17 (7)
2-25	14 (6)
>25 or all	161 (68)
Data not available	45 (19)
Extent of distribution	
Several states	8 (3)
Nationwide and Puerto Rico	82 (35)
Beyond the United States and Puerto Rico	147 (62)
Recalls with adverse events mentioned in FDA Enforcement Reports	0

JAMA Intern Med. 2013;173(10):929-930

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journal homepage: www.elsevier.com/locate/jpba

A multidisciplinary approach for the analysis of an adulterated dietary supplement where the active pharmaceutical ingredient was embedded in the capsule shell

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United States Food and Drug Administration, Forensic Chemistry Center, Trace Examination Section, Cincinnati, OH 45237, United States

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Adulteration

ABSTRACT

Fourier transform infrared (FT-IR) microspectroscopic imaging, Raman microspectroscopy, optical microscopy and high performance liquid chromatography with mass spectrometric (LC/MS) detection were employed to examine a dietary supplement adulterated with an undeclared active pharmaceutical ingredient (API). While a trace level of the API was detected in the capsule contents, a higher concentration of API was found in the capsule shell, which indicated the use of an unconventional manufacturing process to hide the API and thus avoid detection. This study demonstrates the need for a multidisciplinary approach to provide a complete assessment of a suspect adulterated dietary supplement.

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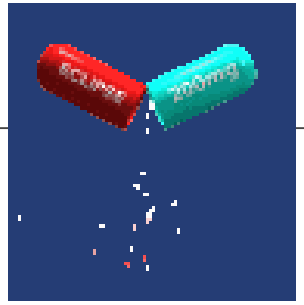

WARNING

Counterfeiters attend Anti-Counterfeiting Conferences

Journal of Pharmaceutical and Biomedical Analysis 57 (2012) 104–108

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Journal of Pharmaceutical and Biomedical Analysis

journal homepage: www.elsevier.com/locate/jpba

Short communication

Isolation and structural elucidation of flibanserin as an adulterant in a health supplement used for female sexual performance enhancement

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ABSTRACT

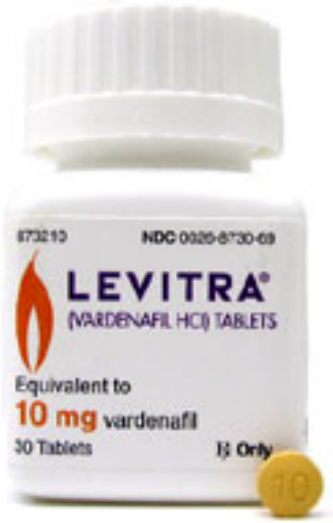
A health supplement used for female sexual performance enhancement was sent to Health Sciences Authority of Singapore for testing. An unknown compound was detected and isolated from the health supplement and its structure was elucidated using LC-DAD, LC-FTMS, NMR and IR. The detected compound was identified to be flibanserin, a non-hormonal treatment developed for pre-menopausal woman with hypoactive sexual desire disorder (HSDD).

In this paper, a report the detection and isolation of flibanserin,
a compound developed to treat HSDD [5–7], from a natural health supplement
(Hypoactive Sexual Desire Disorder (HSDD))

Treatments for ED

- Oral medications
  – phosphodiesterase Type 5 (PDE-5) inhibitors

Viagra (Sildenafil citrate)
Pfizer 1998



Levitra (Vardenafil HCl)
Bayer/GSK 2003

Cialis (Tadalafil)
Lilly 2003

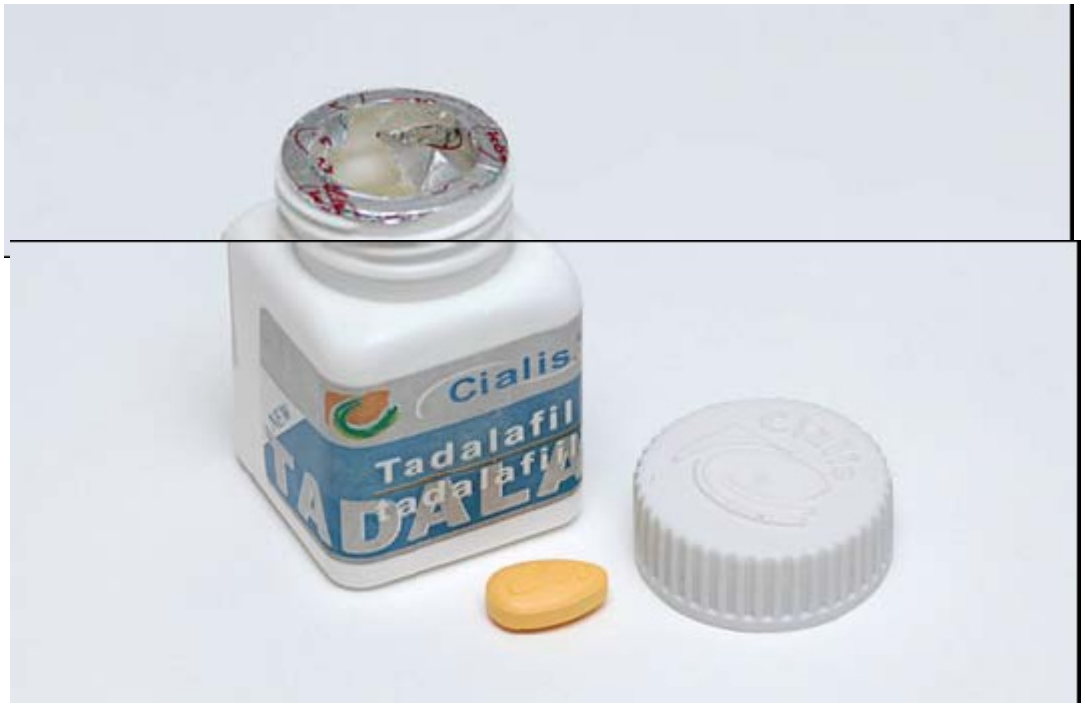
Sexual performance enhancers

Viagra (Pfizer)
Sildenafil citrate

Sildenafil approved (USA) (1998)
Sildenafil detected as adulterant (Asia) (2002)

Power 1 Walnut

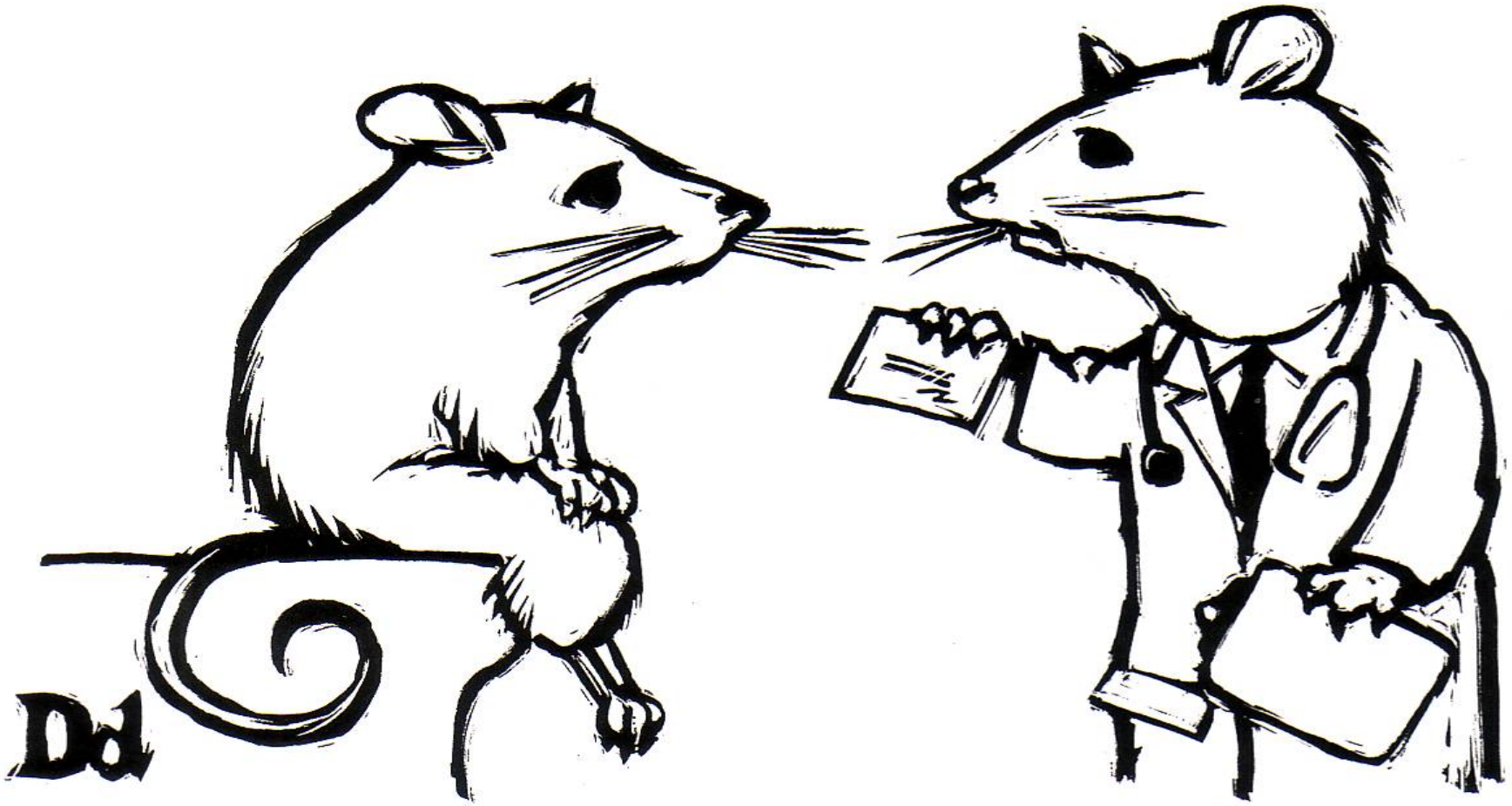
Counterfeit Cialis



Sildenafil & glibenclamide (43 mg)

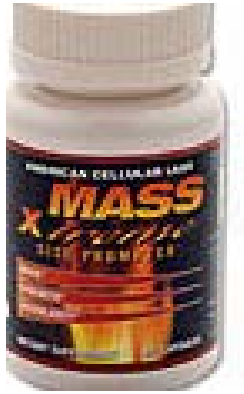
Sildenafil & glibenclamide (45-100 mg)

- sildenafil and high dose glibenclamide detected
- no tadalafil detected



"This stuff worked pretty well on me."

Candy with aminotadalafil



❖**API are chosen to provide specific pharmacological effect.**

HSA May 2008

Sexual Enhancement Products

Both purchased on ebay

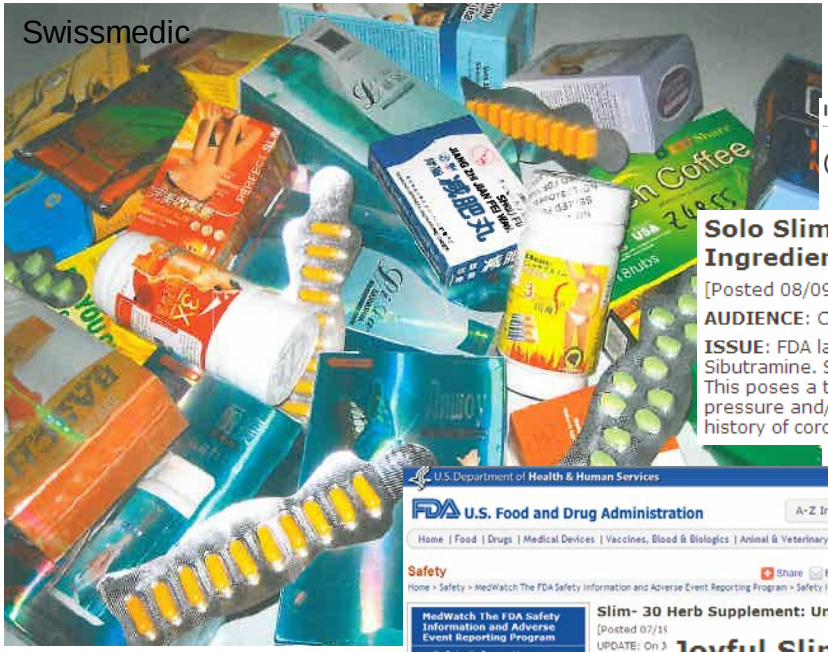
- **France T253**

Sildenafil 140mg

- **Africa Black Ant**

“Free sample”
Sildenafil 96mg +
Tadalafil 6.5mg

Herbal slimming supplements - adulterated with Sibutramin (API)



Warning over unlicensed herbal Payouji tea and Pai You Guo Slim Capsules

The Medicines and Healthcare products Regulatory Agency (MHRA) is warning people of the dangers of taking unlicensed Payouji tea and Pai You Guo Slim Capsules due to concerns over possible side-effects.

Illegale Arzneimittelimporte ...und to contain an

Gefährliche Schlankheitsmittel aus dem Internet

Solo Slim, Solo Slim Extra Strength: Recall - Undeclared Drug Ingredient

[Posted 08/09/2010]

AUDIENCE: Cardiology, Consumer

ISSUE: FDA lab analysis of Solo Slim was found to contain the undeclared drug ingredient Didesmethyl Sibutramine. Sibutramine is an FDA-approved drug used as an appetite suppressant for weight loss. This poses a threat to consumers because ... pressure and/or pulse rate in some patients ... history of coronary artery disease, congestive ...

FDA U.S. Food and Drug Administration

Home > Safety > Recalls, Market Withdrawals, & Safety Alerts

Safety

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Godi International, Corp. Issues a Voluntary Nationwide and International Recall of All weight loss formulas and variation of formulas of Reduce Weight Fruta Planta/Reduce Weight Dietary Supplement.

U.S. Department of Health & Human Services

FDA U.S. Food and Drug Administration

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Safety

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Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Safety Information

Safety Alerts for Human Medical Products

2011 Safety Alerts for Human Medical Products

2010 Safety Alerts for Human Medical Products

Slim- 30 Herb Supplement: Undeclared Drug Ingredient

[Posted 07/1...

UPDATE: On ... action to inclu...

AUDIENCE: C...

ISSUE: FDA l... undeclared N... used as an ap... the safety an...

Joyful Slim Herb Supplement : Recall-Undeclared Drug Ingredient

Posted [07/22/2010]

Audience: Consumers

Issue: FDA lab analysis of this herb supplement was found to contain the undeclared drug, desmethyl sibutramine, an FDA-approved drug used as an appetite suppressant for weight loss. Sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke.

Slimming Beauty Drug Ingredient

[Posted 10/08/2010]

AUDIENCE: Consumers

ISSUE: FDA notified consumers that Slimming Beauty Bitter Orange Slimming Capsules contain the active pharmaceutical ingredient sibutramine, a prescription-only drug which is a stimulant.

Adulteration with API

- **Example 2.** Weight-loss drugs
  - Examples of products claiming to be herbal/all-natural promoters of weight-loss
  - Some of these contain undeclared pharmaceutical substances such as
    - ephedrine (or similar, e.g. pseudoephedrine)
    - sibutramine
    - phenolphthalein

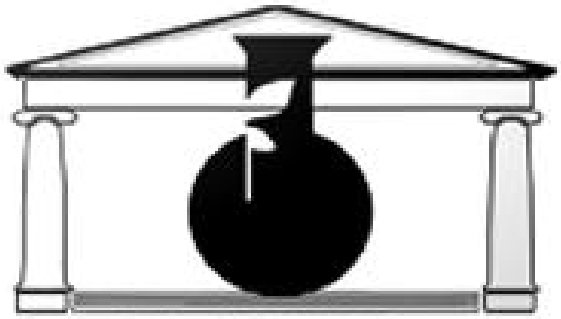
What you need to do to Prevent Adulteration

- Manufacturers: Audit your suppliers and understand their manufacturing processes.
- Greater information-sharing worldwide
- Improved import procedures
- Focus on prevention
- Trust but verify throughout the supply chain.
- Be knowledgeable about the industry.
  - Check FDA's website for warning letters and recalls.
  - Talk to your contract labs if you use them.
- Harmonization of international standards for:
  - Farm-to-table preventative approaches
  - Effective auditing at national, international levels
  - Traceability

Institutions

Botanical Adulterants Program

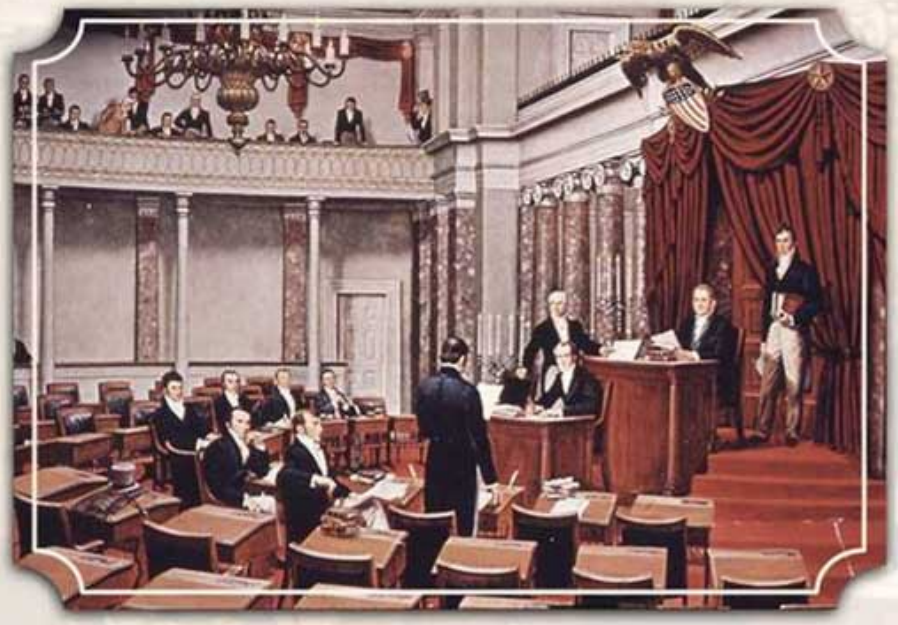
AMERICAN BOTANICAL COUNCIL



NCNPR
THE UNIVERSITY OF MISSISSIPPI

AMERICAN HERBAL PHARMACOPOEIA®

USP's Beginnings



1820

Spalding

Bigelow

Mitchill

USP was founded in 1820 by
11 physicians, in Washington, D.C.

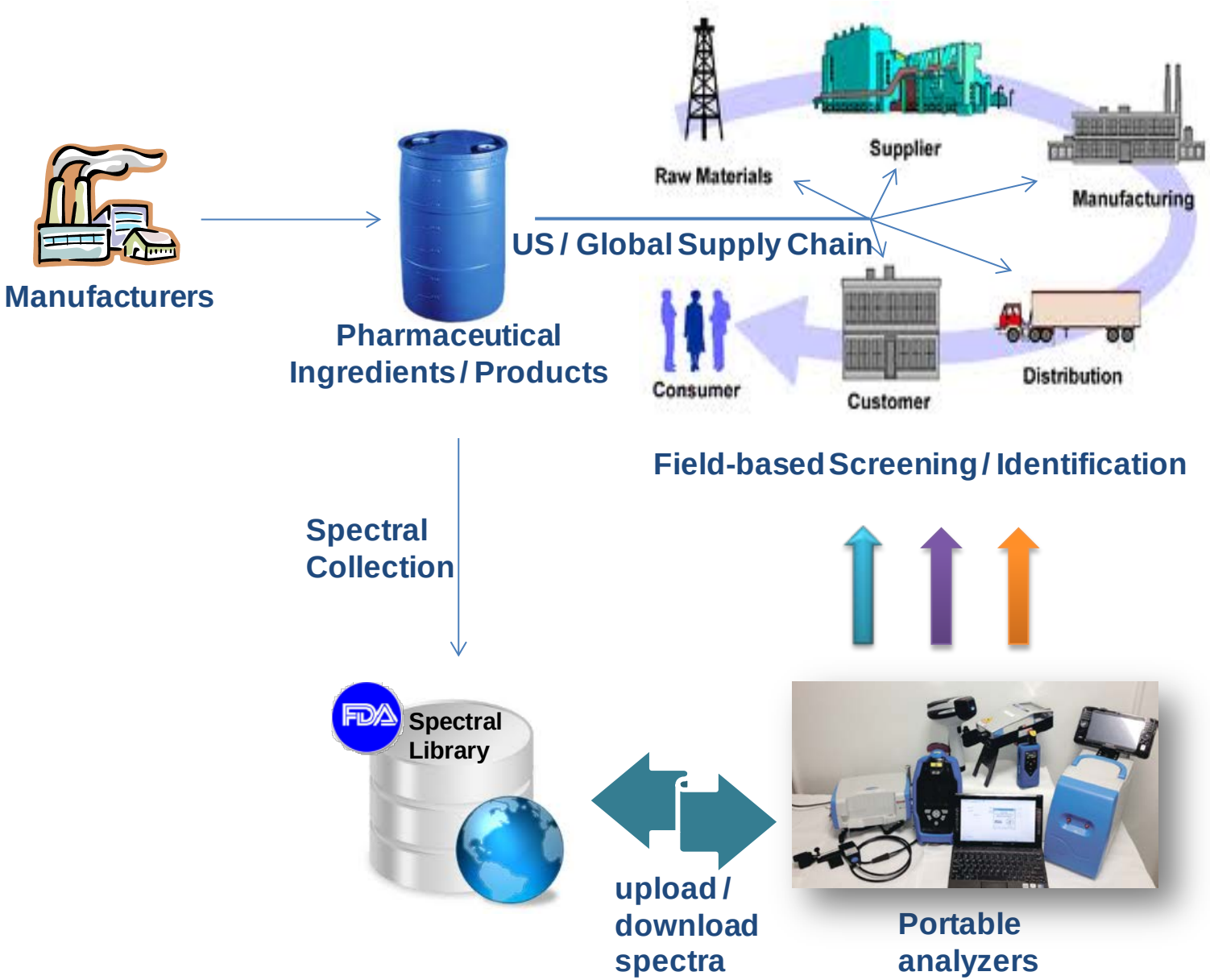
USP Global Sites

Reference Standard Suitability for Use

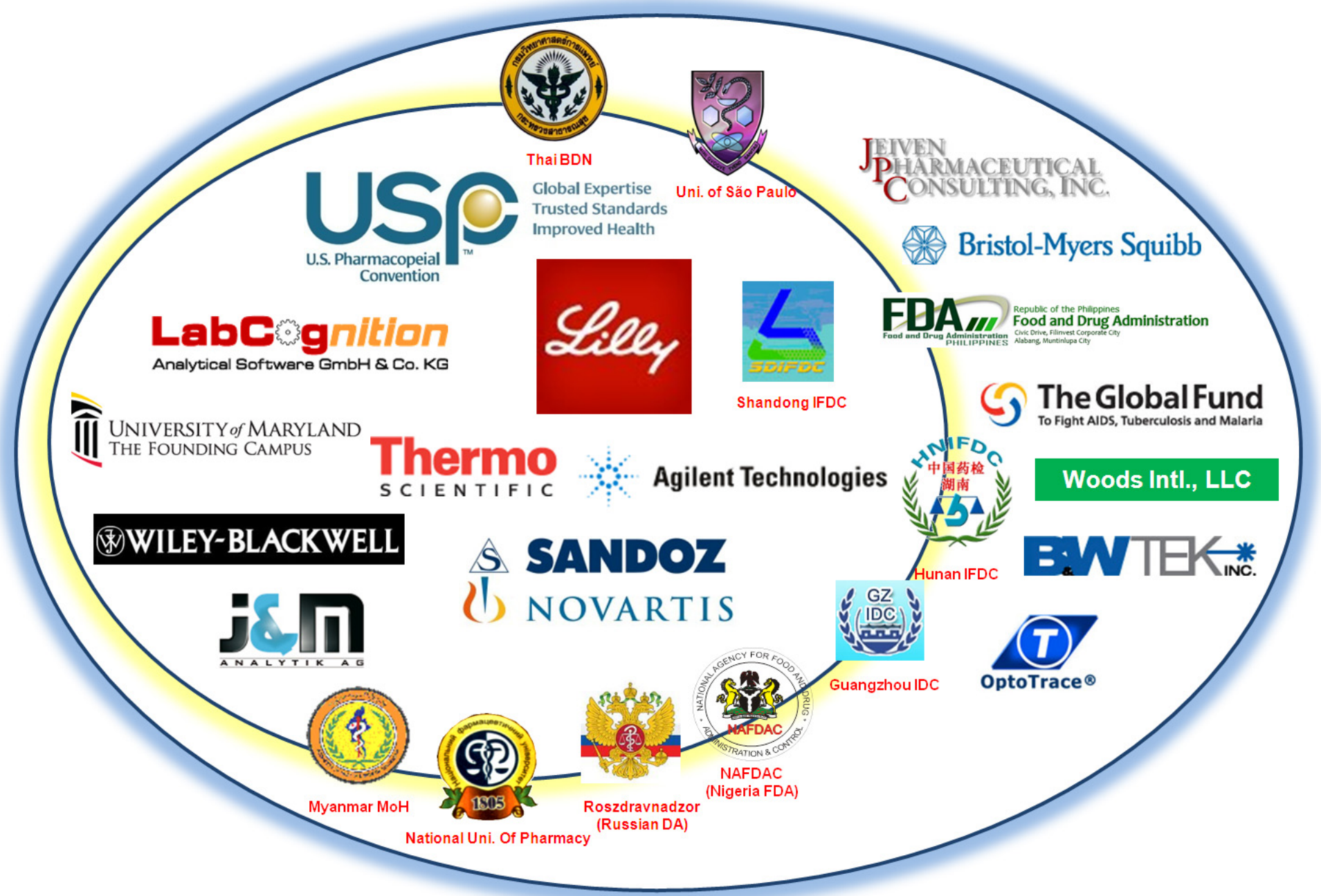
- The *United States Pharmacopeia* and the *National Formulary (USP–NF)*
- *Food Chemicals Codex*
- *USP Dietary Supplements Compendium*
- USP *Medicines Compendium (M*
- *Herbal Medicine Compendium*

- **More than 3,000 Reference Standards for use in compendial tests and procedures**

USP Spectral Library Enables Field-Based Detection of Improper Ingredients Entering US / Global Supply Chain



Strategic Alliances: USP Spectral Library Consortium



Adulteration

General Chapter <2251> Intentional Adulteration of Dietary Supplements with Drugs

Expert Panel – Call for Candidates

http://www.usp.org/usp-nf/notices/call-candidates-intentional-adulteration-dietary-supplements-drugs-expert-panel

Focus on categories of products marketed for sexual enhancement, weight loss, and sport bodybuilding.

To develop screening methods for drugs as adulterants for dietary supplements based on the claimed benefits and similar drug effects of such adulterants.

Food and Dietary Supplement Fraud Database

http://www.foodfraud.org/

STOP COUNTERFEIT MEDICINES

At manufacture

At supply

At point of sale

Summary

- EMA has been around for most of written history.
- Most perpetrators of economic adulteration do not care about GMPs or product safety.
- New adulterants are constantly being developed specifically to "fool" established tests.
- Both targeted and non-targeted screening may be required to verify the purity of an ingredient.
- Stay vigilant and be aware of adulteration trends in the industry.
- Industry and regulatory agencies each have a role to play in preventing adulteration
- **Adherence to quality standards** helps to ensure the quality of the product and the safety of the consumer

Conclusion

- Today we have considerable efforts being made to keep adulterated products from entering the market.
- Many regulatory authorities and industries are making effort to address this issue of quality worldwide.
- There is an urgent need for global harmonization.
- Industry will need to work closely together to accomplish these goals.

Daniel Fabricant, Ph.D,

Acknowledgement

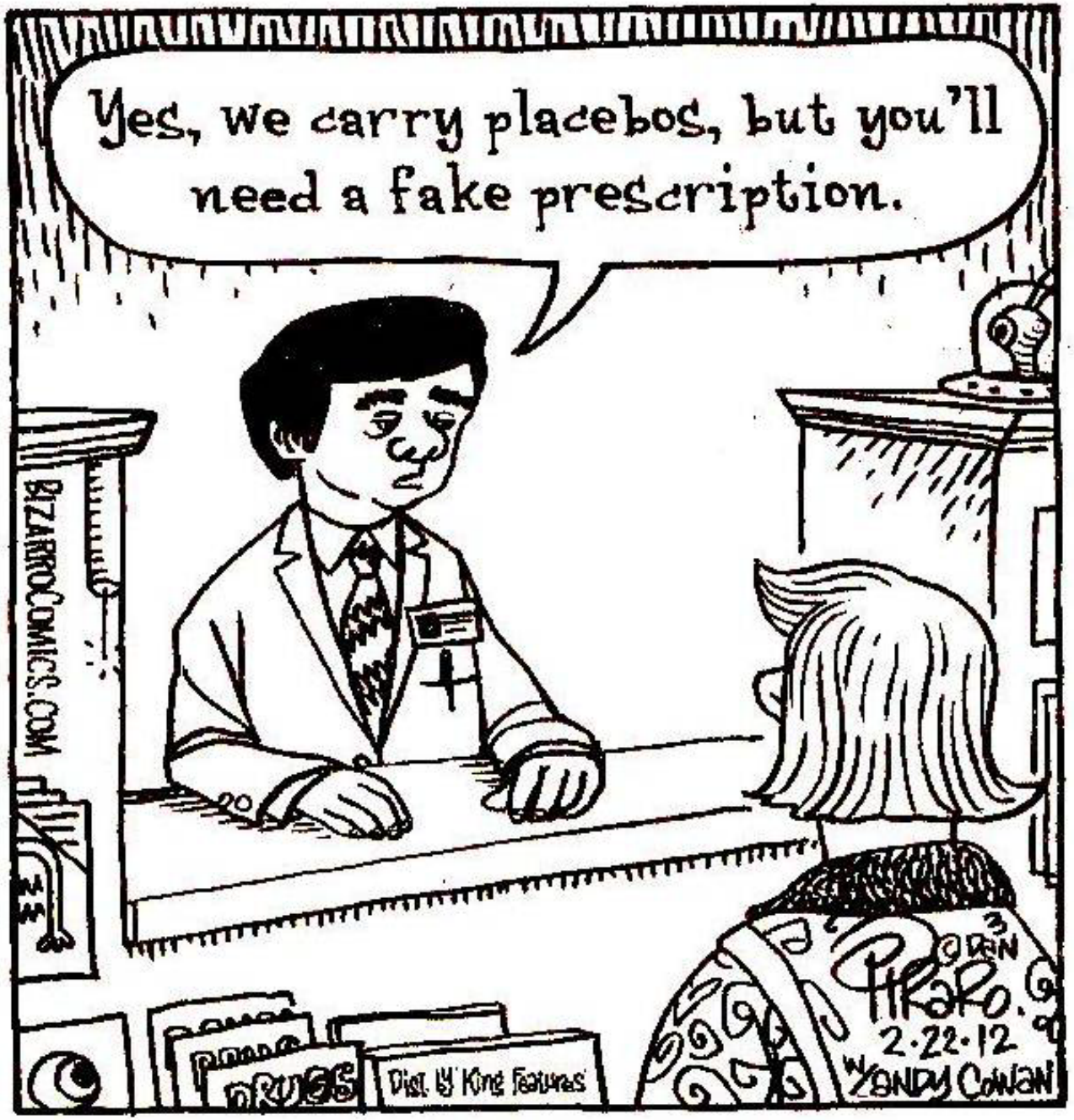
U.S. Pharmacopeia (USP)	United States
Prof. Maurice M. Iwu	Nigeria
BDCP-	Nigeria
InterCEDD	Nigeria
IHP	Nigeria

THANK YOU

QUESTIONS !!!

?

BIZARRO


Yes, we carry placebos, but you'll need a fake prescription.
BIZARROCOMICS.COM
DRUGS
Dist. by King Features
PIRARO
2-22-12
WYNDY CONDON

Limits of Elemental Contaminants of DS Dosage Forms

Element	PDE(µg/day)[a]	
Arsenic (inorganic)[c]	15	(JECFA-WHO 2011)
Cadmium	5	(AHPA to NMT 6 µg/day)
Lead	5	
Mercury (total)	15	
Methylmercury (as Hg)[d]	2	(No limit in GC <232>)

[a] Permitted Daily Exposure (PDE) is derived from the Provisional Tolerable Weekly Intake (PTWI) that is recommended by the Food and Agriculture Organization of the United Nations and World Health Organization (FAO/WHO) by subtracting the daily exposure (µg/day) to each elemental contaminant from air, food, and drinking water. A body weight of 50 kg and a safety factor are used to calculate the PDE. **Other regulations (i.e.: Proposition 65 in California) may require different limits; manufacturers are responsible for compliance with applicable local requirements differing from these PDE values.**

ALOE VERA

Beverages, yogurt, desserts, flavoring.

Extract

Aloe vera, which comes from a succulent plant, is sold as a juice and is added to various other foods and supplements. It is also marketed in various skin care products, for example to treat wounds and burns. Companies make diverse health claims, but scientific evidence is scarce. The National Center for Complementary and Alternative Medicine of the National Institutes of Health concluded that aloe vera "may" help heal burns and abrasions (when used topically), but there is not enough evidence to support other claims. Aloe vera taken orally can cause diarrhea and cramps and is recognized by FDA as a laxative. However, in 2002 FDA banned it from over-the-counter laxatives due to a lack of safety information. Carefully conducted studies by the U.S. government concluded that there was "clear" evidence that aloe vera extracts caused intestinal cancers in male and female rats, but not mice. The form tested, called non-decolorized whole-leaf extract of aloe vera, contains more of the components that are suspected of being cancer-causing—aloin and other anthraquinones—than do some aloe vera products on the market. (The outer leaf pulp of aloe leaves, known as the latex, contains anthraquinones). However, it is not known for sure what components of aloe vera are responsible for the tumors.

The National Center for Complementary and Alternative Medicine also notes several other possible concerns: (1) people with diabetes who use glucose-lowering medication should be cautious about taking aloe vera by mouth since preliminary studies suggest it may lower blood glucose levels; (2) there have been a few case reports of acute hepatitis following oral aloe vera use, but a cause-effect relationship has not been established; and (3) the diarrhea caused by the laxative effect of oral aloe vera can decrease the absorption of many drugs.

Given the possible risks and unsubstantiated benefits, people should not consume aloe vera. People who choose to consume it should at least look for products made with a charcoal filtration process to decolorize and remove anthraquinones, and monitored to ensure than aloin levels are low (e.g., 1 part per million or less). Some solid or semi-solid products have much higher levels of aloin. However, low levels of aloin do not guarantee safety, since it is not known for sure exactly which components of aloe vera triggered cancers in rats.

INCREASING DEMAND FOR DIETARY SUPPLEMENTS WORLD-WIDE: SOME REASONS

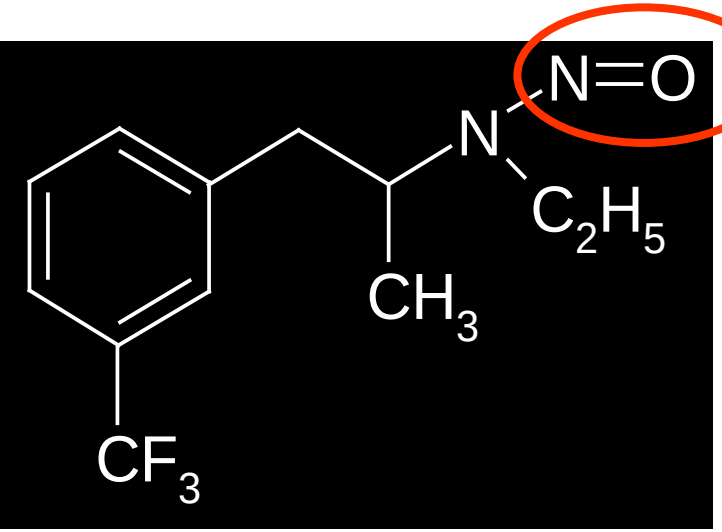
- Greater access to complementary and alternative medicine
- Disenchantment with conventional health care including its increasing cost
- Epidemiological shift from infectious to non-communicable chronic diseases
- Demographic shift to increasing proportions of older population
- Effective distribution and sale channels for dietary supplements

Top 10 Red Flags:

1. **Treat serious, chronic and/or incurable diseases**
2. **“Cure-all” or “miracle cure”**
3. **Personal testimonies**
4. **Fake medical, scientific credentials**
5. **“New discovery”, “scientific breakthrough”, “secret formula,” “ancient remedy”**

Top 10 Red Flags

6. **“Quick fixes” (weight loss, etc)**
7. **“All-natural” = “safer”**
8. **Impressive-sounding scientific terms or ingredients**
9. **Money back guarantee**
10. **“They don’t want you to know about it”**



Nitrosofenfluramine

, needs transplant

Tan: "Andrea
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Shen, Chris-
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ght now, we're
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"At this mo-
ore concerned
r life."

'We hope she will get a transplant while she is still alert. There isn't much we can do once she becomes comatose... We kept her condition a secret from the media because we were hoping that she would turn around.'

— Ms Wendy De Cruz, sister of MediaCorp artiste Andrea De Cruz (above), who has been in hospital for three weeks now

13 down with hepatitis, thyroid problem after taking Slim 10

A TOTAL of 13 people, who had taken a slimming drug called Slim 10, are suffering badly from it, with a few down with hepatitis.

cause of liver toxicity, said a spokesman for HSA.

"There may be other confounding factors, such as a person's bio-

Slim 10 had two controlled substances — nicotinamide and fenfluramine. They were not declared on the product's label.

重金属含量超安全水平

四种印度传统药物被禁

林慧慧●报道

四种在本地售卖的印度传统药物，被发现重金属含量超出安全水平，遭卫生科学局没收销毁。

这些药物是：Annai Aravindh Herbals Rheuma-7 Capsules,Himalayan Diabecon Capsules, Laurel's Diabecs Capsules 和 Goodcare Diabet Guard Granules。它们全部都是在印度生产制造。

卫生科学局劝请持有这些产品的公众，停止服用这些药物，并把剩余的药物丢掉；如果担心健康受影响，应尽早求医。

该局昨天发表文告说，当局是在对入口保健辅助品进行抽样检验时，发现这些药物银和铅的含量超标。

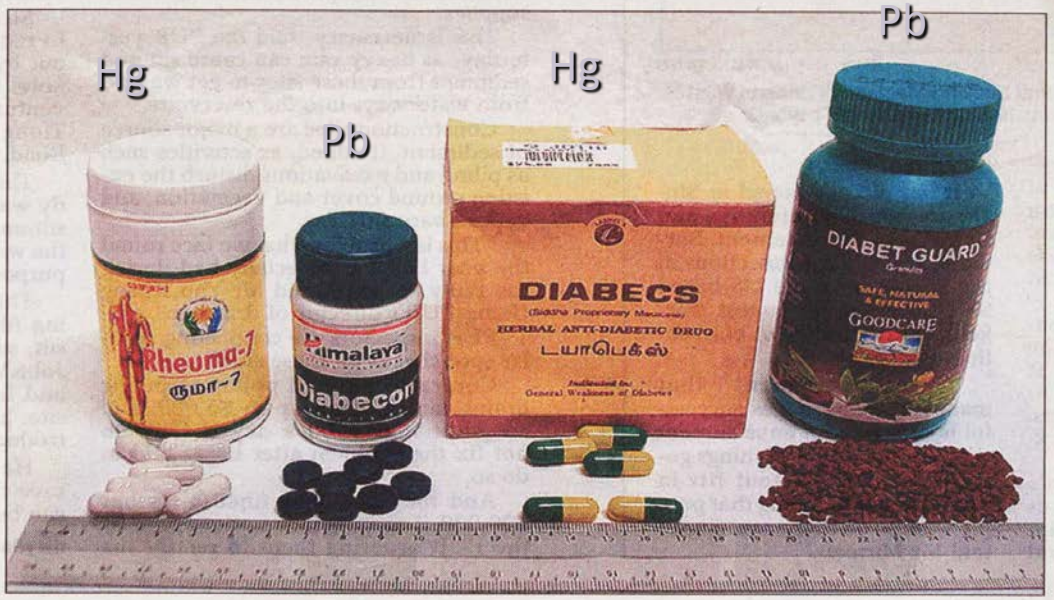
当局所允许的是：水银成分在百之0.5以下，铅则是分之20以下。

这些遭没收的药物被归类为阿育药物（Ayu medicine）。这类药般被视为现代医学种"另类"（alternat法，受到慢性疾病欢迎，他们主要利种"另类"医疗方调养身体。

当中，有三种给糖尿病患者使用外一种则声称有助背痛、肌肉疼痛和炎等症状。

当局指出，有些传统治疗学派会使用含有

Health agency sounds alert on 4 drugs



HEAVY METAL: These four traditional Indian medicines have been found to contain too much lead and mercury, which pose serious health risks when allowed to accumulate in vital body organs.

THE Health Sciences Authority (HSA) has issued a warning against consuming four traditional Indian medicines found to contain too much lead and mercury.

Routine tests found that Annai Aravindh Herbals Rheuma-7 Capsules and Laurel's Diabecs Capsules contained more than the permitted 0.5 part per million (ppm) of mercury, while Himalaya Diabecon Tablets and Goodcare Diabet Guard Granules had more than the allowable 20ppm of lead.

Taking too much heavy metals, such as lead or mercury, poses serious health risks if the metals accumulate in vital body organs, the HSA said in a statement yesterday.

An excess of lead and mercury can lead to abdominal pain, vomiting, diarrhoea, kidney damage and impaired nerves and mental functions.

The HSA advised the public not to consume the medicines, which claim to be effective for pain in joints, back and muscles, and in controlling blood sugar levels.

Anyone found selling products containing more than the permitted limit of heavy toxic metals can be fined up to $5,000 and jailed up to two years.

Members of the public can call the HSA's Centre for Drug Administration on 6866-3485 from 9am to 5pm on weekdays for more information.

Mr Ganesh Natarajan, business head (South-east Asia) of The Himalaya Drug Company, said his firm did not introduce Himalaya Diabecon Tablets in Singapore and did not seek registration for the product.

The company obtains approval from the HSA before selling its products here, he said.

He advised consumers to buy the company's products at its sole retailer, Watsons.

Radio 93.8Live
HSA warns public not to

The Health Sciences Authority is warn
medicines.

They are Annai Aravindh Herbals Rhe
Diabecs Capsules and Goodcare Diab

H-S-A says tests on these products ha
mercury.

Symptoms of lead and mercury toxicity
kidney damage and impairment of the nerves and mental function.
HSA's investigation has indicated that these products are not widely distributed in Singapore and only small quantities were brought in each time from overseas by retailers to meet the needs of

Source: Chan CL, Pharmacovigilance

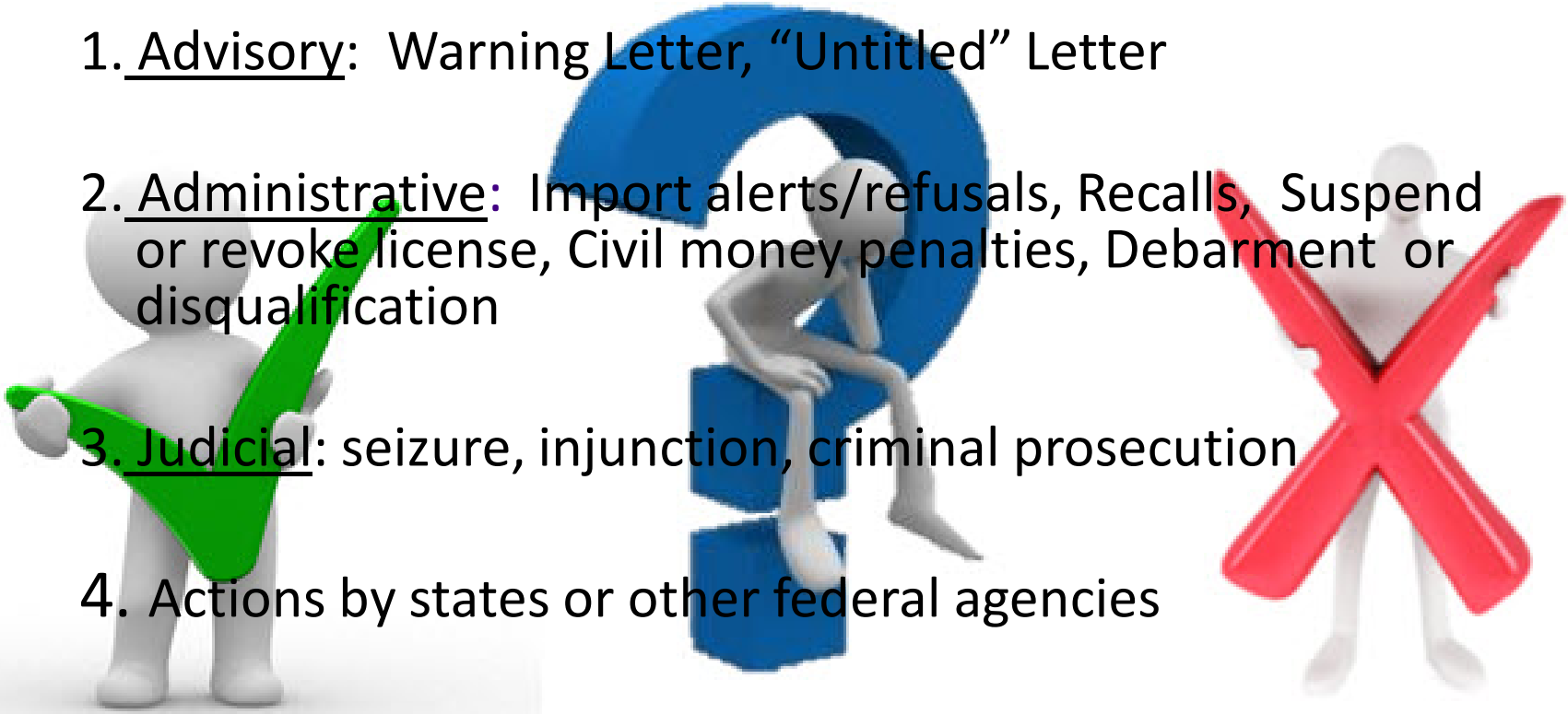
Compliance/Enforcement Options

1. Advisory: Warning Letter, "Untitled" Letter

2. Administrative: Import alerts/refusals, Recalls, Suspend or revoke license, Civil money penalties, Debarment or disqualification

3. Judicial: seizure, injunction, criminal prosecution

4. Actions by states or other federal agencies



Accept 20%	Undecided 60%	Reject 20%