

Before the
Department of Health and Human Services
Food and Drug Administration
Washington, D.C.

In re: Citizen Petition to)
Compel Enforcement and)
Regulation of Amyl Nitrite) Docket No. _____
Pursuant 21 C. F. R. §250.100)

CITIZEN PETITION

Gerald Austin, in propria persona, hereby submits this petition under Chapter 21, Section 250.100 of the Code of Federal Regulations.

I. ACTION REQUESTED

The undersigned requests that the Commissioner of Food and Drugs act immediately to compel the enforcement and regulation of the prescription only drug amyl nitrite aka isopentyl nitrite, molecular formula $(\text{CH}_3)_2\text{CHCH}_2\text{CH}_2\text{ONO}$; branded Jungle Juice, Manscent and otherwise; pursuant 21 C. F. R. §250.100 as it relates to the internet websites www.vhcleaner.com¹ at www.vhcleaner.com/big_bottles²; www.poppersexpress.com at www.poppersexpress.com/index.htm; http://getbooked.com/shop/product_info.php/products_id/5728; and www.nitroaroma.com/premium.html.

II. STATEMENT OF GROUNDS

21 C. F. R. §250.100: Amyl nitrite inhalant as a prescription drug for human use.

(a) Amyl nitrite inhalant has been available over-the-counter for emergency use by the patient in the management of angina pectoris for a number of years. As a result of a proposed policy

2004P-0411

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statement published August 25, 1967 (32 FR 12404), the Commissioner of Food and Drugs received reports of the abuse of this drug by those who do not require it for medical purposes. Additionally, comment included a great deal of concern expressed by individual physicians, medical associations, pharmaceutical associations, manufacturers, and State and local health authorities. Based on the information available, it is the opinion of the Commissioner of Food and Drugs, concurred in by the Food and Drug Administration Medical Advisory Board, that amyl nitrite inhalant is a drug with a potentiality for harmful effect and that it should be removed from over-the-counter status and restricted to sale on the prescription of a practitioner licensed by law to administer such drug.

(b) Therefore, amyl nitrite inhalant will be regarded as misbranded unless the labeling on or within the package from which the drug is to be dispensed bears adequate information for its safe and effective use by physicians, in accordance with Sec. 201.100(c) of this chapter, and its label bears the statement ``Rx only."

(c) Regulatory proceedings may be initiated with regard to the interstate shipment of amyl nitrite inhalant that is labeled, advertised, or dispensed contrary to this statement of policy if such act occurs after July 1, 1969. [40 FR 14033, Mar. 27, 1975, as amended at 67 FR 4906, Feb. 1, 2002]

This drug, sold along with³extremely flammable⁴ banned hazardous isobutyl nitrite⁵ inhalant products⁶ registered to Great Lakes Products⁷ of Indianapolis, Indiana; has been investigated by the Subcommittee on Oversight and Investigations⁸.

The detriment to the public is greatly exacerbated by the fact that, with the intent to obscure criminal wrongdoing, these products are being discretely and inconspicuously shipped aboard

passenger carrying aircraft, vis-à-vis USPS Priority Mail, in contravention with 18 USC §1716(a) and USPS DMM Publication 52, July 1999 Hazardous, Restricted, and Perishable Mail §343.23a.

III. ENVIRONMENTAL IMPACT STATEMENT

This Citizen Petition is categorically excluded from the 21 CFR §10.30(b)C. EIS mandate pursuant 21 CFR §25.30(b) i.e. Recommendation for an enforcement action to be initiated in a Federal Court.

IV. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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JUNGLE JUICE plus® Large

Price: \$19.95

Contents: 30 ml Bottle
Chemical: Isopentyl Nitrite

Your JUNGLE JUICE® can be stored in your freezer for a One year shelf life!



JUNGLE JUICE SPECIAL - Buy 4 bottles and get 1 FREE

3 Welcome to VHCleaner.com

Now Offering:

FULL Sleeves of RUSH (18 Bottles) for just \$99.95

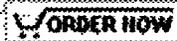
Big Sale
SPECIALS



JUNGLE JUICE - \$19.95

Video Head Cleaner

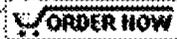
BUY 4 BOTTLES & GET 1 FREE



IRON HORSE - \$19.95

Liquid Aroma

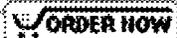
BUY 4 BOTTLES & GET 1 FREE



AMSTERDAM - \$19.95

Liquid Incense

BUY 4 BOTTLES & GET 1 FREE





BLUE BOY - \$18.95

Room Odorizer

BUY 4 BOTTLES & GET 1 FREE

ORDER NOW



MAN SCENT - \$19.95

BUY 4 BOTTLES & GET 1 FREE

ORDER NOW

⁴ 16 C.F.R. § 1500.3(c)(6)(i) The term extremely flammable shall apply to any substance which has a flashpoint at or below 20° F (-6.7° C) as determined by the test method described at Sec. 1500.43a, except that, any mixture having one component or more with a flashpoint higher than 20° F (-6.7° C) which comprises at least 99 percent of the total volume of the mixture is not considered to be an extremely flammable substance.

⁵ Title 15 United States Code §2057a

⁶ Alkyl nitrites including isobutyl nitrite are regulated by the Consumer Product Safety Commission as banned hazardous substances pursuant the Consumer Product Safety Act, 15 USC §§ 2051-2084.

7

USPTO Reg. Number	Word Mark	Check Status	Live/Dead	
<u>76494208</u>		<u>IRON HORSE</u>	<u>TARR</u>	<u>LIVE</u>
<u>76080186</u>		<u>LOCKER ROOM</u>	<u>TARR</u>	<u>LIVE</u>
<u>76407686</u>	<u>2690676</u>	<u>PWD</u>	<u>TARR</u>	<u>LIVE</u>
<u>76336814</u>		<u>JUNGLE JUICE</u>	<u>TARR</u>	<u>LIVE</u>
<u>76178805</u>	<u>2538037</u>	<u>POWER-PAK PELLET</u>	<u>TARR</u>	<u>LIVE</u>
<u>75583269</u>	<u>2298182</u>	<u>PWD</u>	<u>TARR</u>	<u>LIVE</u>
<u>75579280</u>		<u>POP'RS</u>	<u>TARR</u>	<u>DEAD</u>
<u>74282158</u>	<u>1748106</u>	<u>RAM</u>	<u>TARR</u>	<u>LIVE</u>
<u>74282135</u>	<u>1748105</u>	<u>QUICK SILVER</u>	<u>TARR</u>	<u>LIVE</u>
<u>74282136</u>	<u>1765515</u>	<u>HARDWARE</u>	<u>TARR</u>	<u>LIVE</u>
<u>73441272</u>	<u>1393734</u>	<u>GLP</u>	<u>TARR</u>	<u>DEAD</u>
<u>73355772</u>	<u>1246211</u>	<u>RAM</u>	<u>TARR</u>	<u>DEAD</u>
<u>73325937</u>	<u>1218752</u>	<u>LIQUID AROMA</u>	<u>TARR</u>	<u>DEAD</u>
<u>73235513</u>	<u>1210208</u>	<u>QUICK SILVER</u>	<u>TARR</u>	<u>DEAD</u>
<u>73177168</u>	<u>1112107</u>	<u>HARD WARE</u>	<u>TARR</u>	<u>DEAD</u>

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LIVE

⁸ Subcommittee on Oversight and Investigations

June 7, 2001

10:00 AM

2123 Rayburn House Office Building

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[107th Congress House Hearings]

[From the U.S. Government Printing Office via GPO Access]

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CONTINUING CONCERNS OVER IMPORTED PHARMACEUTICALS

HEARING

before the

SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

of the

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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(ii)

C O N T E N T S

	Page
Testimony of:	
Christian, James, Vice President and Head of Global Corporate Security, Novartis International.....	157
deKieffer, Donald, deKieffer & Horgan.....	173
Durant, Elizabeth G., Executive Director of Trade Programs, U.S. Customs Service.....	40
Gibbs, Landon S., First Sergeant, Virginia State Police.....	58
Glover, John D., Vice President, Corporate Security, Bristol-Myers Squibb Company.....	153
Haislip, Gene R., Consultant.....	166
Hubbard, William K., Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration.....	45
Leshner, Alan I., Director, National Institute on Drug Abuse.	55
Nagel, Laura M., Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.....	37
Rode, Rev. Edwin and Helen.....	24
Shepherd, Marvin, Professor, College of Pharmacy, University of Texas.....	146
Trundley, William, Vice President of Corporate Security Investigations, GlaxoSmithKline.....	163
Vereen, Donald R., Jr., Deputy Director, Office of National Drug Control Policy.....	33

(iii)

CONTINUING CONCERNS OVER IMPORTED PHARMACEUTICALS

THURSDAY, JUNE 7, 2001

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Oversight and Investigations,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2123, Rayburn House Office Building, Hon. James C. Greenwood, (chairman) presiding.

Members present: Representatives Greenwood, Bilirakis, Stearns, Gillmor, Largent, Burr, Whitfield, Bass, Deutsch, Stupak, DeGette, and Dingell (ex officio).

Staff present: Alan Slobodin, majority counsel; Ray Shepherd, majority counsel; Will Carty, legislative clerk; and Chris Knauer, minority counsel.

Mr. Greenwood. Good morning. A quorum being present, this hearing of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee will come to order.

The Cambridge Dictionary of American English defines the word ``huckster'' as a person who sells things or puts forward ideas in a very determined way that is often not completely honest.

Sadly, there is a long and infamous history of hucksterism in America. Today, we are here to examine the latest incarnation of this unscrupulous practice of selling people what they either don't need or shouldn't buy. In this case, it is the sale of unapproved mis-branded or adulterated drugs.

Usually ineffectual, and often unsafe, and increasingly over the Internet, the disreputable promoters of these illicit products have added a new twist to the way that modern day stake oil salesmen prey on the needy and the unsuspecting.

Their model might very well be there is a sucker logging on every minute. A few weeks ago, Congressmen Deutsch, Stupak, and I visited the international mail facility near Dulles Airport, and what we found was truly frightening.

And these are some examples of the drugs that we found.

This one is labeled, ``**Jungle Juice.**'' It is **amyl nitrite** and it is a drug that is abused, usually by young people on dance floors I am told, and in discos.