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November 5, 2004

Food and Drug Administration
5600 Fisher Lane
Rockville, MD 20857-0001
Fax: 301-443-6591

Subject: Citizen Petition, FDA Docket #2004P-0411

Dr. Lester M. Crawford, Commissioner:

I am very concerned regarding the practices chronicled in the Citizen Petition supra.

The prescription only¹ drug "amyl nitrite" has recently been used as a "club drug"² aka "party drug"³, often in fatal combination with methamphetamine, ecstasy, Viagra^{®4}, Cialis^{®5} and Levitra^{®6}. This is clearly a matter within the regulatory enforcement purview of the FDA that must be addressed immediately to prevent further needless loss of life.

Perhaps even more important than the abuse of the prescription only drug amyl nitrite is the clandestine shipment of hazardous materials aboard commercial passenger carrying aircraft insofar as it poses an unacceptably grave danger to the flying public at large. Neither isobutyl nitrite, a Division 6.1 Toxic Substance, flashpoint -23° C⁷ nor the extremely flammable corrosive gas ethyl chloride, flashpoint -50° C, may ever, under any circumstances, be transported aboard passenger carrying aircraft.

Insofar as HAZMAT materials are being unlawfully transported, both via USPS and other carriers, it is imperative that the FDA immediately report this matter to the FBI and USAG. The FBI, pursuant 28 USC §535⁸, clearly has cross the board jurisdiction whereas DOT and FAA are somewhat, although not completely, constrained vis-à-vis 49 USC §5126⁹, and the USPS has little authority outside of 18 USC §1716¹⁰.

2004P-0411

EMCA

In the spirit of the Government Paperwork Elimination Act, 44 USC §3504 et seq., I encourage you to respond electronically via email to LRI@comcast.net or facsimile to 215-893-3675.

Insofar as this is a matter of vital health and safety interest, particularly to the flying public, I respectfully request to be kept apprised in re the manner in which the FDA intends to adjudicate said Citizen Petition i.e. 21 CFR §10.30 et seq.

Respectfully yours,
Henry Hadry

c.c.:

CNN Producer Mike Ahlers
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Washington DC 20002
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¹ 21 CFR §250.100

² Mattison AM, Ross MW, Wolfson T, et al. Circuit party attendance, club drug use, and unsafe sex in gay men. J Subst Abuse 2001;13:119-26

³

http://medresource.sympatico.ca/channel_health_news_detail.asp?channel_id=8&menu_item_id=4&news_id=2411

⁴ (REGISTRANT) PFIZER INC. CORPORATION DELAWARE 235 East 42nd Street New York NEW YORK 10017

⁵ (REGISTRANT) Lilly ICOS L.L.C. LIMITED LIABILITY CORPORATION DELAWARE 1209 Orange Street Wilmington DELAWARE 19801

⁶ (REGISTRANT) Bayer Aktiengesellschaft JOINT STOCK COMPANY FED REP GERMANY D-51368 Leverkusen-Bayerwerk FED REP GERMANY

⁷ Quantities greater than 1 gram.

⁸

535. Investigation of crimes involving Government officers and employees; limitations

Release date: 2003-05-15

(a) The Attorney General and the Federal Bureau of Investigation may investigate any violation of title 18 involving Government officers and employees—

(1) notwithstanding any other provision of law; and

(2) without limiting the authority to investigate any matter which is conferred on them or on a department or agency of the Government.

(b) Any information, allegation, or complaint received in a department or agency of the executive branch of the Government relating to violations of title 18 involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency, unless—

(1) the responsibility to perform an investigation with respect thereto is specifically assigned otherwise by another provision of law; or

(2) as to any department or agency of the Government, the Attorney General directs otherwise with respect to a specified class of information, allegation, or complaint.

(c) This section does not limit—

(1) the authority of the military departments to investigate persons or offenses over which the armed forces have jurisdiction under the Uniform Code of Military Justice (chapter 47 of title 10); or

(2) the primary authority of the Postmaster General to investigate postal offenses.

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UNITED STATES CODE SERVICE
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*** CURRENT THROUGH P.L. 108-349, APPROVED 10/21/04 ***

TITLE 49. TRANSPORTATION
SUBTITLE III. GENERAL AND INTERMODAL PROGRAMS
CHAPTER 51. TRANSPORTATION OF HAZARDOUS MATERIAL

GO TO CODE ARCHIVE DIRECTORY FOR THIS JURISDICTION

49 USCS § 5126 (2004)

§ 5126. Relationship to other laws

(a) **Contracts.** A person under contract with a department, agency, or instrumentality of the United States Government that transports or causes to be transported hazardous material, or manufactures, fabricates, marks, maintains, reconditions, repairs, or tests a packaging or a container that the person represents, marks, certifies, or sells as qualified for use in transporting hazardous material must comply with this chapter [49 USCS §§ 5101 et seq.], regulations prescribed and orders issued under this chapter [49 USCS §§ 5101 et seq.], and all other requirements of the Government, State and local governments, and Indian tribes (except a requirement preempted by a law of the United States) in the same way and to the same extent that any person engaging in that transportation, manufacturing, fabricating, marking, maintenance, reconditioning, repairing, or testing that is in or affects commerce must comply with the provision, regulation, order, or requirement.

(b) **Nonapplication.** This chapter [49 USCS §§ 5101 et seq.] does not apply to—

(1) a pipeline subject to regulation under chapter 601 of this title [49 USCS §§ 60101 et seq.]; or

(2) any matter that is subject to the postal laws and regulations of the United States under this chapter [49 USCS §§ 5101 et seq.] or title 18 or 39

HISTORY:

(July 5, 1994, P.L. 103-272, § 1(d), 108 Stat. 783; Aug. 26, 1994, P.L. 103-311, Title I, § 117(a)(2), 108 Stat. 1878.)

HISTORY; ANCILLARY LAWS AND DIRECTIVES

Prior law and revision:

Revised Section	Source (U.S. Code)	Source (Statutes at Large)
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5126(a).....	49 App.:1818. 88 Stat. 2156, Sec. 120; added Nov. 16, 1990, Pub. L. 101-615, Sec. 20, 104 Stat. 3270.	Jan. 3, 1975, Pub. L. 93-633,
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5126(b).....	49 App.:1811(f). Sec. 112(f), 88 Stat. 2181; Nov. 30, 1979, Pub. L. 96-129, Sec. 216(a), 93 Stat. 1015; restated Nov. 16, 1990, Pub. L. 101-615, Sec. 13, 104 Stat. 3260.	Jan. 3, 1975, Pub. L. 93-633,
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In subsection (a), the word "manufactures" is substituted for "manufacturers" to correct an error in the source provisions. The words "of the executive, legislative, or judicial branch", "be subject to and", "substantive and procedural", and "this chapter or any other" are omitted as surplus.

Amendments:

1994. Act Aug. 26, 1994, in subsec. (a), substituted "a packaging or a" for "a package or".

INTERPRETIVE NOTES AND DECISIONS

Regulatory authority of Secretary of Transportation under Hazardous Materials Transportation Act (49 USCS §§ 5101 et seq.) with respect to transportation of hazardous materials is irrelevant to applicability of motor carrier exemption (29 USCS § 213(b)(1)) to Fair Labor Standards Act overtime provisions. Herman v Hector I. Nieves Transp. Inc. (2001, CA1 Puerto Rico) 244 F3d 32, 6 BNA WH Cas. 2d 1441, 143 CCH LC P 34231.

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SHEPARD'S - 21 Citing References

49 U.S.C. secs. 5101 to 5127, 49 U.S.C. secs. 5101 to 5127

SHEPARD'S Signal:

Restrictions: Unrestricted

LEGISLATIVE HISTORY (1 citing reference) • Title Legislative History

1. **Added:**
1994 Stat.

108SI745

CITING DECISIONS (18 citing decisions)

1ST CIRCUIT - COURT OF APPEALS

2. Cited by:

Torres-Rios v. LPS Lab, 152 F.3d 11, 1998 U.S. App. LEXIS 17746, CCH Prod. Lab. Rep. P15303 (1st Cir. P.R. 1998)

152 F.3d 11 p.14

1ST CIRCUIT - U.S. DISTRICT COURTS

3. Cited by:

Tolentino v. UPS, 2001 U.S. Dist. LEXIS 1395 (D. Mass. Jan. 11, 2001)

2001 U.S. Dist. LEXIS 1395, (edition 1994)

4. Cited by:

Ordner v. K-H Corp., 74 F. Supp. 2d 150, 1999 U.S. Dist. LEXIS 20827 (D.R.I. 1999)

74 F. Supp. 2d 150 p.153

5. Cited by:

Ordner v. K-H Corp., 1998 U.S. Dist. LEXIS 22714 (D.R.I. May 14, 1998)

1998 U.S. Dist. LEXIS 22714

4TH CIRCUIT - U.S. DISTRICT COURTS

6. Cited by:

Southern Blasting Servs. v. Wilkes County, 162 F. Supp. 2d 455, 2001 U.S. Dist. LEXIS 13468 (W.D.N.C. 2001)

162 F. Supp. 2d 455 p.461

5TH CIRCUIT - U.S. DISTRICT COURTS

7. Cited by:

Harris County Wrecker Owners for Equal Opportunity v. City of Houston, 943 F. Supp. 711, 1996 U.S. Dist. LEXIS 16146 (S.D. Tex. 1996)

943 F. Supp. 711 p.727

6TH CIRCUIT - COURT OF APPEALS

8. Cited by:

Tennessee v. United States DOT, 326 F.3d 729, 2003 U.S. App. LEXIS 7624, 2003 FED App. 120P (6th Cir.), 56 Env't Rep. Cas. (BNA) 1353, 33 Env't. L. Rep. 20180 (6th Cir. Tenn. 2003)

326 F.3d 729 p.730

6TH CIRCUIT - U.S. DISTRICT COURTS

9. Cited by:

Lyall v. Leslie's Poolmart, 984 F. Supp. 587, 1997 U.S. Dist. LEXIS 17393, 28 Env't. L. Rep. 21165 (E.D. Mich. 1997)

984 F. Supp. 587 p.597

9TH CIRCUIT - COURT OF APPEALS

10. Cited by:

United States v. Torf (In re Grand Jury Subpoena), 350 F.3d 1010, 2003 U.S. App. LEXIS 24041, 2003 Cal. Daily Op. Service 10194, 57 Env't Rep. Cas. (BNA) 1512, 57 Env't. L. Rep. 20180

United States v. V-1 Oil Co., 63 F.3d 909, 1995 U.S. App. LEXIS 23980, 95 Cal. Daily Op. Service 6717, 95 D.A.R. 11476, 41 Env't Rep. Cas. (BNA) 1537, 26 Env'tl. L. Rep. 20058, 33 Fed. R. Serv. 3d (Callaghan) 151 (9th Cir. Idaho 1995)

63 F.3d 909 p.912

11TH CIRCUIT - COURT OF APPEALS

12. **Cited by:**

United States v. SabreTech, Inc., 271 F.3d 1018, 2001 U.S. App. LEXIS 23595, 15 Fla. L. Weekly Fed. C 32, 53 Env't Rep. Cas. (BNA) 1529, 32 Env'tl. L. Rep. 20266 (11th Cir. Fla. 2001)

271 F.3d 1018 p.1023

D.C. CIRCUIT - COURT OF APPEALS

13. **Cited by:**

Chemical Mfrs. Ass'n v. DOT, 323 U.S. App. D.C. 88, 105 F.3d 702, 1997 U.S. App. LEXIS 1632, 27 Env'tl. L. Rep. 20816 (1997)

105 F.3d 702 p.704

323 U.S. App. D.C. 88 p.90

14. **Cited by:**

Massachusetts v. United States DOT, 320 U.S. App. D.C. 227, 93 F.3d 890, 1996 U.S. App. LEXIS 21973, 43 Env't Rep. Cas. (BNA) 1231, 26 Env'tl. L. Rep. 21652 (1996)

93 F.3d 890 p.891

320 U.S. App. D.C. 227 p.228

ADMINISTRATIVE AGENCY DECISIONS

15. **Cited by:**

59 N.R.C. 31

59 N.R.C. 31 p.38

16. **Cited by:**

50 N.R.C. 168

50 N.R.C. 168 p.177

NEW JERSEY SUPREME COURT

17. **Cited by:**

Am. Trucking Ass'ns v. State, 180 N.J. 377, 852 A.2d 142, 2004 N.J. LEXIS 910 (2004)

180 N.J. 377 p.383

852 A.2d 142 p.146

18. **Cited by:**

American Trucking Ass'ns v. State, 164 N.J. 183, 752 A.2d 1286, 2000 N.J. LEXIS 792 (2000)

164 N.J. 183 p.183

752 A.2d 1286 p.1286

NEW JERSEY SUPERIOR COURT

19. **Cited by:**

American Trucking Ass'ns v. State, 324 N.J. Super. 1, 734 A.2d 314, 1999 N.J. Super. LEXIS 207 (N.J. Super. Ct. App. Div. 1999)

324 N.J. Super. 1 p.4

734 A.2d 314 p.316

LAW REVIEWS AND PERIODICALS (2 Citing References)

20. ARTICLE: The Law, Economics, and Politics of Federal Preemption Jurisprudence: A Quantitative Analysis, 87 Cal. L. Rev. 1125 (1999)

87 Cal. L. Rev. 1125 p.1150, (edition 1994)

21. 61 Law & Contemp. Probs. No. 2 155, 61 Law & Contemp. Probs. No. 2 155
61 Law & Contemp. Probs. No. 2 155 p.167, (edition 1994)

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Injurious articles as nonmailable

Release date: 2004-08-06

(a) All kinds of poison, and all articles and compositions containing poison, and all poisonous animals, insects, reptiles, and all explosives, inflammable materials, infernal machines, and mechanical, chemical, or other devices or compositions which may ignite or explode, and all disease germs or scabs, and all other natural or artificial articles, compositions, or material which may kill or injure another, or injure the mails or other property, whether or not sealed as first-class matter, are nonmailable matter and shall not be conveyed in the mails or delivered from any post office or station thereof, nor by any officer or employee of the Postal Service.