



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506

Telephone: 949-608-2900
FAX: 949-608-4415

March 31, 2011

American Civil Liberties Union of Northern California
Attn: Natasha Minsker
39 Drumm St.
San Francisco, CA 94111

Dear Requestor:

Refer to FOI # F11-319

We apologize for the delay. This is in response to your request of January 4, 2011 for record(s) from the Food and Drug Administration pursuant to the Freedom of Information Act regarding: importation of sodium thiopental, pancuronium bromide, and/or potassium chloride for the purpose of execution.

Enclosed are the records you requested:

- 7 Page transmittal for entry 574-0251126-5 including: CBP Form 3461- 1 Page, Letter from AZ Dept of Corrections dated September 24, 2010- 1 Page, Dream Pharma invoices- 2 Pages, and 3 Pages of DEA registration (one page of carrier air bill not included).
- 8 Page transmittal for entry 574-0250322-1 including: CBP Form 3461- 1 Page, Dream Pharma invoice- 1 Page, CBP form 7512- 1 Page, 2 letters from AZ Dept of Corrections- 2 Pages, DEA registration – 2 Pages, Dream Pharma invoice- 1 Page.
- Email, subject: Completed conference with Dan...- 2 Pages
- DEA registration- 1 Page
- Email, subject: Dream Pharma Shipments- 2 Pages
- Email, subject: Entry 574-0250322-1: Lethal Injection Pharmacology- 3 Pages
- Email, subject: FW: Entry number of 9/29/10 shipment- 2 Pages
- Email, subject: FW: Lethal injection pharmacology entry 574-0251126-5 – 5 Pages
- OASIS report for entry 574-0250322-1 dated 09/29/2010 – 1 Page
- OASIS report for entry 574-0251126-5 dated 01/07/2011 – 2 Pages
- OASIS screen printout for 574-0251126-5 – 1 Page
- Email, subject: Update Your Pharmaceutical Entry – 1 Page

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider any particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you would have to right to appeal that decision. Any letter of denial will explain how to make this appeal.

The following charges for this request to date may be included in a monthly invoice:

Reproduction	Search	Review	Fiche	Other	Total
\$ 3.50	\$ 23.00	\$ 46.00	\$ 00.00	\$ 00.00	\$ 72.50

The above total may not reflect final charges for this request. Please *do not* send payment unless you receive an invoice.
All communications concerning this request should be identified with the referenced number above and addressed as follows:

Food and Drug Administration
Division of Freedom of Information, HFI-35
OPILS/OSS/DFOI
12430 Parklawn Drive, Room 1050
Rockville, MD 20857

Sincerely,



John Bryce
Analyst
Los Angeles District

cc: ☒ HFI-35
☒ Please Assess Charges
☐ No Purging Necessary

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection

Form Approved
OMB No. 1616-0024
Exp. 01-31-2012

ENTRY/IMMEDIATE DELIVERY

(b) (4)

(b) (4)

P.O. (b) (4)

000 BOX #

19 CFR 142.2, 142.16, 142.22, 142.24

ABI CERTIFIED

1. ARRIVAL DATE 102610	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 11 INFORMAL -	4. ENTRY NUMBER 574-0251126-5
5. PORT 2605	6. SINGLE TRANS. BOND X891	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER (b) (4)		9. IMPORTER NUMBER (b) (4)
10. ULTIMATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME PHOENIX, AZ 85007-3002	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS CODE(S)/NAME(S) (b) (4)	
15. VESSEL CODE/NAME		16. G.S. NUMBER	18. TOTAL VALUE 1246
17. U.S. PORT OF UNLADING 2605	17. MANIFEST NUMBER		
20. DESCRIPTION OF MERCHANDISE MEDICAL EQUIPMENT			
21. IT/BL/AWB NO. M	22. IT/BL/AWB NO. 12562148505	23. MANIFEST QUANTITY 1	24. H.S. NUMBER 3004909130
			25. COUNTRY OF ORIGIN GB
			26. MANUFACTURER NO. GBDREPHA176LON

27. CERTIFICATION

28. CBP USE ONLY

I hereby make application for entry/Immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

SIGNATURE OF APPLICANT

X ATTY-

PHONE NO. 1-

Fax#: 1-

(b) (4)

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:

SIGNATURE

DATE

Exam Site: (b) (4)

Paperwork Reduction Act Statement: An agency may not conduct or sponsor an information collection and a person is not required to respond to this information unless it displays a current valid OMB control number and an expiration date. The control number for this collection is 1651-0024. The estimated average time to complete this application is 15 minutes. If you have any comments regarding the burden estimate you can write to U.S. Customs and Border Protection, Office of Regulations and Rulings, 799 9th Street, NW., Washington DC 20229.

FX/3451 (1/10)

PART 1

CBP Form 3451 (10/09)

I .d

(b) (4)

(b) (4)

WH21:8 0102 92 200



JANICE K. BREWER
GOVERNOR

Arizona Department of Corrections

1001 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-6467
www.azcorrections.gov



CHARLES L. RYAN
DIRECTOR

September 24, 2010

David Thomas, DCM
FDA Investigations
Food and Drug Administration
Division of Import Operations and Policy
4605 East Elwood Street, Suite 402
Phoenix, Arizona 85040-1948

Re: Execution by Lethal Injection of Arizona Inmate

(b) (6)

Dear Mr. Thomas:


The purpose of this correspondence is to advise your agency of our intent to receive certain pharmaceutical products from Dream Pharma, Ltd. of London, England. We have placed the order with this company for the purpose of securing the necessary drugs for carrying out an execution warrant issued by the Arizona Supreme Court in the matter of State v (b) (6) (b) (6)

In order to proceed with the execution we must have the products ordered through Dream Pharma. Our DEA Registration number is: (b) (7)(E)1 and it expires June 30, 2013. The execution is set by the court for October 26, 2010, and our agency is mandated to advise the court that it possesses the necessary chemicals for the lethal injection protocol as approved, no later than October 1, 2010.

Any steps your agency can take in attending to this shipment expeditiously would be of great assistance to our agency in its effort to abide by the court-ordered dates set by the court. Should your agency have any questions, do not hesitate to contact my office directly at (602) 542-5225 or after normal business hours through our command center at (602) 542-1212.

Thank you in advance for your professional assistance with the processing of this shipment.

Sincerely,



Charles L. Ryan
Director

cc: Charles Flanagan, Deputy Director
Robert Patton, Division Director, Offender Operations
Carson McWilliams, Warden, ASPC Florence

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 22-10-2010

Address:

Arizona State Prison Complex - Florence

(b) (4)

85232

Delivery Address:

(b) (4)

VAT no:

Purchase Order:

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

"This is not for use by the general public"

Order Details

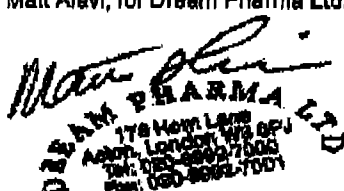
Name/Description	Quantity	Price	Total
Thiopental Injection, powder for reconstitution, thiopental sodium, (b) (4) mg vial packs of (b) (4) Batch No: (b) (4) 3004.90.9130/	(b) (4)	(b) (4)	(b) (4)

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

1.582900
1245.75

Shipping Details

Packing: ONE BOX 39X30X27CM	Gross Weight (Kg): 3.75
Tariff: 30049099	Net Weight (Kg): 3.1875
Declarations: We certify that this invoice is true and correct.	Carrier: (b) (4)
	Matt Alavi, for Dream Pharma Ltd.
	 DREAM PHARMA LTD 176 Horn Lane Acton, London W3 6PJ Tel: 020 8992 7000 Fax: 020 8992 7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: 4637884 VAT No. GB805-5541-41

Director: M. Alavi

Page 1 of 1

Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 22-10-2010

Address:

Arizona State Prison Complex - Florence

(b) (4)

86232

Delivery Address:

(b) (4)

VAT no:

Purchase Order:

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description

Shipping charges for invoice number: (b) (4)

Quantity

(b) (4)

Price

(b) (4)

Total

(b) (4)

Statement Details

Goods Total: (b) (4)

Discount (%): 0

Delivery: 0

Insurance: 0

Subtotal: (b) (4)

VAT (World Zero): 0.00

Previous Balance: 0

Total: (b) (4) GBP - Pounds sterling

Payment Method: Prepayment Thank You

Shipping Details

Packing:

Tariff: 30049089

Declarations:

We certify that this invoice is true and correct.

Gross Weight (Kg):

Net Weight (Kg): 0

Carrier: (b) (4)

Matt Alavi, for Dream Pharma Ltd.

Matt Alavi
DREAM PHARMA LTD
176 Horn Lane
Acton, London W3 6PJ
Tel: 020 8992 7000
Fax: 020 8992 7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: 4637684 VAT No. GB805-6541-41
Director: M. Alavi

Page 1 of 1

DEA REGISTRATION NUMBER (b) (7)(E)		THIS REGISTRATION EXPIRES 06-30-2013		FEE PAID Exempt	
SCHEDULES 2,3N,3 3N,4,5		BUSINESS ACTIVITY HOSPITAL/CLINIC		DATE ISSUED 06-25-2010	
ARIZONA STATE PRISON - FLORENCE, CARSON A., WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85206-0000					

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
 UNITED STATES DEPARTMENT OF JUSTICE
 DRUG ENFORCEMENT ADMINISTRATION
 WASHINGTON, D.C. 20537

This registration is only for use at Federal or State Institutions.

Sections 304 and 1005 (21 U.S.C. 834 and 855) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION WASHINGTON, D.C. 20537					
DEA REGISTRATION NUMBER (b) (7)(E)		THIS REGISTRATION EXPIRES 06-30-2013		FEE PAID Exempt	
SCHEDULES 2,3N,3 3N,4,5		BUSINESS ACTIVITY HOSPITAL/CLINIC		DATE ISSUED 06-25-2010	
ARIZONA STATE PRISON - FLORENCE, CARSON A., WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85206-0000					

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
 UNITED STATES DEPARTMENT OF JUSTICE
 DRUG ENFORCEMENT ADMINISTRATION
 WASHINGTON, D.C. 20537

Sections 304 and 1005 (21 U.S.C. 834 and 855) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, BUSINESS ACTIVITY, OR VALID AFTER THE EXPIRATION DATE.

DEA REGISTRATION NUMBER (b) (7)(E)	THIS REGISTRATION EXPIRES 08-30-2013	FEE PAID FEE EXEMPT
SCHEDULES 3, 3A, 4, 5	REGISTERED ACTIVITY HOSPITAL/CLINIC	ISSUE DATE 08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85033		

<p align="center">CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION WASHINGTON D.C. 20537</p> <p>This registration is only for use at Federal or State Institutions.</p> <p>Sections 304 and 1005 (21 USC 824 and 825) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.</p> <p>THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.</p>

<p align="center">REPORT</p>	<p align="center">REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE</p> <p>To request a change to your registered name, address, the drug schedule or the drug codes you handle, please</p> <p align="center">* visit our web site at deaenforcement.dhs.gov - or</p>
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(b) (4) (b) (4)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEES PAID
(b) (7)(E)	08-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	EXPIRATION DATE
3,3N,4,5	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 829 FLORENCE, AZ 85232-0000		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

This registration is only for use at Federal or State Institutions.

Sections 304 and 408 (21 USC 824 and 828) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEES PAID
(b) (7)(E)	08-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	EXPIRATION DATE
3,3N,4,5	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 829 FLORENCE, AZ 85232-0000		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

This registration is only for use at Federal or State Institutions.

Sections 304 and 408 (21 USC 824 and 828) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

IAPSI

SEP. 29. 2010 9:38AM

NO. 867 P. 2/9

1551-0000-000 15-01-0010

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border ProtectionForm Approved
OMB No. 1551-0024

ENTRY/IMMEDIATE DELIVERY

DI

(b) (4)

000 BOX #

19 CFR 142.3, 142.16, 142.22, 142.24

ABI Certified

1. ARRIVAL DATE 092810	2. ELECTED ENTRY DATE 092810	3. ENTRY TYPE CODE/NAME 007 001 0000000 Consump	4. ENTRY NUMBER 574-0250322-1
5. PORT 2605	6. SINGLE TRANS. BOND XB91	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER (b) (4)		9. IMPORTER NUMBER (b) (4)
10. ULTIMATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME ARIZONA DEPARTMENT OF CORRECTIONS 1601 W. JEFFERSON ST PHOENIX, AZ 85007-3002	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP 000	14. LOCATION OF GOODS-CODE(S)/NAME (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLOADING (b) (4)	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE (b) (4)
20. DESCRIPTION OF MERCHANDISE THIOPENTAL, POTASSIUM, FANCURONI			
21. TBLAND CODE H	22. IT/BL/WB NO. 672136481249	23. MANIFEST QUANTITY 1	24. H.S. NUMBER 3004909130
			25. COUNTRY OF ORIGIN GB
I	200610185		26. MANUFACTURER NO. GBDREPHA176LON
M	02358499140		27. MANUFACTURER NO. GBDREPHA176LON

27. CERTIFICATION

I hereby make application for entry/immmediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT

(b) (4)

PHONE

29. BROKER OR OTHER GOVT. AGENCY USE

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

Pharmacy Program Manager

☐ CBP EXAMINATION REQUIRED.☐ ENTRY REJECTED, BECAUSE:DELIVERY
AUTHORIZED:

SIGNATURE

DATE

Exam Site:

(b) (4)

Paperwork Reduction Act Notice: This information is to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary. The estimated average burden associated with this collection of information is 15 minutes per respondent depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to U.S. Customs and Border Protection, Information Services Branch, Washington, DC 20229, and to the Office of Management and Budget, Paperwork Reduction Project (1551-0024), Washington, DC 20503.

09-28-10 09:08 FROM-ADC Directors Office 602-364-0601

T-087 P0003/0005 F-565

Dream Pharma Ltd.

175 Horn Lane, Aston, London, W3 6PJ
 Tel: 020 8992 7000 Fax: 020 8992 7001
 E-Mail: info@dreampharma.com

Invoice Details

Number: 25791NV

Date: 28-09-2010

Address:

(b) (4)

Delivery Address:

(b) (4)

204.94.9130/FM
 104.20.0000/6.57
 3-2733.37.4100/FM

VAT no:
 Purchase Order:

Currency: GBP - Pounds sterling
 Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Tax
Thiopental Injection, powder for reconstitution thiopental sodium, (b) (4) mg vial packs of (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
POTASSIUM CHLORIDE 1.00M (b) (4) INJ. PACKS OF (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
Penciclovir Injection, penciclovir bromide 2 mg/mL, (b) (4) mL amp packs of (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
Special delivery charges			

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: (b) (4)	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: ONE BOX	Gross Weight (Kg): 25
Trade: 30049000	Net Weight (Kg): 21.25
Declarations: We certify that this invoice is true and correct.	Carrier: (b) (4)
	Mark Alert for Dream Pharma Ltd

Damage, shortage or leakage must be notified in writing to customer within 7 days. Non-Delivery claim 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: 4857884 VAT No. GB405-8541-41
 Director: M. Alavi

Page 1 of 1

**TRANSPORTATION ENTRY AND MANIFEST
OF GOODS SUBJECT TO CBP
INSPECTION AND PERMIT
U.S. Customs and Border Protection**

OMB No. 1551-0003 Exp. 12-31-2010

19 CFR 10.60, 10.61, 123.41, 123.42

Entry No. _____
Port _____
Date _____

Entry No. 200610185
Class of Entry I.T. 61
(I.T.) (T.E.) (W.D.) (Drawback, etc.)

PORT CODE NO. (b) (4) FIRST U.S. PORT OF UNLADING (b) (4)
PORT OF (b) (4)

DATE 29SEP10

Entered or imported by (b) (4) Importer/IRS # (b) (4) to be shipped
in bond via (b) (4) consigned to
(C.H.L. number) (Vessel or carrier) (Car number and initial) (Pier or station)

CBP Port Director PHOENIX, AZ 2605

Final foreign destination

Consignee (b) (4)
(ALCBP port of exit or destination)

Foreign port of lading B/L No. (b) (4) Date of sailing
(Above information to be furnished only when merchandise is imported by vessel)

Imported on the (b) (4) Flag USA on 28SEP10 via STN
(Name of vessel or carrier and motive power) (Date imported) (Last foreign port)

Exported from UNITED KINGDOM on 28SEP10 Goods now at (b) (4)
(Country) (Date) (Name of warehouse, station, pier, etc.)

Marks and Numbers of Packages	Description and Quantity of Merchandise Number and Kind of Packages (Describe fully as per shipping papers)	Gross Weight in Pounds	Value (Dollars only)	Rate	Duty
1 PCS	872136481249 PHARMACEUTICALS NOT RESTRICTED THIOPENTAL INJECTION POWDER FOR RECONSTITUTION THIOPENTAL SODIUM (b) (4) MG VIAL PACKS OF (b) (4) BATCH NO (b) (4) 05.4 POTASSIU *** BROKER INFORMATION *** (b) (4) CONTACT (b) (4)	ESTIMATED NOT (b) (4)	VERIFIED (b) (4) USD		

G.O. No. ☐ Check if withdrawn for Vessel supplies (19 U.S.C. 1309)

**CERTIFICATE OF LADING FOR TRANSPORTATION IN BOND
AND/OR LADING FOR EXPORTATION FOR
PHOENIX, AZ 2605**

(Port)

WITH THE EXCEPTIONS NOTED ABOVE, THE
WITHIN-DESCRIBED GOODS WERE:

Delivered to the Carrier
named above, for delivery to
the CBP Port Director at
destination sealed with CBP
seals Nos. WAIVED
or the packages (were) (were
not) labeled, or corded
and sealed.

Laden on the--

(Vessel, vehicle, or aircraft)

which cleared for--

on _____
(Date)
as verified by export records.

AMS AUTHORIZED
(Inspector)

(Date)

(Inspector)

(Date)

I truly declare that the statements contained herein are true and
correct to the best of my knowledge and belief.

Entered or withdrawn by

(b) (4)

EMP# (b) (4)

To the Inspector: The above-described goods shall be disposed of
AMS AUTHORIZED

For the Port Director

Received from the Port Director of the above CBP location the
merchandise described in this manifest for transportation and
delivery into the custody of the CBP officers at the port named
above, all packages in apparent good order except as noted hereon.

(b) (4)

EMP# (b) (4)

Attorney or Agent of Carrier

CBP Form 7512 (03/08)



JANICE K. BREWER
GOVERNOR

Arizona Department of Corrections

1801 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 642-6497
www.azcorrections.gov



CHARLES L. RYAN
DIRECTOR

September 24 2010

David Thomas, DCM
FDA Investigations
Food and Drug Administration
Division of Import Operations and Policy
4605 East Elwood Street, Suite 402
Phoenix, Arizona 85040-1948

Dear Mr. Thomas:

Thank you for your professional assistance with the processing of this shipment. I am enclosing the original letter addressed to your agency and a copy of our Substance Control Registration Certificate.

Once again, thank you again for your assistance. Should you require additional information, please do not hesitate to contact me.

Sincerely,

Charles L. Ryan
Deputy Director

cc: File

*Dave,
please do not hesitate to
contact me for any reason. I
greatly appreciate your assistance,
Charles*



JANICE K. BREWER
GOVERNOR

Arizona Department of Corrections

1801 WEST JEFFERSON
PHOENIX, ARIZONA 85007
(602) 542-5487
www.azcorrections.gov



CHARLES L. RYAN
DIRECTOR

September 24, 2010

David Thomas, DCM
FDA Investigations
Food and Drug Administration
Division of Import Operations and Policy
4605 East Elwood Street, Suite 402
Phoenix, Arizona 85040-1948

Re: Execution by Lethal Injection of Arizona Inmate
[REDACTED] (b) (6)

Dear Mr. Thomas:


The purpose of this correspondence is to advise your agency of our intent to receive certain pharmaceutical products from Dream Pharma, Ltd. of London, England. We have placed the order with this company for the purpose of securing the necessary drugs for carrying out an execution warrant issued by the Arizona Supreme Court in the matter of State v. [REDACTED] (b) (6)

In order to proceed with the execution we must have the products ordered through Dream Pharma. Our DEA Registration number is: [REDACTED] (b) (7)(E) and it expires June 30, 2013. The execution is set by the court for October 26, 2010, and our agency is mandated to advise the court that it possesses the necessary chemicals for the lethal injection protocol as approved, no later than October 1, 2010.

Any steps your agency can take in attending to this shipment expeditiously would be of great assistance to our agency in its effort to abide by the court-ordered dates set by the court. Should your agency have any questions, do not hesitate to contact my office directly at (602) 542-5225 or after normal business hours through our command center at (602) 542-1212.

Thank you in advance for your professional assistance with the processing of this shipment.

Sincerely,



Charles L. Ryan
Director

cc: Charles Flanagan, Deputy Director
Robert Patton, Division Director, Offender Operations
Carson McWilliams, Warden, ASPC Florence

(b) (4)

(b) (4)

(b) (4)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (7)(E)	06-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232-0000		

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223 (4-07)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (7)(E)	06-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232-0000		

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DEA REGISTRATION NUMBER		THIS REGISTRATION EXPIRES		FEE PAID	
(b) (7)(E)		08-30-2013		Exempt	
SCHEDULES		BUSINESS ACTIVITY		DATE ISSUED	
2,2N,3 3N,4,5		HOSPITAL/CLINIC		08-25-2010	
ARIZONA STATE PRISON - FLORENCE, CARSON A., WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232 0000					

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Form DEA-223 (05/04)

DEA REGISTRATION NUMBER		THIS REGISTRATION EXPIRES		FEE PAID	
(b) (7)(E)		08-30-2013		Exempt	
SCHEDULES		BUSINESS ACTIVITY		DATE ISSUED	
2,2N,3 3N,4,5		HOSPITAL/CLINIC		08-25-2010	
ARIZONA STATE PRISON - FLORENCE, CARSON A., WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232 0000					

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Dream Pharma Ltd.

176 Horn Lane, Acton, London, W3 6PJ
Tel: 020 8992 7000 Fax: 020 8992 7001
E-Mail: info@dreampharma.com

Invoice Details

Number: (b) (4)

Date: 28-09-2010

Address:

(b) (4)
85232

Delivery Address:

(b) (4)

VAT no:

Purchase Order:

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection, powder for reconstitution, thiopental sodium, (b) (4) mg vial packs of (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
POTASSIUM CHLORIDE 1.5GM (b) (4) L INJ. PACKS OF (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
Pancuronium Injection, pancuronium bromide 2 mg/mL, (b) (4) mL amp packs of (b) (4) Batch No: (b) (4)	(b) (4)	(b) (4)	(b) (4)
Special delivery charges	(b) (4)	(b) (4)	(b) (4)

Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): 0	VAT (World Zero): 0.00
Delivery: (b) (4)	Previous Balance: 0
Insurance: 0	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: ONE BOX	Gross Weight (Kg): 25 Net Weight (Kg): 21.25
Tariff: 30049099	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharma Ltd. 176 Horn Lane Acton, London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

Company Registration Number: (b) (4) VAT No (b) (4)

Director: M. Alavi

Bryce, John *

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:37 PM
To: Strickland, Evanguel
Subject: Completed conference with Dan. Out of office at 3:30 PM

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 3:12 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: First entry scenario, complete

Thanks you. This is good.

Is there one for Entry # 574-0251126-5?

From: Thomas, David
Sent: Wednesday, October 27, 2010 3:08 PM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: First entry scenario, complete

Daniel:

This is complete for the first entry.

Entry 574-0250322-1

September 24, 2010 Mr. Charles Flanagan, Deputy Director Arizona Department of Corrections (602) 542-3611 contacted CSO David Thomas from the FDA Office in Phoenix stating he wanted to import a shipment of drugs from overseas and asked the procedures. Mr. Flanagan was directed to U.S.C.B.P. for a list of brokers to choose from to initiate an importation process.

September 27 2010 (b) (4) was chosen by AZ DOC.

(b) (4) sent PHX-RP imports partial entry information which included letter of intent, DEA certificate, and list of products. Products were Thiopental Sodium, Potassium Chloride, and Pancuronium Bromide.

(b) (4) also advised PHX-PR the entry 574-0250322-1 would be transmitted wheels up from the U.K. An email was sent to DIOP and supervision immediately notifying of the proposed import with attached documentation of the information received from (b) (4) Entry review of manufacturer, Dream Pharma Ltd. of London, England revealed the manufacturer was FDA registered for certain drugs, but not the drugs being imported.

1. FDA Investigator was provided with an official letter from the Arizona Department of Corrections stating this shipment of drugs was warranted by the Arizona Supreme Court (State v. (b) (6))
2. Manufacturer Dream Pharma has several FDA registration numbers for drugs; however not for

the aforementioned being imported.

3. Arizona Department of Corrections also has a DEA registration number (b) (7)(E)

September 29, 2010 entry arrived Port of Entry Phoenix via (b) (4)

PHX-RP received email notification from DIOP that entry was available for release. Upon arrival that afternoon, product was confirmed for labeling, count and amount with AZ DOC personnel in accompaniment of the CSO. Product was FDA released, then taken into custody by AZ DOC after the inspection.

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 2:55 PM
To: Thomas, David
Cc: Strickland, Evanguel
Subject: RE: Scenario Initial AZ DOC entry

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (4)	06-30-2013	Exempt

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,6	HOSPITAL/CLINIC	08-25-2010

ARIZONA STATE PRISON - FLORENCE, CARSON A.,
WARDEN
1305 BUTTE AVE.
P.O. BOX 629
FLORENCE, AZ 85232 0000

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DRUG ENFORCEMENT ADMINISTRATION
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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (4)	06-30-2013	Exempt

SCHEDULES	BUSINESS ACTIVITY	DATE ISSUED
2,2N,3 3N,4,6	HOSPITAL/CLINIC	08-25-2010

ARIZONA STATE PRISON - FLORENCE, CARSON A.,
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Form DEA-223 (05/04)

Bryce, John *

From: Thomas, David
Sent: Thursday, October 28, 2010 6:28 AM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: Dream Pharma Shipments

Importance: High

Attachments: Dream Pharma FEI 3004744216.doc

Daniel:

I see 6 shipments of possible Lethal Injection Drugs from Dream Pharma beginning 6-28-10, in bold font. Shipments to POE PHX 2605, are observed as dates 9-29-10 and 10-25-10 for entries 574-0250322-1 and 574-0251126-5 respectively.



Dream Pharma
I 3004744216.doc

David Thomas, DCM
FDA Investigations
Phoenix, Office

Products Shipped:

Product Code	Description	GPI Code	Device Class	Last Shipment Date
60QLK28	Thiopental Sodium (Anesthetic)	DR - Drugs		10/25/2010
60QCY28	Thiopental Sodium (Anesthetic)	DR - Drugs		10/07/2010
65QLK25	Pancuronium Bromide (Relaxant)	DR - Drugs		09/29/2010
60QCN28	Thiopental Sodium (Anesthetic)	DR - Drugs		09/20/2010
60QIY28	Thiopental Sodium (Anesthetic)	DR - Drugs		07/27/2010
60QCR28	Thiopental Sodium (Anesthetic)	DR - Drugs		06/28/2010
(b) (4)	(b) (4)	DR - Drugs		(b) (4)
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DE - Devices 1		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		
		DR - Drugs		

Bryce, John *

From: Thomas, David
Sent: Wednesday, September 29, 2010 9:57 AM
To: Verbeten, John E. (ORA); Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Solis, Daniel; Strickland, Evanguel
Subject: Entry 574-0250322-1: Lethal Injection Pharmacology

Importance: High

Attachments: 57402503221.pdf



57402503221.pdf
f (630 KB)

John:

The above entry of Lethal Injection pharmacology has been transmitted for the purpose of execution of a Arizona prisoner.

The issue involves 3 products from manufacturer Dream Pharma, London, UK, FEI 3004744216. Product 1) Thiopental Sodium NDC 000703-2556, product 2) Pancuronium Bromide NDC 000074-4645, and product 3) Potassium Chloride Injectable NDC 000469-6520 do not appear to have valid DRLS numbers for the manufacturer. However, Dream Pharma is registered under the aforementioned FEI.

Arizona Department of Corrections Director, Charles Ryan, 602-542-5225, has related in previous correspondence that his agency must have these products in hand today to be accountable to the Arizona Supreme Court by September 30, 2010 for the intended purpose above. (see attached AZ DOC correspondence)

Currently the product is being trucked into Phoenix from Los Angeles. (b) (4) mistakenly routed the product from (b) (4) to Los Angeles, CA instead of the planned flight to Phoenix, AZ.

Lastly, I have attached the entry documentation and held the entry in my inbox, pending Agency approval of a release.

May I hear from you soon,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----

From: Verbeten, John E. (ORA)
Sent: Wednesday, September 29, 2010 3:54 AM
To: Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel
Subject: Re: Lethal Injection Pharmacology

(b) (5)

----- Original Message -----

From: Notzon, Stella
To: Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel; Verbeten, John E. (ORA)
Sent: Mon Sep 27 13:06:53 2010
Subject: FW: Lethal Injection Pharmacology

Huascar, et.al,

(b) (5)

Stella

-----Original Message-----

From: Thomas, David
Sent: Monday, September 27, 2010 11:33 AM
To: Notzon, Stella
Cc: Strickland, Evangel; Solis, Daniel
Subject: FW: Lethal Injection Pharmacology
Importance: High

Stella:

FYI

Dave Thomas
FDA Imports
Phoenix, AZ

-----Original Message-----

From: Thomas, David
Sent: Monday, September 27, 2010 8:23 AM
To: Taube, Anthony C
Cc: Strickland, Evangel; Solis, Daniel; 'DEAN, MICHAEL K'; 'CHARLES FLANAGAN'
Subject: Lethal Injection Pharmacology
Importance: High

~~Prior Notice Center Director, Anthony Taube:~~

RE: Lethal Injection pharmacology:

Sir:

I have an entry of 3 components of a lethal injection, 1) Thiopental, 2) Pancuronium, 3) Potassium Chloride departing London this afternoon, destination (b) (4) with Port of Entry 2605, Phoenix. As of this communication, no entry has been made.

These pharmaceuticals are needed to carry out an execution here in Arizona, and are not for public consumption. Attached is Please find attached explanatory documentation and DEA registration for the Arizona Corrections facility.

Lastly, should I be advising anyone else?

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

Charles:

We are in receipt of your communication and PDF attachments. I have CC'd my Supervisor, Mr. Strickland, and our Imports Director Mr. Solis for their review.

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----

From: CHARLES FLANAGAN [mailto:CFLANAG@azcorrections.gov]
Sent: Friday, September 24, 2010 5:04 PM
To: Thomas, David
Subject: Pharmaceuticals from Dream Pharma, LTD. of London, England

Good Afternoon Mr. Thomas:

Thank you so much for your assistance with this matter. I have attached to this email a copy of the correspondence what will be shipped with the pharmaceuticals. It also includes the Department of Corrections' "Substance Control Registration Certificate". The second attachment is a list of the items that will be shipped to our facility; to include quantities purchased and the last attachment is the revised DEA Registration which includes certification for Schedule 2 drugs.

Once again, thank you again for your assistance. Should you require additional information, please do not hesitate to contact me. Here is my information:

Charles Flanagan
Deputy Director
Arizona Department of Corrections
1601 W. Jefferson - MC 445
Phoenix, Arizona 85007
(602) 542-3611 Office
(602) 377-5334 Cell
(602) 364-0601 Fax
cflanag@azcorrections.gov

Bryce, John *

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 1:44 PM
To: Thomas, David; Strickland, Evanguel
Subject: FW: Entry number of 9/29/10 shipment

This is what I have so far. More details I am working on:

- September 24, 2010 = Charles Flanagan, Deputy Director Arizona Department of Corrections (602) 542-3611 contacted CSO from the FDA Office in Phoenix, Az, David Thomas, regarding shipment under Entry 574-0251126-5. This initial email was to inform Phoenix of the incoming shipment from London (Dream Pharma, Ltd. Of London, England) destination (b) (4) with Port of Entry 2605, Phoenix, Az.
- Shipment was of 3 chemical components: Sodium Thiopental, Pancuronium Bromide and Potassium Chloride
- FDA Investigator was provided with an official letter from the Arizona Department of Corrections stating this shipment of drugs was warranted by the Arizona Supreme Court (State v. (b) (6) (b) (6))
- In order to execute the warrant, the Arizona Department of Corrections, needed the products from dream Pharma. (Dream Pharma has an FDA registration number and has drugs and devices reg and listing).
- Arizona Department of Corrections also has a DEA registration number (b) (7)(E)

From: Roh, Mark S
Sent: Wednesday, October 27, 2010 1:39 PM
To: Solis, Daniel
Subject: Re: Entry number of 9/29/10 shipment

I'm anxiously awaiting your summary report.
Mark Roh
Pacific Regional Director
Office phone - 510-637-3960
Mobile phone - 510-590-3001

From: Solis, Daniel
Sent: Wednesday, October 27, 2010 03:51 PM
To: Veneziano, Domenic J.
Cc: Elder, David K.; Rogers, Michael; Roh, Mark S
Subject: RE: Entry number of 9/29/10 shipment

I just finished talking to Charles Flanagan from the Arizona Dept. of Corrections. He provided me with some insight. You can't wait for my summary report or we can have a quick phone con on what I found out.

From: Veneziano, Domenic J.
Sent: Wednesday, October 27, 2010 12:26 PM
To: Solls, Daniel
Cc: Elder, David K.; Rogers, Michael; Roh, Mark S
Subject: Entry number of 9/29/10 shipment

Dan the entry number for the LA shipment is 574-0250322-1/1/1

Domenic J. Veneziano
CDR U.S. Public Health Service
Director, Division of Import Operations and Policy
Work: (301) 443-6553
FAX: (301) 594-0413
Cell: (240) 888-9316

Bryce, John *

From: Thomas, David
Sent: Wednesday, October 27, 2010 12:19 PM
To: Solis, Daniel
Cc: Strickland, Evanguel
Subject: FW: Lethal injection pharmacology entry 574-0251126-5

Importance: High

Attachments: 574-0251126-5.pdf

Daniel:

Attached is the original email and documentation of the last of 2 entries.

David Thomas, DCM
FDA Investigations
Phoenix, Office

From: Thomas, David
Sent: Tuesday, October 26, 2010 8:47 AM
To: Batista, Huascar R
Cc: Verbeten, John E. (ORA); Solis, Daniel; Strickland, Evanguel
Subject: Lethal injection pharmacology entry 574-0251126-5
Importance: High

Husacar:

I have the same product coming into Phoenix Port of entry 2605, Sodium Thiopental, imported by the same Arizona Department of Corrections (DOC), manufactured by the same company, Dream Pharma Ltd. The entry is for the same purpose, lethal injection pharmacology.

Does the previous email notification, dated September 29, 2010, hold true for this shipment?

Please find attached entry documentation for the above.



574-0251126-5.
pdf (407 KB)

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----

From: Batista, Huascar R
Sent: Wednesday, September 29, 2010 10:35 AM
To: Thomas, David
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

Correct.

-----Original Message-----

From: Thomas, David
Sent: Wednesday, September 29, 2010 1:33 PM
To: Batista, Huascar R
Cc: Solis, Daniel; Strickland, Evanguel; Verbeten, John E. (ORA); Notzon, Stella; Bormel, Frances Gail; Anderson, Kathleen R
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

Huascar:

I am in receipt of your communication, thank you. To confirm, CDER is not objecting to the release of the above entry of 3 pharmaceuticals from U.K.

Thank you for your timely reply. I will advise AZ DOC of the new FDA entry status.

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----

From: Batista, Huascar R
Sent: Wednesday, September 29, 2010 10:28 AM
To: Thomas, David
Cc: Solis, Daniel; Strickland, Evanguel; Verbeten, John E. (ORA); Notzon, Stella; Bormel, Frances Gail; Anderson, Kathleen R
Subject: RE: Entry 574-0250322-1: Lethal Injection Pharmacology

(b) (5)

Huascar Batista
Imports & Exports Compliance Team Leader
Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
WO-51, 5374
Silver Spring, MD 20993
Tel: 301.796.3411

-----Original Message-----

From: Thomas, David
Sent: Wednesday, September 29, 2010 12:57 PM
To: Verbeten, John E. (ORA); Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Solis, Daniel; Strickland, Evanguel
Subject: Entry 574-0250322-1: Lethal Injection Pharmacology
Importance: High

John:

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The issue involves 3 products from manufacturer Dream Pharma, London, UK, FEI 3004744216. Product 1) Thiopental Sodium NDC 000703-2556, product 2) Pancuronium Bromide NDC 000074-4645, and product 3) Potassium Chloride Injectable NDC 000469-6520 do not appear to have valid DRLS numbers for the manufacturer. However, Dream Pharma is registered under the aforementioned FEI.

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David Thomas, DCM
FDA Investigations
Phoenix, Office

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To: Notzon, Stella; Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel
Subject: Re: Lethal Injection Pharmacology

(b) (5)

----- Original Message -----

From: Notzon, Stella
To: Batista, Huascar R; Bormel, Frances Gail; Anderson, Kathleen R
Cc: Thomas, David; Solis, Daniel; Verbeten, John E. (ORA)
Sent: Mon Sep 27 13:06:53 2010
Subject: FW: Lethal Injection Pharmacology

Huascar, et.al,

(b) (5)

Stella

-----Original Message-----

From: Thomas, David
Sent: Monday, September 27, 2010 11:33 AM
To: Notzon, Stella
Cc: Strickland, Evanguel; Solis, Daniel
Subject: FW: Lethal Injection Pharmacology
Importance: High

Stella:

FYI

Dave Thomas

FDA Imports
Phoenix, AZ

-----Original Message-----

From: Thomas, David
Sent: Monday, September 27, 2010 8:23 AM
To: Taube, Anthony C
Cc: Strickland, Evanguel; Solis, Daniel; 'DEAN, MICHAEL K'; 'CHARLES FLANAGAN'
Subject: Lethal Injection Pharmacology
Importance: High

Prior Notice Center Director, Anthony Taube:

RE: Lethal Injection pharmacology:

Sir:

I have an entry of 3 components of a lethal injection, 1) Thiopental, 2) Pancuronium, 3) Potassium Chloride departing London this afternoon, destination (b) (4) with Port of Entry 2605, Phoenix. As of this communication, no entry has been made.

These pharmaceuticals are needed to carry out an execution here in Arizona, and are not for public consumption. Attached is Please find attached explanatory documentation and DEA registration for the Arizona Corrections facility.

Lastly, should I be advising anyone else?

Respectfully,

David Thomas, DCM
FDA Investigations
Phoenix, Office

Charles:

We are in receipt of your communication and PDF attachments. I have CC'd my Supervisor, Mr. Strickland, and our Imports Director Mr. Solis for their review.

David Thomas, DCM
FDA Investigations
Phoenix, Office

-----Original Message-----

From: CHARLES FLANAGAN [mailto:CFLANAG@azcorrections.gov]
Sent: Friday, September 24, 2010 5:04 PM
To: Thomas, David
Subject: Pharmaceuticals from Dream Pharma, LTD. of London, England

Good Afternoon Mr. Thomas:

Thank you so much for your assistance with this matter. I have attached to this email a copy of the correspondence what will be shipped with the pharmaceuticals. It also includes the Department of Corrections' "Substance Control Registration Certificate". The second attachment is a list of the items that will be shipped to our facility; to include quantities purchased and the last attachment is the revised DEA Registration which includes certification for Schedule 2 drugs.

Once again, thank you again for your assistance. Should you require additional information, please do not hesitate to contact me. Here is my information:

Charles Flanagan
Deputy Director
Arizona Department of Corrections

1601 W. Jefferson - MC 445
Phoenix, Arizona 85007
(602) 542-3611 Office
(602) 377-5334 Cell
(602) 364-0601 Fax
cflanag@azcorrections.gov

David Thomas, DCM
FDA Investigations
Phoenix, Office

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1

Notice Number: 1
September 29, 2010

Filer:

(b) (4)

Attention:

(b) (4)

Broker Box:

(b) (4)

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Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4);

Date Received: September 29, 2010

Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002

Consignee: (b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	THIOPENTAL SODIUM 500 MG	(b) (4)	Released 09-29-2010
002/001	PANCURONIUM INJECTION	(b) (4)	Line Split
002/001A	PANCURONIUM BROMIDE	(b) (4)	Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE	(b) (4)	Released 09-29-2010

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry 574-0250322-1. Any status changes are reflected in the Line summary and line detail sections.

David C. Thomas, Investigator
U.S. Food & Drug Administration
51 W. 3rd Street, Suite E-265
Tempe, AZ 85281

(480) 829-7396 ext. 12
(480) 829-7677 (FAX)
DAVID.THOMAS@FDA.HHS.GOV

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: JRB

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5

Notice Number: 1

January 7, 2011

Filer:

(b) (4)

Attention:

(b) (4)

Broker Box:

(b) (4)

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Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4)

Date Received: October 25, 2010

Arrival Date: October 26, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002

Consignee: (b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
* 001/001	THIOPENTAL SODIUM, POWDER	(b) (4)	Released 01-06-2011

* = Status change since the previous notice. Read carefully the sections which follow for important information regarding these lines.

@ = Consignee ID

This is the final notice concerning entry 574-0251126-5. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA	Product Description
001/001	THIOPENTAL SODIUM, POWDER

Comments: FDA releases this shipment, which is being imported by or on behalf of state correctional authorities. In keeping with established practice, FDA does not review or approve products for the purpose of lethal injection. FDA has not reviewed the products in this shipment to determine their identity, safety, effectiveness, purity or any other characteristics.

Ruben Delagarza, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700

(310) 971-2297
(310) 971-2363 (FAX)
laimports@FDA.HHS.GOV

Notice of FDA Action
Entry Number: 574-0251126-5

Notice Number 1
Page: 2

San Pedro, CA 90731

LINES RELEASED

Line ACS/FDA	Product Description
001/001	THIOPENTAL SODIUM, POWDER
Ruben Delagarza, Compliance Officer (Region/District) U.S. Food and Drug Administration 222 W. 6th St., Suite 700 San Pedro, CA 90731	(310) 971-2297 (310) 971-2363 (FAX) laimports@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

Notice Prepared For: The District Director, U.S. Food and Drug Administration
Notice Prepared By: JRB

Bryce, John *

From: Thomas, David
Sent: Friday, November 05, 2010 6:54 AM
To: 'CHARLES FLANAGAN'; 'CHARLES RYAN'
Cc: Levy, Michael; Strickland, Evanguel; Solis, Daniel; 'DEAN, MICHAEL K'
Subject: Update Your Pharmaceutical Entry

Importance: High

Charles:

I have been asked by Mr. Levy's office to update you on your Agency's entry of Sodium Thiopental. As of this writing, no entry status change has been made by our Headquarters office; however, a decision is forthcoming. Thus, your pharmaceutical entry is still pending FDA review.

Your Agency's concern is very much appreciated and has been noted. Should you have any questions in the interim, please feel free to call on me.

Regards,

David Thomas, DCM
FDA Investigations
Phoenix, Office
Blackberry 602-908-2437