From: Boulmay, Christopher

Sent: Tuesday, November 30, 2010 4:00 PM

To: 'McAuliffe, John@CDCR'

Cc: Kernan, Scott@CDCR; Halpenny, Susan M; Dixon, Ruth P

Subject: RE: FDA entry item # 112-99-38358-2

John,

This entry is currently under review by our DIOP branch. (b) (5)

. If you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

Christopher Boulmay

Consumer Safety Officer
US Food & Drug Administration

NOL-DO: Memphis R.P. **Phone:** (901) 333-3528 **Fax:** (901) 333-3577

From: McAuliffe, John@CDCR [mailto:John.McAuliffe@cdcr.ca.gov]

Sent: Tuesday, November 30, 2010 3:37 PM

To: Boulmay, Christopher **Cc:** Kernan, Scott@CDCR

Subject: FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to (b) (4)

(b) (6) is the (b) (4) contact person) I also called your phone number 901-333-3528 and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

John McAuliffe

California Department of Corrections and Rehabilitation

Trepagnier, Timothy

From: Budweg, Greta L

Sent: Monday, September 27, 2010 12:02 PM

To: Halpenny, Susan M

Cc: Dixon, Ruth P; Thomas, David; Chan, Hoi-May (CBER); Samaan, Marian; Chung, Phap;

Cowels, Allyson

Subject: RE: Lethal Injection Pharmacology

Susan,

We are running sweeps in CBP's ATS database to find this shipment prior to arrival. We've identified 2 similar shipments with our sweep with UPS-9066861-5 and 112-8992979-0. We'll keep you posted on anything we find.

Greta

Greta L. Budweg
Watch Commander
FDA/ORA/ORO/Prior Notice Center
866-521-2297 main phone
703-261-8439 phone
703-261-8625 fax
greta.budweg@fda.hhs.gov

----Original Message----

From: Halpenny, Susan M

Sent: Monday, September 27, 2010 12:44 PM

To: Thomas, David

Cc: Dixon, Ruth P; Budweg, Greta L

Subject: FW: Lethal Injection Pharmacology

Importance: High

Good day,

It would be helpful if you could provide Memphis the airway bill for this shipment. We can follow-up with the broker to see if/and when the shipment is bein

able to track the shipment thru

any information you can provide.

Also we would be ance.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521

1

----Original Message----

From: Budweg, Greta L

Sent: Monday, September 27, 2010 11:31 AM

To: Schafer, Patricia

Cc: ORA SE NOL Import Supervisors; Taube, Anthony C

Subject: FW: Lethal Injection Pharmacology

Importance: High

Hi Pat,

I suggested to Dave Thomas that this information would be helpful to the Memphis entry reviewers. Dave indicated that no entry has been made at this time. I'll continue to pass on any information related to this shipment.

Greta

Greta L. Budweg Watch Commander FDA/ORA/ORO/Prior Notice Center 866-521-2297 main phone 703-261-8439 phone 703-261-8625 fax greta.budweg@fda.hhs.gov

----Original Message----

From: Thomas, David

Sent: Monday, September 27, 2010 11:50 AM

To: Budweq, Greta L

Subject: FW: Lethal Injection Pharmacology

Importance: High

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 Memphis 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

OFFICE OF THE SECRETARY

P.O. Box 942883 Sacramento, CA 94283-0001

December 9, 2010



Ms. Ruth Dixon
Department of Health and Human Services
Food and Drug Administration

Dear Ms. Dixon:

Since 1993, California law has authorized capital punishment by lethal injection pursuant to Penal Code Section 3604. The law states the punishment of death shall be inflicted by the administration of an intravenous injection of substances in a lethal quantity sufficient to cause death. On May 1, 2009, the California Department of Corrections and Rehabilitation (CDCR) promulgated regulations setting forth the requirements for administering capital punishment by lethal injection pursuant to Administrative Procedure Act. Those regulations became effective on August 29, 2010. The regulations provide for the use of three chemicals; sodium thiopental, pancuronium bromide, and potassium chloride.

There is a national shortage of sodium thiopental. California, like many other states, has been actively seeking supplies of the sodium thiopental for future executions. California's supply of sodium thiopental expired on October 1, 2010. On November 22, 2010, CDCR notified the United States District Court for the Northern District of California that it had ordered for grams of sodium thiopental that expires in 2014 from a manufacturer based in England (FDA # 112-99-38358-2). CDCR expected to receive the sodium thiopental during the week of November 29, 2010. Although CDCR followed all proper procedures and the Drug Enforcement Agency and United States Customs has approved the shipment, this shipment is currently be held by your office.

Per your conversation with John McAuliffe, we are asking for the immediate release and shipment of the [5] (4) grams of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or Mr. McAuliffe at (707) 480-6766.

Sincerely,

BENJAMIN T. RICE General Counsel

cc: John McAuliffe

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Tuesday, December 07, 2010 7:14 AM

To: Halpenny, Susan M **Subject:** clearance delay Good morning Susan,

It has been a month since the FDA has chosen to delay delivery of a package sent from England to the South Carolina Department of Corrections. From our last conversation I understand there is a discussion regarding "jurisdiction" between the FDA and the DEA. If it does not appear that there will be a solution to this stalemate in the near future (think next 24 hours) can you direct me to someone who might be able to help expedite a decision?

John

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999 From: Dixon, Ruth P

Sent: Thursday, December 09, 2010 2:24 PM

To: Veneziano, Domenic J. **Cc:** Halpenny, Susan M

Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf

Good day Domenic,

Before I had the opportunity to return the call to the Undersecretary I received this message with the enclosed letter. Mr. McAuliffe also followed up with a phone call...they will be trying to call the Commissioner's office and you via the general phone numbers since they are receiving significant pressure from the Governor's office.

Ruth P. Dixen

Supervisory Investigator New Orleans District Import Operations

From: Kernan, Scott@CDCR [mailto:Scott.Kernan@cdcr.ca.gov]

Sent: Thursday, December 09, 2010 2:03 PM

To: Dixon, Ruth P

Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR

Sent: Thursday, December 09, 2010 11:58 AM

To: Kernan, Scott@CDCR Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi Executive Assistant to Scott Kernan Undersecretary, Operations (916) 341-7015 From: Halpenny, Susan M

Sent: Thursday, December 09, 2010 1:38 PM

To: 'John Solomon' **Subject:** RE: status Good day Dr. Solomon,

I have asked for an update on the status of your shipment from our Center for Imports but unfortunately they do not have any updates to give me. I will continue to check on this daily.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Thursday, December 09, 2010 6:51 AM

To: Halpenny, Susan M

Subject: status

Good morning Susan,

May we have a status report with particular attention as to why the FDA continues to intervene in this particular drug purchase? Also, the delay now borders on being excessive. Does anyone have any idea when a decision will be rendered to release the shipment? Thank you for continuing assistance.

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

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Attachments: Letter to Ms. Dixon0001.pdf

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Ruth P. Dixen

Supervisory Investigator New Orleans District Import Operations

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Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

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And Rehabilitation

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Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

From: McAuliffe, John@CDCR [John.McAuliffe@cdcr.ca.gov]

Sent: Monday, December 20, 2010 12:44 PM

To: Dixon, Ruth P

Cc: Kernan, Scott@CDCR

Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf

Ms. Dixon

Could you please update us on the approval of delivery of the Sodium Thiopental to the California Department of Corrections and Rehabilitation. Thank you in advance.

John McAuliffe

From: McAuliffe, John@CDCR

Sent: Thursday, December 09, 2010 12:10 PM

To: McClease, Kelly@CDCR **Subject:** FW: Letter to Ms. Dixon

FYI

From: Kernan, Scott@CDCR

Sent: Thursday, December 09, 2010 12:03 PM

To: Ruth.Dixon@FDA.HHS.gov

Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

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Undersecretary
California Department of Corrections
And Rehabilitation

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Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi

Executive Assistant to Scott Kernan

Undersecretary, Operations (916) 341-7015

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Monday, December 20, 2010 9:29 AM

To: Halpenny, Susan M **Cc:** David Tatarsky

Subject: Delay of Shipment

Good morning Šusan,

The FDA imposed delay is an increasing concern to us. Is there anyone who can give us a reasonable explanation for the FDA's decision to stop the shipment to South Carolina? For the FDA to stop the shipment and then refuse to communicate the reason for its decision is unconscionable. Your assistance with this matter is appreciated.

John

Copy to David Tatarsky - General Counsel for the Department of Corrections

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999 From: Halpenny, Susan M

Sent: Monday, December 20, 2010 10:25 AM

To: 'John Solomon' Cc: David Tatarsky

Subject: RE: Delay of Shipment

Good day,

I have not heard anything from our Director of Import Operations and Policy at this time. If you would like to follow up with him, our Director is Domenic Veneziano and his phone number is (301) 594-3849. You can also contact the office of our FDA commissioner, Margaret Hamburg at (301) 796-5000.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

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Sent: Monday, December 20, 2010 9:29 AM

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Director of Health Services
South Carolina Department of Corrections
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Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

Trepagnier, Timothy

From: Thomas, David

Sent: Monday, September 27, 2010 2:23 PM **To:** Budweg, Greta L; Halpenny, Susan M

Cc: Dixon, Ruth P; Chan, Hoi-May (CBER); Samaan, Marian; Chung, Phap; Cowels, Allyson;

Strickland, Evanguel; Solis, Daniel; 'DEAN, MICHAEL K'

Subject: RE: Lethal Injection Pharmacology

Greta:

Thank you for your courteous, informative and timely reply. I have advised the Broker, Arizona Customs Brokerage, Phoenix, AZ, Filer # 574, to transmit all entry documentation, regarding the above, prior to wheels-up, including AWB. I will then forward same to you and all principals.

As of this communication, the Filer has not received the paperwork to perform entry data for transmission to Custom's ACS system from the Automatic Broker Interface software.

Respectfully,

David Thomas, DCM FDA Investigations Phoenix, Office

----Original Message----

From: Budweg, Greta L

Sent: Monday, September 27, 2010 10:02 AM

To: Halpenny, Susan M

Cc: Dixon, Ruth P; Thomas, David; Chan, Hoi-May (CBER); Samaan,

Marian; Chung, Phap; Cowels, Allyson

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Susan,

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Greta

Greta L. Budweg
Watch Commander
FDA/ORA/ORO/Prior Notice Center
866-521-2297 main phone
703-261-8439 phone
703-261-8625 fax
greta.budweg@fda.hhs.gov

----Original Message----

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To: Thomas, David

Cc: Dixon, Ruth P; Budweg, Greta L

Subject: FW: Lethal Injection Pharmacology

Importance: High

Good day,

It would be helpful if you could provide Memphis the airway bill for this shipment. We can follow-up with the broker to see if/and when the shipment is bein.

Also we would be able to track the shipment thru

any information you can provide.

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From: Budweg, Greta L

Sent: Monday, September 27, 2010 11:31 AM

To: Schafer, Patricia

Cc: ORA SE NOL Import Supervisors; Taube, Anthony C

Subject: FW: Lethal Injection Pharmacology

Importance: High

Hi Pat,

I suggested to Dave Thomas that this information would be helpful to the Memphis entry reviewers. Dave indicated that no entry has been made at this time. I'll continue to pass on any information related to this shipment.

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Greta L. Budweg
Watch Commander
FDA/ORA/ORO/Prior Notice Center
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----Original Message----

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To: Budweg, Greta L

Subject: FW: Lethal Injection Pharmacology

Importance: High

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 Memphis 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.

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----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







United States Customs Department

Corrections

South Carolina

Department of

SUBJECT: Thiopental Injection Purchase

Dear Customs Agent:

The South Carolina Department of Correction (SCDC) uses Thiopental Injection for capital punishment purposes, S. C. Code Ann. § 24-3-530 provides as follows:

Death by electrocution or lethal injection -"A person convicted of a capital crime and having imposed upon him the sentence of death shall suffer the penalty by electrocution or, at the election of the person, lethal injection under the direction of the Director of the Department of Corrections. The election for death by electrocution or lethal injection must be made in writing fourteen days before the execution date or it is waived. If the person waives the right of election, then the penalty must be administered by lethal injection."

The SCDC has been unable to locate this drug in the United States. In order to carry out its statutory obligation in capital punishment cases, SCDC has purchased Thiopental from a provider in Great Britain. Enclosed are the following drugs:

NAME/DESCRIPTION	QUANTITY
Thiopental Injection, powder for reconstitution, thiopental sodium, 500 mg vial packs of 25's	(b) (4)

Shipping Location:

South Carolina Department of Corrections Kirkland Correctional Institution - Pharmacy

ATTN: Rose Mayer 4344 Broad River Road Columbia, South Carolina 29210

Telephone: (803) 896-1995

US Drug Enforcement Agency Number (DEA): R50206765 Expires: 02/28/2011

I will be the point of contact for the purchase and can be reached by telephone: 001-803-896-1995 or by

email: solomon.john@doc.state.sc.us.

6hn P. Solomon, PhD, MBA

Director of Health Services

JP/spz

P.O. Box 21787 - 4444 Broad River Road - Columbia, SC 29221-1787 - Telephone (803) 896-8555

Trepagnier, Timothy

From: Bradford, Jacquelyn

Sent: Monday, September 27, 2010 4:14 PM

To: Dixon, Ruth P

Subject: FW: Lethal Injection Pharmacology

Importance: High

Attachments: Thomas, David - FDA Investigations (London Shipment) 2010-09-24.pdf; DOC092310_1.pdf;

DEA Registration.pdf







Thomas, DOC092310_ DEA

- FDA Investi1.pdf (20 KB):ration.pdf (39

----Original Message----

From: Halpenny, Susan M

Sent: Monday, September 27, 2010 4:04 PM

To: Bradford, Jacquelyn

Subject: FW: Lethal Injection Pharmacology

Importance: High

Please use documentation as example for other shipment going to correction facility in ARK.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

----Original Message----

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Subject: FW: Lethal Injection Pharmacology

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information related to this shipment.

Greta

Greta L. Budweg Watch Commander FDA/ORA/ORO/Prior Notice Center 866-521-2297 main phone 703-261-8439 phone 703-261-8625 fax greta.budweq@fda.hhs.gov ----Original Message----From: Thomas, David Sent: Monday, September 27, 2010 11:50 AM To: Budweg, Greta L Subject: FW: Lethal Injection Pharmacology Importance: High 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:

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Charles Flanagan
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(602) 377-5334 Cell
(602) 364-0601 Fax
cflanag@azcorrections.gov

Arizona Department of Corrections



1601 WEST JEFFERSON PHOENIX, ARIZONA 85007 (602) 542-5497 www.azcorrections.gov



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.

Dave,
please do not lusitate to
contact me for any reason. I
greatly appreciate your consistance,
Clarles

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

Charles Flanagar Deputy Director

cc: File

FDA_08.18.11_000028

Arizona Department of Corrections



1601 WEST JEFFERSON PHOENIX, ARIZONA 85007 (602) 542-5497 www.ezcorrections.gov



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

Jeffrey Timothy Landrigan #082157

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. Jeffrey Timothy Landrigan, CR-90-0323 AP.

In order to proceed with the execution we must have the products ordered through Dream Pharma. Our DEA Registration number is: FA2203571 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

ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN
1305 BUTTE AVE.
P.O. BOX 629
FLORENCE, AZ 85232-0000-000

Ī	DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
	FA2203571	06-30-2013	FEE EXEMPT
	SCHEDULES	BUSINESS ACTIVITY	ISSUE DATÈ
	3,3N,4,5,	IOSPITAL/CLINIC	08-25-2010
	ARIZONA STATI WARDEN 1305 BUTTE AV P.O. BOX 629 FLORENCE, AZ		CE, CARSON

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 1008 (21 USC 824 and 958) 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.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION

DRUG ENFORCEMENT ADMINISTRATION WASHINGTON D.C. 20537

NUMBER	EXPIRES	PAID
FA2203571	06-30-2013	FEE EXEMPT
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SCHEDULES	HOSPITAL/CLINIC	ISSUE DATE 08-25-2010
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This registration is only for use at Federal or State institutions.

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

Sections 304 and 1008 (21 USC 824 and 958) 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.

m DEA-223 (4/07

DEA DECISTRATION

06-30-2013 BUSINESS ACTIVITY SPITAL/CLINIC	FEE EXEMPT
SPITAL IOLINIC	
OF LEMENOR HAIO	08-25-2010
PRISON - FLOI	RENCE,

CONTROLLED SUBSTANCE/REGULATED CHEMICAL 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 1008 (21 USC 824 and 958) 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.

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REPORT Form DEA-223/511 (4/07) **CHANGES** PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

- 1. visit our web site at deadlyersion.usdoj.gov or 2. call our customer Service Center at 1-(800) 882-9539 or 3. submit your change(s) in writing to:

Drug Enforcement Administration P.O. Box 28083 Washington, DC 20083

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Procurement Services 1601 W. Jefferson, M/C 55302 Phoenix, AZ 85007 (602) 542-1172 Fax: (602) 364-3780

AZ Department of Corrections



	Matt Alavi	From:	Karen Ingram, Contracts Manag	
	Dream Pharma, LTd			
Company/ Institution:	176 Horn Lane	Pages:	1	
	Acton, London W3 6PJ			
Fax:	44 208-992-7001	Date:	9/23/10	
Phone:	44-208-992-7000	Re:	Urgent Order USA	
☐ Urgent	☐ For Review ☐ Please Comm	ent 🗆 Pleas	e Reply	
d on previous con :	versations between the Arizona Departr	ment of Correctio	ns, we are placing the following	
THIOPENT vial packs of 2 Item Cost:	TAL INJECTION (powder for re	0		
THIOPENT vial packs of 2 Item Cost: Quantity:	TAL INJECTION (powder for re	econstitution, um bromide	thiopental sodium, 500- 2 mg/ml, 2-ml amp)	



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.

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OFFICE OF THE SECRETARY P.O. Box 942883 Sacramento, CA 94283-0001

December 9, 2010



Ms. Ruth Dixon
Department of Health and Human Services
Food and Drug Administration

Dear Ms. Dixon:

Since 1993, California law has authorized capital punishment by lethal injection pursuant to Penal Code Section 3604. The law states the punishment of death shall be inflicted by the administration of an intravenous injection of substances in a lethal quantity sufficient to cause death. On May 1, 2009, the California Department of Corrections and Rehabilitation (CDCR) promulgated regulations setting forth the requirements for administering capital punishment by lethal injection pursuant to Administrative Procedure Act. Those regulations became effective on August 29, 2010. The regulations provide for the use of three chemicals; sodium thiopental, pancuronium bromide, and potassium chloride.

There is a national shortage of sodium thiopental. California, like many other states, has been actively seeking supplies of the sodium thiopental for future executions. California's supply of sodium thiopental expired on October 1, 2010. On November 22, 2010, CDCR notified the United States District Court for the Northern District of California that it had ordered (b) (4) of sodium thiopental that expires in 2014 from a manufacturer based in England (FDA # 112-99-38358-2). CDCR expected to receive the sodium thiopental during the week of November 29, 2010. Although CDCR followed all proper procedures and the Drug Enforcement Agency and United States Customs has approved the shipment, this shipment is currently be held by your office.

Per your conversation with John McAuliffe, we are asking for the immediate release and shipment of the (b) (4) of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or Mr. McAuliffe at (707) 480-6766.

Sincerely,

BENJAMIN T. RICE General Counsel

cc: John McAuliffe





Food and Drug Administration New Orleans District Import Operations 959 Ridgeway Loop, Suite 100 Memphis, Tn. 38120

Telephone: (901) 333-3520 FAX: (901) 333-3579

January 7, 2011

UNITED PARCEL SERVICE Delivery Signature Requested

Benjamin Rice, Chief Counsel Office of Legal Affairs California Department of Corrections & Rehabilitation 1515 S Street, Suite 502 S Sacramento, California 95811

RE: Entry Number 112-9938358-2

Dear Mr. Rice:

This letter provides the status of Entry Number 112-9938358-2, consisting of (b) (4) vial packets, each vial containing 500 mg of Thiopental Sodium. FDA received documentation for this shipment and verified it is destined for a state correctional facility.

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.

Sincerely,

Hatricia K. Schafer Patricia K. Schafer

Acting District Director

New Orleans District Office

From: Dixon, Ruth P

Sent: Friday, January 07, 2011 3:43 PM

To: 'Rice, Benjamin@CDCR'

Cc: 'McAuliffe, John@CDCR'; 'Kernan, Scott@CDCR'

Subject: RE: Letter to Ms. Dixon

Attachments: FDA Letter 010711.pdf

Good afternoon,

Enclosed is the FDA letter regarding the FDA Release of entry 112-9938358-2.

Ruth P. Dixon

Supervisory Investigator New Orleans District Import Operations

From: Kernan, Scott@CDCR [mailto:Scott.Kernan@cdcr.ca.gov]

Sent: Thursday, December 09, 2010 2:03 PM

To: Dixon, Ruth P

Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan Undersecretary California Department of Corrections

And Rehabilitation

From: Gaddi, Kathy@CDCR

Sent: Thursday, December 09, 2010 11:58 AM

To: Kernan, Scott@CDCR **Subject:** Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi Executive Assistant to Scott Kernan Undersecretary, Operations (916) 341-7015

2-781 8637-

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number:

112-7818637-8

Notice Number:

3 August 13, 2010

Importer:

Port of Entry:

2095, FedEx - Memphis, Memphis, TN

Carrier:

(b) (4)

Date Received: June 28, 2010 Arrival Date:

June 28, 2010

Filer of Record:

FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Consignee:

(b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	688760417429/THIOPENTAL 500MG	(b) (4)	Released after Detention 08- 12-2010

^{* =} 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 112-7818637-8. Any status changes are reflected in the Line summary and line detail sections.

LINES RELEASED AFTER DETENTION

Line ACS/FDA

Product Description

001/001

688760417429/THIOPENTAL

500MG

Rebecca A. Asente, Compliance Officer

(Region/District)

U.S. Food and Drug Administration 6600 Plaza Drive, Suite 400

New Orleans, LA 70127

(504) 219-8818 ext. 104 (504) 219-8813 (FAX) REBECCA.ASENTE@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all

Notice of FDA Action

Entry Number: 112-7818637-8

Notice Number: 3

Page: 2

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: LPW

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number:

112-7818637-8

Notice Number:

2

July 16, 2010

(b) (4)

Port of Entry:

(b) (4) (b) (4)

Memphis, TN

Carrier:

. .

Date Received: June 28, 2010

Arrival Date:

June 28, 2010

Filer of Record:

FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Importer of Record:

HOLD DESIGNATED

Summary of Current Status of Individual Lines

Line ACS/FDA		Product Description	Quantity	Current Status
*	001/001	688760417429/THIOPENTAL 500MG	(b) (4)	Detained 07-15-2010

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

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	688760417429/THIOPENTAL	August 4, 2010

Notice of FDA Action

Entry Number: 112-7818637-8

Notice Number 2

Page: 2

500MG

FD&CA Section 502(o), 801(a)(3); MISBRANDING

It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k). Mfr not Listed or Registered with FDA.

Please direct your response to:

Rebecca A. Asente, Compliance Officer (Region/District) U.S. Food and Drug Administration 6600 Plaza Drive, Suite 400 New Orleans, LA 70127 (504) 219-8818 ext. 104 (504) 219-8813 (FAX) REBECCA.ASENTE@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

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

Notice Prepared By: MJS

Spikes, Michael

From:

Asente, Rebecca

Sent:

Wednesday, June 30, 2010 3:23 PM

To:

Spikes, Michael

Cc: Subject: Schafer, Patricia Import Entries Update 2nd for Today

Hi Michael,

These are the last of the entries I received via Mark yesterday.

completed 1-1-2010

Released:

Created an LEX for: 112 7818637-8 ^

I will put in interoffice mail the paperwork corresponding with the released entries.

Now, I will start working on the DTRs you just sent me today. I will send future updates to "reply all" from the emails you send w/the DTR hyperlinks.

Good to talk with you, R

Rebecca A. Asente, M.S., R.D., Compliance Officer

U.S. FDA, New Orleans District, Metairie Resident Post, Metairie Center, Suite 410, 2424 Edenborn Avenue, Metairie, LA 70001

(504) 219-8818 ext. 104; fax (504) 219-8813

This e-mail message is intended for the exclusive use of the recipient(s) named above. The contents of this message are mine personally and do not necessarily reflect any position of the Government or the Food and Drug Administration. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail in error, please contact the sender immediately at rebecca.asente@fda.hhs.gov.

Detarred RAA 7-15-2010

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DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

Form Approved OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

FEDEX TRADE NETWORKS
TRANSPORT & BROKERAGE, INC.

AIR EXPRESS

TEL: (901) 752-3000

19 CFR 142.3, 142.16, 142.22, 142.24 1. ARRIVAL DATE 2. ELECTED ENTRY DATE 3. ENTRY TYPE CODE/NAME 4. ENTRY NUMBER 062810 11 112-7818637-8 7. BROKER/IMPORTER FILE NUMBER 5. PORT 6. SINGLE TRANS, BOND (b) (4) 2095 8. CONSIGNEE NUMBER 9. IMPORTER NUMBER (b) (4) NAME/ADDRESS 11. IMPORTER OF RECORD NAME. 14. LOCATION OF GOODS-CODE(S)/NAME(S) 12. CARRIER CODE 13. VOYAGE/FLIGHT/TRIP (b) (4) (b) (4) (b) (4) 15. VESSEL CODE/NAME 16. U.S. PORT OF UNLADING 19. TOTAL VALUE 17. MANIFEST NUMBER 18 GO NUMBER (b) (4) 2095 20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS NOT RESTRICTED 24. H.S. NUMBER 25. COUNTRY OF ORIGIN 26. MANUFACTURER ID. 22. IT/BL/AWB NO. TOTAL 3004.90.9190 GBDREPHA176LON GB M Н 27. CERTIFICATION 28. CUSTOMS USE ONLY I hereby make application for entry/immediate delivery. I certify that the above OTHER AGENCY ACTION REQUIRED, NAMELY: 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 PHONE NO. CUSTOMS EXAMINATION REQUIRED. (b) (4) 06/28/10 29. BROKER OR OTHER GOVT. AGENCY USE ENTRY REJECTED, BECAUSE: SIGNATURE DATE DELIVERY AUTHORIZED:

Paperwork Reduction Act Notice: This information is needed 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.

06/28/10 19:45:47 ECO

Released 8/12/10 CUE

Customs Form 346 1 (010189) FDA_08.18.11_000043

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: 2583INV.

Address:



VAT no: Purchase Order: Date: 24-06-2010

Delivery Address:

Currency: GBP - Pounds sterling Heading: PHARMACEUTICALS

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AS3393 EXP: 02/14	(b)	(4)	84.22
Admin fee for orders below £250	1	15	15

Statement Details

Goods Total: 99.22	Subtotal: 99.22
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total: 99.22 GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing: (b) (4)	Gross Weight (Kg):(b) (4) Net Weight (Kg):(b) (4)
Tariff: 30049099	Carrier: (b) (4)
Declarations:	Matt Alavi, for Dream Pharma Ltd.
We certify that this invoice is true and correct.	Auton London Wij GF J. Auton

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) /AT No. Director: M. Alavi

Page 1 of 1

ENTRY NUMBER: 112 7818637 8

AWB/BL NBR : (b) (4) INVOICE # 06/28/2010

LINE CONSOL. WORKSHEET 07:49 PM

ITEMS MARKED 1 C/O- GB

ITEMS MARKED 1 C/O- GB LINE VALUE- GBP TARIFF # 3004.90.9190

QTY 1: KG
(b) (4)

84.22

84.22

** (b) (4)

**** 84.22

ENTRY NUMBER: 112 7818637 8
AWB/BL NBR : (b) (4) INVOICE #

SHIPPER : DREAM PHARMA LTD

PAGE: 06/28/2010

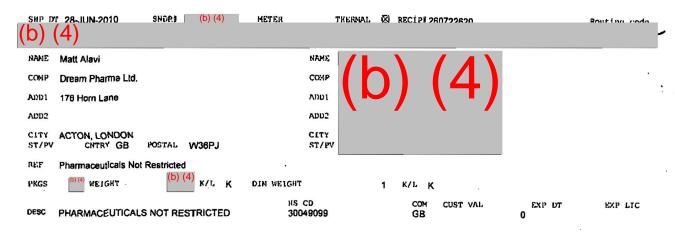
07:49 PM

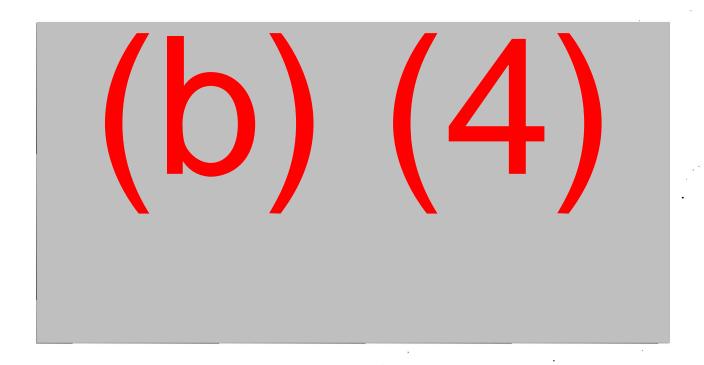
ITEM MARKED REFERENCE

INVOICE ITEM TARIFF COUNTRY VALUE-GBP

LINE# MARK NUMBER OF ORIG. RATE OF DUTY

(b) (4) KG Q: 1 3004.90.9190 GB 84.22





FDA_08.18.11_000047

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-7818637-8

NAME MATT ALAVI
COMP DREAM PHARMA LTD.
ADD1 176 HORN LANE
ADD2
CITY ACTON, LONDON
ST/PV CNTRY GB POSTAL W36PJ

PKGS K/L WEIGHT COM CURR
K (b) (4) GB UKL CARR VAL CUSTOMS VAL EX LIC HDLG UNITS
99.22

DESC: PHARMACEUTICALS NOT RESTRICTED

From: Boulmay, Christopher

Sent: Tuesday, November 30, 2010 4:00 PM

To: 'McAuliffe, John@CDCR'

Cc: Kernan, Scott@CDCR; Halpenny, Susan M; Dixon, Ruth P

Subject: RE: FDA entry item # 112-99-38358-2

John,

This entry is currently under review by our DIOP branch.

(b) (5)

If you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

Christopher Boulmay

Consumer Safety Officer
US Food & Drug Administration

NOL-DO: Memphis R.P. **Phone:** (901) 333-3528 **Fax:** (901) 333-3577

From: McAuliffe, John@CDCR [mailto:John.McAuliffe@cdcr.ca.gov]

Sent: Tuesday, November 30, 2010 3:37 PM

To: Boulmay, Christopher Cc: Kernan, Scott@CDCR

Subject: FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to (b) (4)

(b) (6) is the (b) (4)X contact person) I also called your phone number 901-333-3528 and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

John McAuliffe

California Department of Corrections and Rehabilitation

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number:

112-8992979-0

Notice Number:

September 28, 2010

Importer:



Port of Entry:

2095, FedEx - Memphis, Memphis, TN

Carrier:

(b) (4)

Date Received: September 20, 2010 Arrival Date:

September 17, 2010

Filer of Record:

FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Consignee:

Arkansas Department Of Correctio, Pine Bluff, AR 71602-9411

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	688760418241/THIOPENTAL SODIUM	(b) (4)	Released after Detention 09- 27-2010

^{* =} 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 112-8992979-0. Any status changes are reflected in the Line summary and line detail sections.

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA), or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	688760418241/THIOPENTAL SODIUM	November 1, 2010
	801(a)(3); UNAPPROVED NEW DRUG a new drug without an approved new d	rug application. Unapproved drug w/o written

DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

Form Approved OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

FEDEX TRADE NETWORKS
TRANSPORT & BROKERAGE, INC.

AIR EXPRESS

TEL: (901) 752-3000

		19 CFR 142.3. 14	2.16, 142.22, 142.24		
1. ARRIVAL DA	NTE.	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME		4. ENTRY NUMBER
091710)		11		112-8992979-0
5. PORT		6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBE	R	
2095			(b) (4)		3
		8. CONSIGNEE NUMBER			9. IMPORTER NUMBER
		NAME/ADDRESS			(b) (4)
ARKANS	CONSIGNEE NAME SAS DEPARTMENT OF	С	11. IMPORTER OF RECORD NAME.		м
		_	(h)	(4)	
	PRINCETON PIKE		(6)	(")	
PINE E	BLUFF AR	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(S)/	NAME(S)	
(b) (4)	*	(b) (4)	(b) (4)	.,	
15. VESSEL CO	ODE/NAME				
16. U.S. PORT	OF UNLADING	17. MANIFEST NUMBER	16. G.O. NUMBER		19. TOTAL VALUE
2095			625		893
20. DESCRIPTI	ION OF MERCHANDISE				
	CEUTICALS/THIOPE				
21. IT/BL/AWB	22. IT/BL/AWB NO:	23. MANIFEST QUANTITY	24, H.S. NUMBER	25. COUNTRY OF ORIGIN	
	TOTAL	(b) (4)	3004.90.9140	GB	GBDREPHA176LON
M	(6)(4)				
H					_
			-11 0 2		
	27. CERTIFICATIO	N .	28.	CUSTOMS US	E ONLY
	nake application for entry/immediate of		OTHER AGENCY ACTIO	ON REQUIRED,	NAMELY:
	n is accurate, the bond is sufficient, and of 19 CFR Part 142 have been in				
	OF APPLICANT				
	(b) (6)				
PHONE NO.	· · · · · · · · · · · · · · · · · · ·	DATE	<u> </u>		
(b) (4)	09/20/10	CUSTOMS EXAMINATION	ON REQUIRED.	
\	29. BROKER OR OTHER GOVT		1_		
	planes and transcribes in 196 3651 coasts incarage where the	3 2007 10, 10070 10, 30400	ENTRY REJECTED, BE	CAUSE:	
3•€					W
Λ.,					
1115		(1)			
CV	1.		DELIVERY		DATE
· al	1110		AUTHORIZED:		
71	10		DTE-AAP/R	CA	
	21/10		DIE WITTE	(4)	
	100				
				Fſ	OA 08 18 11 000051

Paperwork Reduction Act Notice: This information is needed 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.

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: 2668INV

Address:

Arkansas Department of Correction Central Administration Office 6814 Princeton Pike Pine Bluff, AR 71602-9411 Fedex: 4512-1458-6

VAT no:

Purchase Order:

Tel: 870-550 - 7307

Date: 17-09-2010

Delivery Address:

Arkansas Department of Correction Att: Wendy Kelley. Deputy Director Central Administration Office 6814 Princeton Pike Pine Bluff, AR 71602-9411

Fedex: 4512-1458-6 870-550 - 7307

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection, powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's	(b) (4)		590.25
Batch No: AW6022 EXP: 05/14			

Statement Details

Goods Total: 590.25	Subtotal: 590.25
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total: 590.25 GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Gross Weight (K(b) (4)
Net Weight (Kg):
Carrier: (b) (4) PHAP
Matt Alayi Br Bream Pharma Lau
176 Horn Lane
Acton/London W3 6PJ
A 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

ENTRY NUMBER: 112 8992979 0 PAGE: 1
AWB/BL NBR : (b) (4) INVOICE # 09/20/2010
LINE CONSOL. WORKSHEET 05:55 PM

ITEMS MARKED 1 C/O- GB LINE VALUE- GBP

TARIFF # 3004.90.9140 QTY 1: KG

(b) (4) 590.25

** 590.25

**** 590.25

ENTRY NUMBER: 112 8992979 0
AWB/BL NBR : (b) (4) INVOICE #

PAGE: 1 09/20/2010 05:55 PM

SHIPPER : DREAM PHARMA LTD

ITEM MARKED REFERENCE

INVOICE ITEM LINE# MARK TARIFF

COUNTRY

NUMBER OF ORIG. RATE OF DUTY

VALUE-GBP

1

3004.90.9140 GB

Q:

(b) (4) _{KG} 590.25

To: 0019017523034

P.1/4

Thiopental injection - electronic Medicines Compendium (eMC) - print friendly

Page 1 of 4

Archimedes Pharma UK Ltd

250 South Oak Way, Green Park, Reading, RG2 6UG,

UK

Telephone: +44 (0)118 931 5050

Fax: +44 (0)118 931 5056

WWW: http://www.archimedespharma.com

Before you contact this company: often several companies will market medicines with the same active ingredient. Please check that this is the correct

company before contacting them. Why?

Archimedes

Aii (b) (7)(C)

Summary of Product Characteristics last updated on the eMC: 05/05/2004

Thiopental injection

(b) (4) TRACKING #7

1. NAME OF THE MEDICINAL PRODUCT

Thiopental Injection BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Thiopental Sodium BP 500mg

3. PHARMACEUTICAL FORM

Freeze-dried powder for solution for injection in a vial.

4. CLINICAL PARTICULARS

4.1 Therapoutic Indications

- 1. Thiopental is used for the induction of general anaesthesia and is also used as an <u>adjunct</u> to provide hypnosis during balanced anaesthesia with other anaesthetic agents, including analgesics and muscle relaxants.
- 2. Thiopental is also used as an <u>adjunct</u> for control of convulsive disorders of various aetiology, including those caused by local anaesthetics.
- 3. Thiopental has now been used to reduce the intracranial pressure in patients with increased intracranial pressure, if <u>controlled</u> ventilation is provided.

4.2 Posology and mothod of administration

Intravenous injection.

Thiopental Injection BP is administered intravenously normally as a 2.5% w/v (500mg in 20ml) solution. On occasions it may be administered as a 5% w/v solution (500mg in 10ml).

The intravenous injection preparation should be used after reconstitution of the sterile powder with Water for Injections, usually to produce a 2.5% w/v solution and this should be discarded after seven hours.

Use in anaesthesia

Normal dosage for the induction of anaesthesia is 100mg to 150mg injected over 10 to 15 seconds. If necessary a repeat dose of 100mg to 150mg may be given after one minute. No fixed dosage recommendations for the intravenous injection can be given, since the dosage will need to be carefully adjusted according to the patient's response. Factors such as age, sex, and weight of the patient should be taken into consideration. Thiopental sodium reaches effective concentrations in the brain within 30 seconds and anaesthesia is normally produced within one minute of an intravenous dose.

http://www.medicines.org.uk/EMC/printfriendlydocument.aspx?documentid=14338&comp... 20-09-10

Thiopental injection - electronic Medicines Compendium (eMC) - print friendly

Page 2 of 4

Adult

100mg to 150mg intravenously over 10 to 15 seconds, normally as a 2.5% w/v solution.

A repeat dose of 100mg to 150mg may be given after one minute.

The intravenous injection should be given slowly and the amounts given titrated against the patient's response to minimise the risk of respiratory depression or the possibility of overdosage. The average dose for an adult of 70kg is roughly 200mg to 300mg (8mis to 12mis of a 2.5% w/v solution) with a maximum of 500mg.

Children

2 to 7mg/kg bodyweight, intravenously over 10 to 15 seconds, normally as a 2.5% w/v solution. A repeat dose of 2 to 7mg/kg may be given after one minute. The dose is 2 to 7mg/kg based on the patient's response. The dose for children should not exceed 7mg/kg.

Elderly

Smaller adult doses are advisable.

Use in convulsive states

75mg to 125mg (3mls to 5mls of a 2.5% w/v solution) should be given as soon as possible after the convulsion begins. Further doses may be required to control convulsions following the use of a local anaesthetic. Other regimens, such as the use of intravenous or rectal diazepam, may be used to control convulsive states.

Use in neurological patients with raised intracranial pressure

Intermittent bolus injections of 1.5 to 3mg/kg of bodyweight may be given to reduce elevations of intracranial pressure if controlled ventilation is provided.

4.3 Contraindications

Thiopental is contraindicated in respiratory obstruction, acute asthma, severe shock and dystrophia myotonica. Administration of any barbiturate is contraindicated in porphyria.

Care should also be exercised with severe cardiovascular diseases, severe respiratory diseases and hypertension of various aetiology.

Patients with hypersensitivity reactions to barbiturates.

4.4 Special warnings and precautions for use

Special care is needed in administering thiopental to patients with the following conditions:- hypovolaemia, severe haemorrhage, burns, dehydration, severe anaemia, cardiovascular disease, status asthmaticus, severe liver disease, myasthenia gravis and muscular dystrophies, adrenocortical insufficiency (even when controlled by cortisone), cachexia and severe toxaemia, raised intracranial pressure, raised blood urea, raised plasma potassium, metabolic disorders e.g. thyrotoxicosis, myxoedema, diabetes.

Thiopental may precipitate acute circulatory failure in patients with cardiovascular disease, particularly constrictive pericarditis.

Thiopental can cause respiratory depression and a reduction in cardiac output.

Headache is also reported with the use of barbiturate anaesthetics.

Reduced doses are recommended in shock, dehydration, severe anaemia, hyperkalaemia, toxaemia, myxoedema or other metabolic disorders. Thiopental sodium is metabolised primarily by the liver so doses should be reduced in patients with hepatic impairment. Reduced doses are also indicated in the elderly and in

http://www.medicines.org.uk/EMC/printfrlendlydocument.aspx?documentid=14338&comp... 20-09-10

Page 3 of 4

patients who have been premedicated with narcotic analgesics.

Thiopental has been shown to interact with sulphafurazole. Reduced initial doses may be required to achieve adequate anaesthesia, but repeat doses may also be necessary to maintain anaesthesia.

Increased doses may be necessary in patients who have either an habituation or addiction to alcohol or drugs of abuse. Under these circumstances it is recommended that supplementary analgesic agents are used.

Accidental intra-arterial injection of thiopental causes severe arterial spasm and an intense burning pain around the injection site. In the case of accidental intra-arterial injection of thiopental the needle should be left in-situ so that an injection of an antispasmodic, such as papaverine or prilocaine hydrochloride may be given. Anticoagulant therapy may also be started to reduce the risk of thrombosis.

Thiopental injection should be used with caution in patients with adrenocortical insufficiency or with raised intragranial pressure.

4.5 Interaction with other medicinal products and other forms of interaction

Thiopental has been shown to interact with sulphafurazole.

It should be noted that thiopental will interact with beta-blockers and calcium antagonists causing a fall in blood pressure.

The sedative properties of antipsychotics and anxiolytics may be potentiated by thiopental.

4.6 Pregnancy and lactation

Thiopental readily crosses the placental barrier and also appears in breast milk. Therefore, breast-feeding should be temporarily suspended or breast milk expressed before the induction of anaesthesia. It has been shown that thiopental can be used without adverse effects during pregnancy although the total dose should not exceed 250mg. However, when considering use of thiopental the clinician should only use the drug when the expected benefits outweigh any potential risks.

4.7 Effects on ability to drive and use machines

Post-operative vertigo, disorientation and sedation may be prolonged and out-patients given thiopental should therefore be advised not to drive or use machinery, especially within the first 24 to 36 hours.

4.8 Undesirable effects

Laryngeal spasm may occur, together with coughing or sneezing, during the induction procedure. For this reason it is not advised to use thiopental alone for peroral endoscopy.

Extravasation causes local tissue necrosis and severe pain. This can be relieved by application of an ice pack and local injection of hydrocortisone. The 5% w/v solution is hypertonic and may cause pain on injection and thrombophiebitis.

Allergic reactions, skin reactions and hypersensitivity have been rarely reported.

Bronchospasm, respiratory depression and myocardial depression or cardiac arrhythmias may occur.

4.9 Overdose

Overdosage produces acute respiratory depression, hypotension, circulatory failure and apnoea. Treatment must be artificial ventilation, lowering of the patient's head and infusion of plasma volume expanders.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Thiopental is a short-acting substituted barbiturate that is more lipid soluble than other groups of barbiturates. The drug reversibly depresses the activity of all excitable tissues. The CNS is particularly sensitive and normally a general anaesthesia can be achieved with thiopental without significant effects on peripheral tissues.

http://www.medicines.org.uk/EMC/printfriendlydocument.aspx?documentid=14338&comp... 20-09-10

Thiopental injection - electronic Medicines Compendium (eMC) - print friendly

Page 4 of 4

Thiopental acts through the CNS with particular activity in the mesencephalic reticular activating system. The barbiturates exert different effects on synaptic transmission, mostly those dependent on GABA. Autonomic gangila of the peripheral nervous system are also depressed.

5.2 Pharmacokinetic properties

Following intravenous administration, unconsciousness occurs within 30 seconds and will be continued for 20 to 30 minutes after a single dose. Rapid uptake occurs to most vascular areas of the brain followed by redistribution into other tissues.

Thiopental is strongly bound to plasma protein, which impairs excretion through the kidney. The metabolites are usually inactive and are then excreted. Thiopental, therefore, whilst having a short duration of action, may have a long elimination phase.

5.3 Proclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Solutions of thiopental injection have a pH of 10 to 11 and are strongly alkaline in order to maintain stability. Solutions are incompatible with acid, acidic salts and solutions such as pethidine, morphine and promethazine

6.3 Shalf life

48 months.

6.4 Special precautions for storage

Do not store above 25°C. Store reconstituted solution between 2°C to 8°C in an apright position and use within 2 hours. Use once following reconstitution and discard any residue.

6.5 Nature and contents of container

20ml Type III clear glass vials with 20mm bromylbutyl caoutchouc siliconised rubber closures.

Pack size: 25 vials per pack.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Link Pharmacouticals Limited, Bishops Weald House, Albion Way, Horsham, West Sussex RH12 1AH, UK

8. MARKETING AUTHORISATION NUMBER(5)

PL 12405/0014

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5 April 1999

10. DATE OF REVISION OF THE TEXT

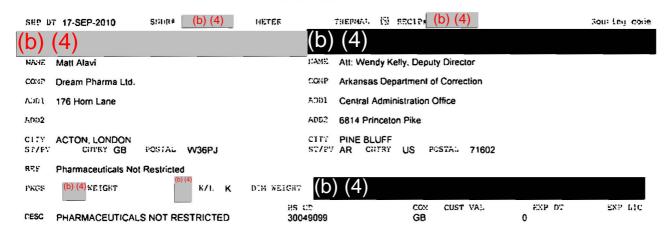
January 2003

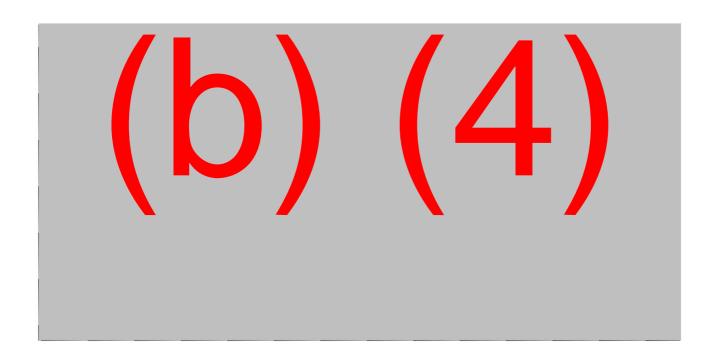
11. Legal Category

POM

http://www.medicines.org.uk/EMC/printfriendlydocument.aspx?documentid=14338&comp... 20-09-10

(b) (4) Manifest report





page

LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY ENT# 112-8992979-0 FLT/TRK FX001 FTDT 17SEP10 BCH MTR CLC CHKR AB OF ROUTE FX001 CONT DOC/NC N CO BAG RECIPIENT PH (870)550-7307 NAME ATT: WENDY KELLY, DEPUTY DIRECTO NAME MATT ALAVI COMP DREAM PHARMA LTD. COMP ARKANSAS DEPARTMENT OF CORRECTIO ADD1 176 HORN LANE ADD1 CENTRAL ADMINISTRATION OFFICE ADD2 ADD2 6814 PRINCETON PIKE CITY ACTON, LONDON CITY PINE BLUFF CNTRY GB POSTAL W36PJ ST/PV AR CNTRY US POSTAL 71602 ST/PV REF WEIGHT COM CURR
(b) (4) GB UKL PKGS K/L CARR VAL CUSTOMS VAL EX LIC HDLG UNITS (b) (4) 590.25 K

DESC: PHARMACEUTICALS NOT RESTRICTED

FDA_08.18.11_000060





Arkansas Department of Correction

Wendy Kelley
Deputy Director of Health &
Correctional Programs
P.O. Box 8707
Pine Bluff, Arkansas 71611-8707
Phone: (870) 267-6361
Fax: (870) 267-6363
WENDY KELLEY @ARKANSAS.GOV

FAX COVER SHEET

SEND TO: Pagguelyn FROM: Wendy Kelley FAX#: 901.333.3579 DATE: 9.27.10

TOTAL PGS (INCLUDING COVER): 3

Comments:

PLEASE NOTE: This facsimile and any attachments is the property of the State of Arkansas and may be protected by state and federal laws governing disclosure of private information. It is for the Intended recipient only. If an addressing or transmission error has misdirected this facsimile, please notify the sender. If you are not the intended recipient you may not use, disclose, distribute, copy, print or rely on this facsimile. You are notified that the document(s) provided may contain health information that is legally privileged, confidential and protected by law from disclosure. Copying or distributing this information except as required for the direct care and treatment of the designated patient, without the express authorization of the Arkansas Department of Correction, Office of the Administrator of Mental Health or Medical Services, is prohibited.



Arkansas Department of Correction

Wendy Kelley
Deputy Director of Health &
Correctional Programs
P.O. Box 8707
Pine Bluff, Arkansas 71611-8707
Phone: (870) 267-6361
Fax: (870) 267-6363
WENDY.L.KELLEY@ARKANSAS.GOV

September 10, 2010

Dream Pharma Ltd. ATTN: Matt Alavi 176 Horn Lane Action, London W3 6PJ

SUBJECT: Thiopental Injection Purchase

Dear Mr. Alavi,

The Arkansas Department of Corrections (GDC) uses Thiopental Injection to carry out Capital Punishment in Arkansas. In accordance Arkansas State Law, A.C.A. § 5-4-617, "The sentence of death is to be carried out by intravenous lethal injection of one (1) or more chemicals, as determined in kind and amount in the discretion of the Director of the Department of Correction. The chemical or chemicals injected may include one (1) or more of the following substances: one (1) or more ultra-short-acting barbiturate, one (1) or more chemical paralytic agents, potassium chloride, or any other chemical or chemicals, including but not limited to saline solution." The Director of the Arkansas Department of Correction by Administrative Directive has ordered that sodium pentothal or Thiopental sodium be used for the first chemical.

The Arkansas Department of Correction placed an order earlier this year with a manufacturer in the United States, but has been advised that they have none in stock, nor is any expected this year. In order to carry out the State of Arkansas' constitutional mandates in death penalty cases, we desire to make the following purchase:

Name/Description Quantity	Quantity	Price (ea)	Total
Thiopental Injection, power for reconstitution, thiopental sodium, 500mg vial packs of 25's	(b) (4)	GBP	590.25 GBP

Shipping Location:

Arkansas Department of Correction Central Administration Office ATTN: Wendy Kelley, Deputy Director 6814 Princeton Pike Pine Bluff, AR 71602-9411 Telephone: 870-550-7307

United States Drug Enforcement Agency Number (DEA): FA1835199

Our Federal Express account is (b) (4)

I understand the expiration date of the chemical currently available is February 2014. I can be reached by telephone at 001-870-550-7307 or by e-mail: wendy.kelley@arkansas.gov

Sincerely,

Wendy L. Kelley,

Deputy Director for Health & Correctional Programs

Arkansas Department of Corrections

From: Kernan, Scott@CDCR [Scott.Kernan@cdcr.ca.gov]

Sent: Thursday, December 09, 2010 2:03 PM

To: Dixon, Ruth P

Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR

Sent: Thursday, December 09, 2010 11:58 AM

To: Kernan, Scott@CDCR Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi Executive Assistant to Scott Kernan Undersecretary, Operations (916) 341-7015

DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

FEDEX TRADE NETWORKS TRANSPORT & BROKERAGE, INC. AIR EXPRESS

TEL: (901) 752-3000

		19 CFR 142.3, 14	2.16, 142.22, 142.24					
1. ARRIVAL DATE		2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME			4. ENTRY NUMBER		
100610			11			112-9247186-3		
5. PORT 6. SINGLE TRANS. SOND		7. BROKER/IMPORTER FILE NUMBER						
2095			(b) (4)			527		
		8. CONSIGNEE NUMBER				9. IMPORTER NUMBER		
NAME/ADI		NAME/ADDRESS		(b) (4)				
IO THYBIATE	CONGIUNE NAME		11. IMPORTER OF R	ECORD NAME.				
	0) (4)			(b)	<u> </u>			
12, CARRIER	CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(SYNAME(S)					
(b) (4)		(b) (4)	(b) (4)					
15. VESSEL C	CODENAME							
16. U.S. PORT	OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER			19. TOTAL VALUE		
2095						(b) (4)		
20. DESCRIPT	TION OF MERCHANDISE	•	-					
	ACEUTICALS NOT RES	TRICTED						
21. IT/BL/AWB	22, 17/BUAWB NO.	23 MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER		25. COUNTRY OF ORIGIN	28. MANUFACTURER ID.		
	TOTAL	(2) (1)	3004.90.	9190	GB	GBDREPHA176LON		
M H	(b) (4)							
	27. CERTIFICATION			28. C	USTOMS US	E 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:					
(b) (6)								
PHONE NO. DATE 10/07/10		CUSTOMS EXAMINATION REQUIRED.						
28. BROKER OR OTHER GOVT, AGENCY USE		ENTRY REJECTED, BECAUSE:						
						ä		
			CONTRACTOR	SIGNATURE		DATE		
	a	,	DELIVERY AUTHORIZED:	o o maiorite				
			l					

Paparwork Reduction Act Notice: This information is needed 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.

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: 2682INV	Date: 06-10-2010
(b) (4)	Delivery Address: (b) (4)
VAT no:	Currency: GBP - Pounds sterling
Purchase Order:	Heading: PHARMACEUTICALS NOT RESTRICTED
Order Details	
Name/Description	; Quantity Price Total
Thiopental Injection , powder for reconstitution, thi mg vial packs of 25's Batch No: AW6022 EXP: 05/14	
Previous balance	(b) (4)
Statement Details	
Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%):(b) (4)	VAT (World Zero): (b) (4)
Deliver(b) (4)	Previous Balance: (b) (4)
Insurance:(b) (4)	Total: (b) (4) GBP - Pounds sterling
	Payment Method: Prepayment Thank You
Shipping Details	
Packing:	Gross Weight (Kg ^(b) (4)
one bax	Net Weight (Kg)(b) (4)
Tariff: 30049099	Carrier: (b) (4) //
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Phatty ALR.
	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 propeny 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

ENTRY NUMBER: 112 9247186 3 AWB/BL NBR : (b) (4)

INVOICE #

LINE CONSOL. WORKSHEET

PAGE: 1 10/07/2010 05:38 PM

ITEMS MARKED 1 C/O- GB TARIFF #

QTY 1: KG

3004.90.9190

LINE VALUE- GBP

ENTRY NUMBER: 112 9247186 3 AWB/BL NBR : (b) (4) INVOICE #

1 (b)(4) 3004.90.9190 GB

SHIPPER : DREAM PHARMA LTD

PAGE: 1 10/07/2010

05:38 PM

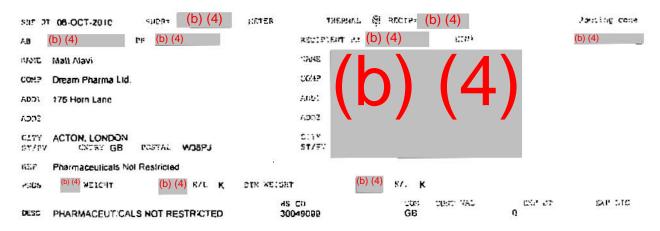
ITEM MARKED REFERENCE

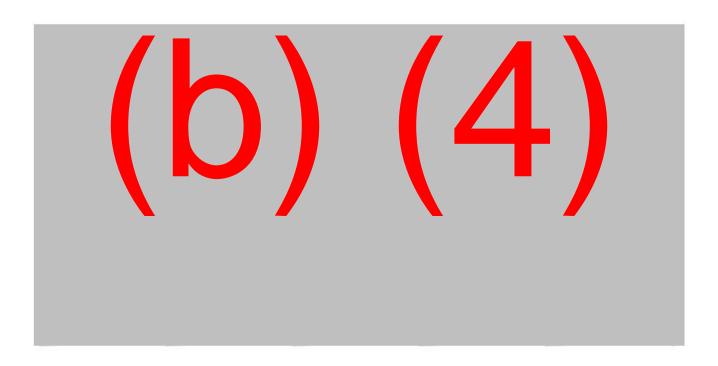
INVOICE ITEM TARIFF COUNTRY

LINE# MARK NUMBER OF ORIG. RATE OF DUTY VALUE-GBP

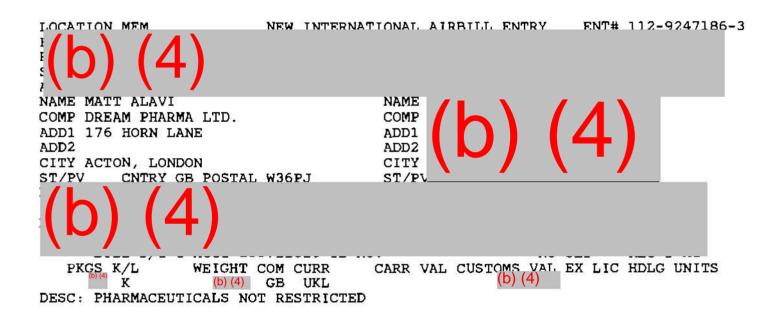
Q:

(b) (4) Manifest report





FDA_08.18.11_000069



From: McAuliffe, John@CDCR [John.McAuliffe@cdcr.ca.gov]

Sent: Monday, December 20, 2010 12:44 PM

To: Dixon, Ruth P

Cc: Kernan, Scott@CDCR

Subject: FW: Letter to Ms. Dixon

Attachments: Letter to Ms. Dixon0001.pdf

Ms. Dixon

Could you please update us on the approval of delivery of the Sodium Thiopental to the California Department of Corrections and Rehabilitation. Thank you in advance.

John McAuliffe

From: McAuliffe, John@CDCR

Sent: Thursday, December 09, 2010 12:10 PM

To: McClease, Kelly@CDCR **Subject:** FW: Letter to Ms. Dixon

FYI

From: Kernan, Scott@CDCR

Sent: Thursday, December 09, 2010 12:03 PM

To: Ruth.Dixon@FDA.HHS.gov

Cc: McAuliffe, John@CDCR; Rice, Benjamin@CDCR

Subject: FW: Letter to Ms. Dixon

Ms. Dixon,

Thank you for working with Mr. McAuliffe on obtaining FDA approval for the delivery of Sodium thiopental to California. Please find attached a letter detailing our legal procurement of the drug and our urgent interest in obtaining the shipment as soon as possible. Your immediate attention to this matter is greatly appreciated.

Please feel free to contact me should you have any questions. (916) 801-4358.

Sincerely,

Scott Kernan
Undersecretary
California Department of Corrections
And Rehabilitation

From: Gaddi, Kathy@CDCR

Sent: Thursday, December 09, 2010 11:58 AM

To: Kernan, Scott@CDCR Subject: Letter to Ms. Dixon

Ruth.Dixon@FDA.HHS.gov

Kathy Gaddi

Executive Assistant to Scott Kernan

Undersecretary, Operations (916) 341-7015

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number:

112-9673446-4

Notice Number: January 6, 2011

2

Consignee:

Kirkland Correctional Institutio 4344 Broad River Rd Columbia, SC 29210-4010

Port of Entry:

2095, FedEx - Memphis, Memphis, TN

Carrier:

(b) (4)

Date Received: November 5, 2010 Arrival Date:

November 5, 2010

Filer of Record:

FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Importer of Record:

(b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status	
*	001/001	688760418804/THIOPENTAL SODIUM	(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 112-9673446-4. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA

Product Description

001/001

688760418804/THIOPENTAL

SODIUM

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

Denise D. Duncan, Compliance Officer

(901) 333-3520

(Region/District)

(901) 333-3579 (FAX) DENISE.DUNCAN@FDA.HHS.GOV Notice of FDA Action

Entry Number: 112-9673446-4

Notice Number: 2

Page: 2

U.S. Food and Drug Administration 959 Ridgeway Loop Road, Suite 100

Memphis, TN 38120-4042

LINES RELEASED

Line ACS/FDA

Product Description

001/001

688760418804/THIOPENTAL

SODIUM

Denise D. Duncan, Compliance Officer

(Region/District)

(901) 333-3520 (901) 333-3579 (FAX)

U.S. Food and Drug Administration 959 Ridgeway Loop Road, Suite 100

Memphis, TN 38120-4042

DENISE.DUNCAN@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: DDD

Aug 10 2010 15:01

P. 01 -

**

#2 Martin Luther King, Jr. Drive East Tower, Room 754 Atlanta, GA 30334 Fax (404) 657-4399 Voice (404) 656-5999

Georgia Department of Corrections Purchasing



TO: BJEFFERSON	From:	SMITH
Fax: 701,3333577	Pages: 3 (INCLUBING COVER PAG
Phone:	Date:	
TRBEILING # 688 760 417429 Re: ENTRY # 112-7818637-8	CC:	
☐ Urgent ☐ For Review ☐ Please Con	nment □Pl	ease Reply □ Please Recycle



GEORGIA DEPARTMENT OF CORRECTIONS

COMMISSIONER'S OFFICE SUITE 866, EAST TOWER 2 MARTIN LUTHER KING, JR. DRIVE, S.E. ATLANTA, GEORGIA 30334-4900 404/656-4644 FAX 404/651-6818

Sonny Perdue Governor Brian Owens Commissioner

August 4, 2010

FEDEX

ATTN: Customer Relations

3875 Airways, Module H3 Department 4634

Memphis, TN 38116

SUBJECT: Thiopental Injection Purchase

To whom it may Concern:

The Georgia Department of Corrections (GDC) uses Thiopental Injection in its Death Sentence cases. In accordance with Official Code of Georgia, § 17-10-3, Article 2 in capital punishment cases: "All persons who have been convicted of a capital offense and have had imposed upon them a sentence of death shall suffer such punishment by lethal injection."

The GDC has been unable to locate this drug in the United States and because there is a need for the drug to carry out the State of Georgia's constitutional requirement in death sentence cases we have purchased, from Dream Pharma LTD., 176 Horn Lane, Action London, the supplies listed below:

Name/Description Quantity	Quantity	Price (ea)	Total
Thiopental Injection, power for reconstitution, thiopental sodium, 500mg vial packs of 25's	(b) (4)		91.88 GBP

Shipping Location:



SUBJECT: Thiopental Injection Purchase Georgia Department of Corrections

Mr. Charles H. Smith, Jr., Director of Procurement will be the point of contact for this purchase. He can be reached by telephone 404-656-6442 or by e-mail: smithc12@dcor.state.ga.us.

Fax: 404-657-4399

Sincerely,

Derrick D.

Assistant Commissioner, Chief of Staff Georgia Department of Corrections

DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

Form Approved OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

FEDEX TRADE NETWORKS
TRANSPORT & BROKERAGE, INC.
TEL: (901) 752-3000

AIR EXPRESS

		19 CFR 142.3, 14	2.16, 142.22, 142.24		L. ENEWLAUNDED
1. ARRIVAL DATE		2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME		4. ENTRY NUMBER
110510			11		112-9673446-4
5. PORT		6. SINGLE TRANS, BOND		7. BROKER/IMPORTER FILE NUMBER	
2095			(b) (4)		÷.
		8. CONSIGNEE NUMBER		•	9. IMPORTER NUMBER
		NAME/ADDRESS			(b) (4)
10. ULTIMATE CONSIGNEE NAME KIRKLAND CORRI 4344 BROAD RIV COLUMBIA		N	11. IMPORTER OF RECORD NAME.	(4)	
12. CARRIER CODE		13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(S)	NAME(S)	
(b) (4)		(b) (4)	(b) (4)		
15. VESSEL CODE/NAME					
16. U.S. PORT OF UNLADING		17. MANIFEST NUMBER	18. G.O. NUMBER		19. TOTAL VALUE
2095					1034
20. DESCRIPTION OF MERCHANDIS	SE .				1034
PHARMACEUTICAI	S NOT DES	かりょくかたり			
21. IT/BL/AWB 22. IT/BL/AWB NO.	D NOI KED	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
CODE	TOTAL	(b) (4)	3004.90.9135	GB	GBDREPHA176LON
M (b)	(A)		3004.90.9133	GD	GBDREF HAT / OLON
$^{\text{\tiny H}}$ \mid \mid \mid \mid \mid \mid	(4)				
	4				
ľ					
	27. CERTIFICATION		28.	CUSTOMS US	E ONLY
	bond is sufficient, va	ivery. I certify that the above lid, and current, and that all	OTHER AGENCY ACT	on required,	NAMELY:

Paperwork Reduction Act Notice: This information is needed 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.

DELIVERY AUTHORIZED:

CUSTOMS EXAMINATION REQUIRED.

ENTRY REJECTED, BECAUSE:

SIGNATURE

DATE

29. BROKER OR OTHER GOVT. AGENCY USE

W20

11/05/10

PHONE NO.

(b) (4)

DATE

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: 2716INV

Address:

South Carolina Department of Corrections Kirkland Correctional Institution- Pharmacy

4344 Broad River Road

Columbia, South Carolina 29210

United States

Tel: 803 - 896-1995

VAT no:

Purchase Order:

Date: 05-11-2010

Delivery Address:

South Carolina Department of Corrections Att: John Solomon and Rose Mayer Kirkland Correctional Institution- Pharmacy

4344 Broad River Road

Columbia, South Carolina 29210

United States 803 - 896-1995

Currency: USD - US Dollar

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description

Thiopental Injection , powder for reconstitution, thiopental sodium, 500mg vial packs of 25's

Batch No: AW6022 EXP: 05/14

Quantity Price Total

1033.5

Statement Details

Goods Total: 1033.50 Subtotal: 1471.00

Discount (%): 0 , VAT (World Zero): 0.00

Delivery: 437.5 Previous Balance: 0

Insurance: 0 Total: 1471.00 USD - US Dollar

Payment Method: Prepayment Thank You

Shipping Details

Packing:

(b) (4)

Tariff: 30049099

Declarations:

We certify that this invoice is true and correct.

Gross Weight (Kg):

Net Weight (Kg):

(b) (4)

Carrier:

(b) (4)

Matt Alavi, for Dream Pharma Ltd.

Meton, London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

a

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

ENTRY NUMBER: 112 9673446 4

AWB/BL NBR: (b) (4) INVOICE # 11/05/2010

LINE CONSOL. WORKSHEET 08:19 PM

ITEMS MARKED 1 C/O- GB LINE VALUE- USD TARIFF # 3004.90.9135

TARIFF # 30 QTY 1: KG

1,033.50

** 1,033.50

**** 1,033.50

ENTRY NUMBER: 112 9673446 4 AWB/BL NBR : (b) (4) INVOICE #

SHIPPER : DREAM PHARMA LTD

PAGE: 11/05/2010

08:19 PM

ITEM MARKED REFERENCE

INVOICE ITEM LINE# MARK

TARIFF NUMBER COUNTRY OF ORIG.

RATE OF DUTY

VALUE-USD

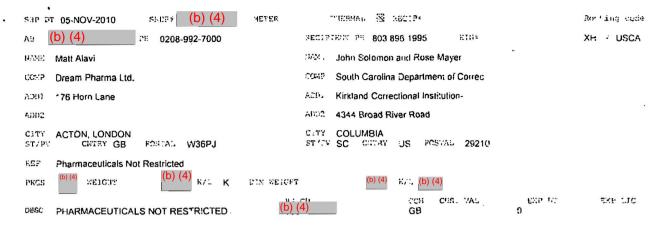
1

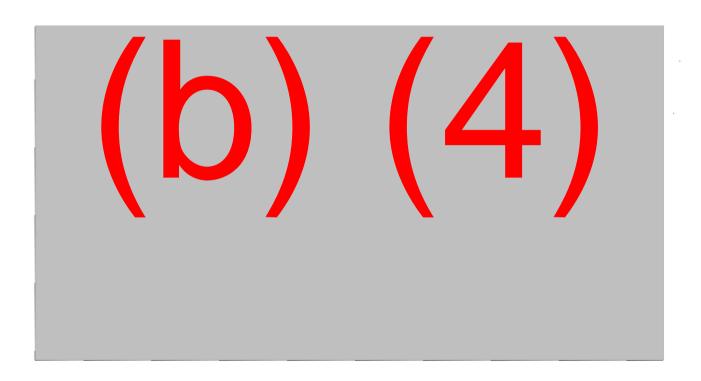
3004.90.9135 GB

Q:

(b) (4) _{KG} 1,033.50

(b) (4) Manifest report





FDA_08.18.11_000082

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-9673446-4

NAME MATT ALAVI

COMP DREAM PHARMA LTD.

ADD1 176 HORN LANE

ADD2

CITY ACTON, LONDON

ST/PV CNTRY GB POSTAL W36PJ

REF

RECIPIENT PH (803)896-1995

NAME JOHN SOLOMON AND ROSE MAYER

COMP SOUTH CAROLINA DEPARTMENT OF COR ADD1 KIRKLAND CORRECTIONAL INSTITUTIO

ADD2 4344 BROAD RIVER ROAD

CITY COLUMBIA

ST/PV SC CNTRY US POSTAL 29210

K

WEIGHT COM CURR (b) (4) GB USD

CARR VAL CUSTOMS VAL EX LIC HDLG UNITS

1471.00

DESC: PHARMACEUTICALS NOT RESTRICTED

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number: 112-9673446-4 Notice Number: 1

November 8, 2010

Consignee:

Kirkland Correctional Institutio 4344 Broad River Rd Columbia, SC 29210-4010

>

Port of Entry: 2095, FedEx - Memphis, Memphis, TN

Carrier: (b) (4)
Date Received: November 5, 2010
Arrival Date: November 5, 2010

Filer of Record: FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Importer of Record: (b) (4)

HOLD DESIGNATED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	688760418804/THIOPENTAL SODIUM	(b) (4)	Pending FDA Review 11- 05-2010

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

@ = Consignee ID

FDA will not request redelivery for examination or sampling, if the products not released by FDA are moved, following USCS conditional release to a location within the local metropolitan area or to a location approved by the FDA office at the number below.

All products in this entry not listed above may proceed without FDA examination. This notice does not constitute assurance the products involved comply with provisions of the Food, Drug, and Cosmetic Act or other related acts, and does not preclude action should the products later be found violative.

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

Notice Prepared By: MJS

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

ENTRY/IMMEDIATE DELIVERY

ACB IMPORT SERVICES, INC DBA ARIZONA CUSTOMS BROKERS P.O. BOX 20082 PHOENIX, AZ 85036

000 BOX #

	18 CFR 142.	9, 142.16, 142.22. 142.24		ABI CERTIFIED
, ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME		4. ENTRY NUMBER
.02610		11 INFORMA		574-0251126-5
S. FORT	6. BINGLE TRANS. BOND	7. BACKER/IMPORTER FILE NUM	SÉA	
605	(b) (4)	001267045		
	E. CONSIGNEE NUMBER			S. IMPORTER NUMBER
	86-600479107		<u> </u>	86-600479106
O. ULTIMATE CONSIGNEE NAME	I CONDIEN	11. IMPORTER OF RECORD NAM	-	A CORRECTIONS
RIZONA STATE PRISON	N COMPLEX			OF CORRECTIONS
.305 BUTTE AVE FLORENCE, AZ 85232		1601 W. JEFFE PHOENIX, AZ 8		
	13, VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-COD		
ARRIER CODE	(b) (4)	(b) (4)	E(9)/NAMe(8)	
S, VESSEL CODE/NAME		(b) (4)		
G. VEGGET COOPERANTE		PHOENIX, AZ 8	5034	
16, U.S. PORT OF UNLADING	17 MANIFEST NUMBER	16. G.O. NUMBER		19. TOTAL VALUE
605				1246
20. DESCRIPTION OF MERCHANDISE				
MEDICAL EQUIPMENT				
21. IT/BL/AWE 22. IT/BL/AWS NO.	23. MANIFEST QUANITY	24, H.S. NUMBER	ZE. COUN	TRY 26. MANUFACTURER NO.
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27. CERT	IFICATION		28. CBP US	ONLY
hereby make application for entry/immed information is accurate, the bond is suffic equirements of 19 CFR Part 142 have be SIGNATURE OF APPLICANT	ent, veild, and current, and that a		ACTION REC	QUIRED, NAMELY:
X ATTY-IN-FACT/ACB	W /1//			
HONE NO. (b) (6)		CDE EVALUATION	011 0no.us=	.
<u>Fax#:</u> (b) (6)	10/25/2010	CBP EXAMINATION	ON RECIDINE	u.
29. BROKER OF OTHER	GOVT. AGENCY USE	ENTRY REJECTE	-	
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		DELIVERY SIGNATUR	RE	DATE
		AUTHORIZED:		
				
		1		
Exam Site: (b) (4)				

FX/3461 (1/10)

PART 1

CBP Form 34B1 (10/09) FDA_08.18.11_000085

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I.q 6022730805

Arizona Department of Corrections



1801 WEST JEFF SRECH PHOENIX, ARIZONA 88007 (802) 542-6487 WWW.82001700Tokin.gov



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

Jeffrey Timothy Landrigan #082157

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. Jeffrey Timothy Landrigan, CR-90-0323 AP.

In order to proceed with the execution we must have the products ordered through Dream Pharma. Our DEA Registration number is: FA2203571 and it expires June 30, 2013. The execution is set by the court for October 26, 2010, and our agency is mendated 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

Number: 2701 NV

Address:

Arizona State Prison Complex - Florence Attention: Carson McWilliams, Warden 1305 Butte Avenue Post Office Box 629

Florence, Arizona

65232

Tel: 602-364-3791

VAT no:

Purchase Order:

Date: 22-10-2010

Delivery Address:

Arizona State Prison Complex - Florence Attention: Carson McWillams, Warden

1305 Butte Avenue Post Office Box 629 Florence, Arizona

85232

502-364-3791

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED "This is not for use by the general public"

Order Details

Name/Description	Quentity	Price	Total
Thiopental injection, powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW8022 EXP: 05/14 3004, 90. 9130/	(b) ((b) (4)	787

Statement Detaile : 391 . Build of the shall a '14 it has a was t

Goods Total: 787.00 Subtotal: 787.00 Discount (%): 0 VAT (World Zero): 0.00 Delivery: 0 Previous Balance: 0 insurance: 0 Total: 787.00 GBP - Pounds sterling Payment Method: Prepayment Thank You

Shipping Details

Packing:	Groza Weight (Kg): (Kg)
(b) (4)	Net Weight (Kg):(b) (4)
Tariff: 30049099	Carrier: (b) (4)
Declarations:	Matt Alevi, for Dream Pharma Ltd.
We certify that this involce is true and correct.	MATTING THE PROPERTY OF THE PARTY OF THE PAR

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

> Company Registration Number: 4837884 VAT No. GB805-5541-41 Director: M. Alavi

> > Page 1 of 1

Dream Pharma Ltd.

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

Involca Details

Number: 2702INV

Address:

Arizona State Prison Complex - Florence Attention: Carson McWilliams, Warden

1305 Butte Avenue Post Office Box 829 Florence, Arizona

85232

Tel: 602-384-3791

VAT no:

Purchase Order:

Date: 22-10-2010

Delivery Address:

Arizona State Prison Complex - Florence Attention: Carson McWilliams, Warden

1305 Butte Avenue Post Office Box 629 Florence, Arizona

85232

602-364-3791

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

Name/Description	Quantity	Price	Total
Shipping charges for invoice number 2701inv	(b) (i	(b) (4)	250

Statement Detailed:

Goods Total: 250.00

Discount (%): 0

Delivery: 0

Insurance: 0

Subtotal: 250.00

VAT (World Zero): 0.00

Previous Balance: 0

Total: 250.00 GBP - Pounds sterling

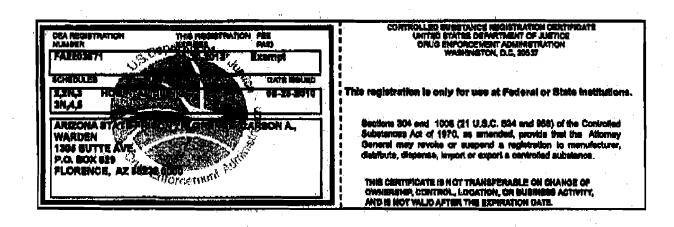
Payment Method: Prepayment Thank You

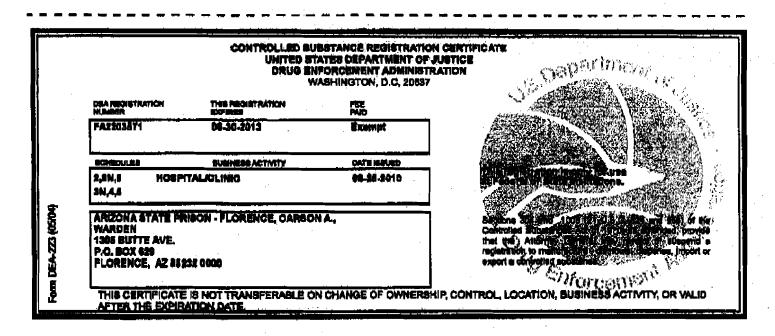
Packing:	Gross Weight (Kg):
	Net Weight (Kg):
Tariff: 30049099	Carrier: (b) (4)
Declarations:	Matt Alevi, for Dream Pharma Ltd.
We certify that this invoice is true and correct.	MARIMA TARRESTON

Damage, shortage or leakage must be notified in writing to cursaives 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. GB805-5641-41 Director: M. Alavi

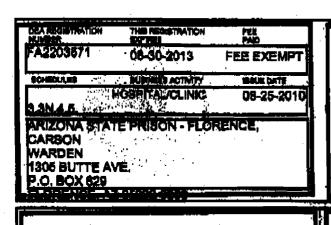
> > Page 1 of 1





https://www.deadiversion.usdoj.gov/webforms/dupeCertPrintCert.do

9/24/2010



CONTROLLED SUBSTANCE/REQUILATED CHEMICAL REQUISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG EMFORCEMENT ADMINISTRATION WASHINGTON D.C. 20597

This registration is only for use at Pederal or State Instituti

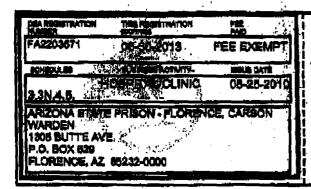
Segions 304 and 1008 (21 USC 884 and 984) of the Controlled Substantes Act of 1970, as amended, provide that the Albaney General may revoke or exepend a registration to minusketure, distribute, dispense, import or expect a controlled substante.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF DIMERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPENATION BATE.

REQUESTING MODIFICATIONS TO YOUR REQUESTRATION CHRISPICATE

To request a change to your registered name, address, the drug actionals or the drug action you hamile, please

* year wir und die al floorff vir than Andrew - er



CONTROLLED SUBSTANCE RESISTINATION CENTRACATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20087

This repletention is only for use at Federal or State healthings.

Sections 304 and 1006 (21 USC 834 and 666) of the Controlled Substances Act of 1970, as amended, provide that the Aborney Control may revolve or suspend a registration to establishment distribute, displante, import or export a controlled substance.

THE CERTIFICATE IN NOT TRANSPIRABLE ON CHANGE OF COMMERCHIP, CONTROL, LOCATION, OR EVENEES ACTIVITY, AND IT IS NOT VALLE AFTER THE EXPINATION DATE.

CONTROLLED BUBSTANCS PEGISTRATION CERTIFICATE UNITED STATES DEPARTMENT OF JUSTICE DRUG EMPORCEMENT ADMINISTRATION WASHINGTON D.C. 20537

DEA PERINSTRATION NUMBER	THE REGISTRATION BUTTERS	PEÉ PARD
FA2203671	06-30-2013	FEE EXEMPT
ACHEDIA 64	SUSPIESS ACTIVITY	MOVE 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

Trie inglamation in only for the at Patient or State in all his ta

Sections 394 sept 4006 (21 USC \$24 and 958) of the Controlled Busideridae act of 1970, es amended, provide that the Atlorney Geristal 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 DATS.

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Wednesday, January 05, 2011 9:21 AM

To: Halpenny, Susan M **Subject:** Na Thiopental Good morning Susan,

The drugs have not been released as of 10:15 this morning. Have you heard anything this morning that is encouraging about this matter?

John

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999 From: Halpenny, Susan M

Sent: Wednesday, January 05, 2011 10:20 AM

To: 'John Solomon'

Subject: RE: Na Thiopental

Good day,

Our Director of Imports, Domenic Veneziano, advised me yesterday that we may not receive the information he was preparing until today. I will let contact you once I have received this information and released the shipments.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Wednesday, January 05, 2011 9:21 AM

To: Halpenny, Susan M Subject: Na Thiopental

Good morning Susan,

The drugs have not been released as of 10:15 this morning. Have you heard anything this morning that is encouraging about this matter?

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

NO.867 P.2/9

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

Form Approved OMB No. 1651-0024

ENTRY/IMMEDIATE DELIVERY

ACB IMPORT SERVICES. INC DBA ARIZONA CUSTOMS BROKERS R.D. BOX 20082 FHOENIX, AZ 85036

DOO BOX # ABI Certified 19 CFR 142.3, 142.16, 142.22, 142,24 2. ELECTED ENTRY DATE 3. ENTRY TYPE GODE NAME COnsump ARRIVAL DATE 4. ENTRY NUMBER IP 574-0250322-1 092810 7. BROKER/IMPORTER FILE NUMBER (b) (4) 5. PORT 6. SINGLE TRANS. BOND 2605 X871 8. CONSIGNEE NUMBER 9. IMPORTER NUMBER 86-600479107 (b) (4) 10. ULTIMATE CONSIGNEE NAME 11. IMPORTER OF RECORD NAME ARIZONA DEPARTMENT OF CORRECTIONS ARIJONA STATE PRISON COMPLEX JEFFERSON ST 1305 BUTTE AVE 1601 W. PHDENIX, AZ 85007-3002 FLORENCE, AZ 85232 2. CARRIER CODE (b) (4) 113. VDVAGE/FLIGHT/TRIP CODE/CVAIAME/CI 15, VESSEL CODE/NA VE 16 U.S. PORT OF UNLADING 17. MANIFEST NUMBER 18. G.O. NUMBER 19. TOTAL VALUE 6849 2095 1 20. DESCRIPTION OF WERCHANDISE MITHIOPENTAL, FOTABSIUM, PANCURONI 21 TELANBOWE 22. IT/BL/AWB NO. . 23. MANIFEST QUANTITY (b) (4) S. COUNTRY OF CANGIN 24, H.S. NUMBER 3004907130 2933394100 GRDREPHA 176LO GB. : G₽ 3104200000 GBDREPHA176LDN $\Theta_{p,q}$ 27. CENTIFICATION 28. CBP USE ONLY I hereby make application for entry/immediate delivery. I certify that the OTHER AGENCY ACTION REQUIRED, NAMELY: 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 Pharmacy Program Manager PHONE NO. 09/28/2010 CBP EXAMINATION REQUIRED. 29. Broker of other govt. Agency USE ENTRY REJECTED, BECAUSE: DATE SIGNATURE DELIVERY AUTHORIZED: Exam Sites FEDERAL EXPRESS

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 hability for payment of duties and taxes. Your response is necessary. The estimated everage outden 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 20228, and to the Office of Management and Suggestions of Services Project (1881-9024), Washington, DC 20503.

09-28-'18 09:90 FROM-ADC Directors Office 602-364-0601

T-087 P0003/0005%F-565^{* *}

Dream Pharma Ltd.

175 Horn Lene, Acton, London, WS 6PJ Tel: 020 5992 7000 Fax: 020 8992 7001 E-Mail: Info@dreamphama.com

In	VO	ice	Dı	oto.	16

Number: 2570 NV

Date: 28-09-2010

Addrese:

Arizona State Priton Complex - Florence Attention: Carsor: McWilliams. Worden 1305 Butto Avenue Post Office Box 629

Florence, Arizonti 85232 Tel: 802-384-3791

VAT no: Purchase Order

Delivery Address: Asizona State Prison Complex - Florence Attention: Carson McWilliams, Warden

1806 Butte Averus Post Office Box 629

Florence, Arizona R6232 602-384-3701

1-3004.94.9130/ Fre-2-3104. 20.0004/ 6.5%

Currency: GBP - Pounds starting 3 - 2733.37.4100 (14) Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Thispental injection , powder for reconstitution, thispental sectium, 500-ing vial packs of 25's Batch No: AW8022 EXP: 05/14

> Contract Contracts a Barrior and a particular

POTASSIUM CHI JORIDE 1.60M 10ML INJ. PACKE OF 10 Seich No. 002087 EXP. 01/13

Panetronium in setion, panetronkim bromide 2 mg/mt., 2-mt. amp. packs of 10's Batch No. 949064 EXP: 11/11

Special delivery, sherges

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			`	270	.9	171
, 24 Pr				17,0		te i p
رم 14.				254	2.85	ķi

Statement De alle

Goods Total: 4243.26

Discount (%): 0

Delivery: 275

Insurance: 0

A628.26

VAT (World Zero): 0.00

Previous Balance: 0

Total: 4528.25 GBP - Pounds starting

Payment Method: Prepayment Thank You

Shipping Details

Tariff: 30049009 Decigrations! We certify that this invoice is true and correct.

The second secon

OF EXECUTE A CONTROL OF A A CONTROL AND A

Gross Weight ((G): (D)(d) Net Weight ((G):(D) (4) Camer (D) (4)

Company Registration Number: 4837884 VAT No. 98805-6841-41 Director: M. Alevi

Page 1 of 1

Port Date Entered or importin bond via (b) CBP Port Director Consignee CAR	ted try (b) (4) (4) PHOENIX, RSON MCWILL	AZ 26	(Vessel or carner) 05 WARDEN), ARIZONA STAT	BJECT TO CBP AND PERMIT Border Protection U.S. PORT UNLADING MEMPE ALS, TN Importer/IF (Car number and initial) Final foreign destin	es#(b)	Entry N Class o (I.T.) (T. N DATE (4) (Pier	o. 2000 f Entry E.) (WD. sr slaton) er experta RENCE	I.T. 61 (E) (Drawback, etc.) 29SEP10 to be shipped consigned to
imported on the			Flag USA	on (b	(Date impo		via <u>S</u> TI	(Last foreign port)
Exported from U	NITED KING		on285EPIC	Goods now at (b) (4)	ne of warehou	ise, station	, Dior, etc.)
Marks and Numbers of Packages	Desc	notion and Number a	Quantity of Merchandise nd Kind of Packages	Grosa Weight In Pounds	Val (Dollar	UB	Rate	Duty
b) (4)	872136481 PHARMACEU THIOPENTA FOR RECON THIOPENTA OF 051.4 POTA **** BROKE ARIZONA C	249 TICALS L STITUT L SODI 25' SSIU R INFO USTOMS RIZ, A	UM 500- MG VIAL PACKS S BATCH NO AW6022 EXE RMATION *** Z, US, 85040	ESTIMATED NOT (b) (4)	VERIFIE 6822. USD	D		
G.O. No.	E OF LADING		LI Check if withdrawn for Vess NSPORTATION IN BOND			nts contain	ed herei	n are true and
MITH THE EXC WITHIN-DESCRIPTION OF THE CBP Port Distriction seels see to Nos. WAI or the packages not) labeled, or and seeled. AMS AUTHORI	EFOENIX EFOENIX CEPTIONS NO RIBEC GOODS Carrier or delivery to birector at ed with CBP VED (Were) (Were cordet)	TED ABOWERE: Laden of which close on	ORTATION FOR 505 (Port) OVE, THE of the	Entered or withdrawn FEDERAL EXPRES EMF# (b) (6) To the inspector: The	above-do AMS AUT This body of the neppare	eacribed go THOR I ZEI For the ab manifest for CBP office nt good ord	ods sha a Port Pire ove CBF or transpiers at the	It be disposed of control the contains and port named
funsbed	<u>-</u>		(Inspector)) (6)		
(Date			(Date)	· ·		Attomey	r Agent of	Camer P Form 7512 (03/08)
					ļ		20	· · Attit (A IN JANIAR)

Arizona Department of Corrections



1601 WEST JEFFERSON PHOENIX, ARIZONA 85007 (602) 542-5497 www.azcorrections.gov



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.

Charles Flanagan Deputy Director

cc: File

Dave,
please do not busitate to
Contact me for any reason. I
greatly appreciate your consistance,
Charles

Arizona Department of Corrections



1601 WEST JEFFERSON PHOENIX, ARIZONA 85007 (802) 542-5497 www.azcorrections.gov



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

Jeffrey Timothy Landrigan #082157

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. Jeffrey Timothy Landrigan, CR-90-0323 AP.

In order to proceed with the execution we must have the products ordered through Dream Pharma. Our DEA Registration number is: FA2203571 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

ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN
1305 BUTTE AVE.
P.O. BOX 629
FLORENCE, AZ 85232-0000-000
Hullahadhalladha

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA2203571	06-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	IGSUE DATE
3,3N,4,5,	IOSPITAL/CLINIC	08-25-2010
ARIZONA STATE WARDEN 1305 BUTTE AVI P.O. BOX 629 FLORENCE, AZ	The second second	CE, CARSON

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 1008 (21 USC 824 and 958) 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.

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

DEA REGISTRATION THIS REGISTRATION FEE PAID

FA2203571 06-30-2013 FEE EXEMPT

SCHEDULES BUSINESS ACTIVITY ISSUE DATE

HOSPITAL/CLINIC 08-25-2010

3,3N,4,5,

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

Form DEA-223 (4/07)

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

Sections 304 and 1008 (21 USC 824 and 958) 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.

Printable DEA Certificate Page 1 of 1

DEA REGISTRATION THIS REGISTRATION FEE FA2203571 06-30-2013 Exempt SCHEDULES **BUSINESS ACTIVITY** DATE ISSUED 08-25-2010 2,2N,3 HOSPITAL/CLINIC 3N,4,5 ARIZONA STATE PRISON - FLORENCE, CARSON A., 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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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: 2679INV

Address:

Arizona State Prison Complex - Florence Attention: Carson McWilliams, Warden

1305 Butte Avenue Post Office Box 629 Florence, Arizona

85232

Tel: 602-364-3791

VAT no:

Purchase Order:

Date: 28-09-2010

Delivery Address:

Arizona State Prison Complex - Florence Attention: Carson McWilliams, Warden

1305 Butte Avenue Post Office Box 629 Florence, Arizona

85232

602-364-3791

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW6022 EXP: 05/14	(b)	(4)	1180.5
POTASSIUM CHLORIDE 1.5GM 10ML INJ. PACKS OF 10 Batch No: 002067 EXP: 01/13			279.9
Pancuronium Injection, pancuronium bromide 2 mg/mL, 2-mL amp packs of 10's Batch No: 949064 EXP: 11/11			2642.85
Special delivery charges	1	150	150

Statement Details

Goods Total: 4253.25	Subtotal: 4528.25
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 275	Previous Balance: 0
Insurance: 0	Total: 4528.25 GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing:	Gross Weight (Kg): (b) (4)
(b) (4)	Net Weight (Ka)(b) (4)
Tariff: 30049099	Carrier: (b) (4)
Declarations:	Matt Alavi, for Dream Pharma Atd
We certify that this invoice is true and correct.	176 Horn Lane
	Acton London Walen L
	Q Tel: 020-8992-7000

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

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Wednesday, January 05, 2011 9:21 AM

To: Halpenny, Susan M **Subject:** Na Thiopental Good morning Susan,

The drugs have not been released as of 10:15 this morning. Have you heard anything this morning that is encouraging about this matter?

John

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999 From: Halpenny, Susan M

Sent: Wednesday, January 05, 2011 10:20 AM

To: 'John Solomon'

Subject: RE: Na Thiopental

Good day,

Our Director of Imports, Domenic Veneziano, advised me yesterday that we may not receive the information he was preparing until today. I will let contact you once I have received this information and released the shipments.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Wednesday, January 05, 2011 9:21 AM

To: Halpenny, Susan M Subject: Na Thiopental

Good morning Susan,

The drugs have not been released as of 10:15 this morning. Have you heard anything this morning that is encouraging about this matter?

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

Bryce, John *

From:

Thomas, David

Sent:

Thursday, October 28, 2010 6:28 AM Solis, Daniel

To:

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.dc

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
63BIZ02	Albuterol Sulfate (Bronchodilator)	DR - Drugs		04/02/2010
61EIZ04	Budesonide (Anti-Asthmatic)	DR - Drugs		04/02/2010
63BAY02	Albuterol Sulfate (Bronchodilator)	DR - Drugs		03/27/2008
63BIY32	Formoterol Fumarate	DR - Drugs		12/20/2007
77KCO	Inhaler, Nasal	DE - Devices	1	12/20/2007
62TCE02	Lansoprazole (Anti-Secretory)	DR - Drugs		06/22/2007
55PP55	Silica Gel (Pharmaceutic Necessity)	DR - Drugs		06/19/2007
55PY55	Silica Gel (Pharmaceutic Necessity)	DR - Drugs		06/11/2007
62FBO20	Iodine (Anti-Infective, Topical)	DR - Drugs		04/24/2006
61EIY99	Anti-Asthmatic, N.E.C.	DR - Drugs	,	03/18/2006
61ECQ99	Anti-Asthmatic, N.E.C.	DR - Drugs		01/16/2006
62CCK16	Diazoxide (Anti-Hypertensive)	DR - Drugs		10/10/2005
62CCY16	Diazoxide (Anti-Hypertensive)	DR - Drugs		09/17/2004

Firm Services vv2.1.02 July 15, 2010 (fdsul09623.fda.gov) | Copyright 2008 | U.S. Food and Drug Administration

From: Halpenny, Susan M

Sent: Wednesday, December 01, 2010 2:35 PM

To: 'John Solomon'

Subject: RE: shipment delay FDA entry # 112967344464

Good afternoon,

I apologize for the delay but our Director of Import Operations has been in meetings this week on this subject, and I have not received any word back as yet. I will contact you as soon as hear something.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Wednesday, December 01, 2010 2:03 PM

To: Halpenny, Susan M

Subject: shipment delay FDA entry # 112967344464

Hello Susan,

I checked the tracking on the shipment and find it is still delayed. Is there any movement toward a decision on who has jurisdiction (FDA or DEA)? Is there agreement on a time for a decision to be made? If this is not resolved soon we may be exchanging Christmas cards.

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

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: To: Wednesday, October 27, 2010 3:12 PM

To: Cc: Thomas, David 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: To: Wednesday, October 27, 2010 3:08 PM

Cc:

Solis, Daniel

Subject:

Strickland, Evanguel 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 Arizona Customs Brokers, ACB, was chosen by AZ DOC.

ACB 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. ACB 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 ACB. 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. Jeffrey Timothy Landrigan, CR-90-0323 AP).
- 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 -FA2203571.

September 29, 2010 entry arrived Port of Entry Phoenix via Memphis, TN.

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 Strickland, Evanguel

Cc: Subject:

RE: Scenario initial AZ DOC entry

From: Halpenny, Susan M

Sent: Wednesday, December 01, 2010 2:35 PM

To: 'John Solomon'

Subject: RE: shipment delay FDA entry # 112967344464

Good afternoon,

I apologize for the delay but our Director of Import Operations has been in meetings this week on this subject, and I have not received any word back as yet. I will contact you as soon as hear something.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Wednesday, December 01, 2010 2:03 PM

To: Halpenny, Susan M

Subject: shipment delay FDA entry # 112967344464

Hello Susan,

I checked the tracking on the shipment and find it is still delayed. Is there any movement toward a decision on who has jurisdiction (FDA or DEA)? Is there agreement on a time for a decision to be made? If this is not resolved soon we may be exchanging Christmas cards.

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

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.pd 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 Injectible 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 Memphis, TN 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----

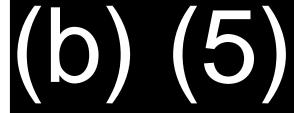
From: Verbeten, John E. (ORA)

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



---- 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 Memphis 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

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Tuesday, December 07, 2010 7:14 AM

To: Halpenny, Susan M **Subject:** clearance delay Good morning Susan,

It has been a month since the FDA has chosen to delay delivery of a package sent from England to the South Carolina Department of Corrections. From our last conversation I understand there is a discussion regarding "jurisdiction" between the FDA and the DEA. If it does not appear that there will be a solution to this stalemate in the near future (think next 24 hours) can you direct me to someone who might be able to help expedite a decision?

John

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Consignee:

Arizona State Prison Complex 1305 Butte Ave Florence, AZ 85232

>

Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4)

Date Received: September 29, 2010

Arrival Date: September 28, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040

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

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		Line Split
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE		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

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Filer:

Arizona Customs Brokers

2153 East Jones Ave

Phoenix, AZ 85040

Attention:

(b) (6)

Broker Box:

>

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: Arizona State Prison Complex, Florence, AZ 85232

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		Line Split
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE		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

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Importer:

Arizona Department Of Correction 1601 W Jefferson St Phoenix, AZ 85007-3002

>

Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4)

Date Received: September 29, 2010

Arrival Date: September 28, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040 Consignee: Arizona State Prison Complex, Florence, AZ 85232

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		Line Split	
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010	
002/001B	POTASSIUM CHLORIDE INJECTIBLE		Released 09-29-2010	

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

From: Halpenny, Susan M

Sent: Thursday, December 09, 2010 1:38 PM

To: 'John Solomon' **Subject:** RE: status Good day Dr. Solomon,

I have asked for an update on the status of your shipment from our Center for Imports but unfortunately they do not have any updates to give me. I will continue to check on this daily.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Thursday, December 09, 2010 6:51 AM

To: Halpenny, Susan M

Subject: status

Good morning Susan,

May we have a status report with particular attention as to why the FDA continues to intervene in this particular drug purchase? Also, the delay now borders on being excessive. Does anyone have any idea when a decision will be rendered to release the shipment? Thank you for continuing assistance.

John

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Thursday, December 09, 2010 6:51 AM

To: Halpenny, Susan M

Subject: status Good morning Susan,

May we have a status report with particular attention as to why the FDA continues to intervene in this particular drug purchase? Also, the delay now borders on being excessive. Does anyone have any idea when a decision will be rendered to release the shipment? Thank you for continuing assistance.

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(Fax) 803-896-1999

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Consignee:

Arizona State Prison Complex 1305 Butte Ave Florence, AZ 85232

>

Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4)

Date Received: September 29, 2010

Arrival Date: September 28, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040

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

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		Line Split	
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010	
002/001B	POTASSIUM CHLORIDE		Released 09-29-2010	

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@ = 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

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Filer:

Arizona Customs Brokers

2153 East Jones Ave

Phoenix, AZ 85040

Attention:

(b) (6)

Broker Box:

>

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: Arizona State Prison Complex, Florence, AZ 85232

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
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Notice Prepared For: The District Director, U.S. Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1 Notice Number: 1
September 29, 2010

Importer:

Arizona Department Of Correction 1601 W Jefferson St Phoenix, AZ 85007-3002

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Port of Entry: 2605, Phoenix, AZ

Carrier: (b) (4)

Date Received: September 29, 2010

Arrival Date: September 28, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040 Consignee: Arizona State Prison Complex, Florence, AZ 85232

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

 Line ACS/FDA	Product Description	Quantity	Current Status	
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Notice Prepared For: The District Director, U.S. Food and Drug Administration

From: John Solomon [Solomon.John@doc.state.sc.us]

Sent: Monday, December 20, 2010 9:29 AM

To: Halpenny, Susan M **Cc:** David Tatarsky

Subject: Delay of Shipment

Good morning Šusan,

The FDA imposed delay is an increasing concern to us. Is there anyone who can give us a reasonable explanation for the FDA's decision to stop the shipment to South Carolina? For the FDA to stop the shipment and then refuse to communicate the reason for its decision is unconscionable. Your assistance with this matter is appreciated.

John

Copy to David Tatarsky - General Counsel for the Department of Corrections

John P. Solomon, Ph.D., MBA Director of Health Services South Carolina Department of Corrections 4444 Broad River Rd. Columbia, SC 29210 (Tele) 803-896-1995 (Fax) 803-896-1999 From: Halpenny, Susan M

Sent: Monday, December 20, 2010 10:25 AM

To: 'John Solomon' Cc: David Tatarsky

Subject: RE: Delay of Shipment

Good day,

I have not heard anything from our Director of Import Operations and Policy at this time. If you would like to follow up with him, our Director is Domenic Veneziano and his phone number is (301) 594-3849. You can also contact the office of our FDA commissioner, Margaret Hamburg at (301) 796-5000.

Susan M. Halpenny Supervisory Investigator FDA, New Orleans District, Imports Voice (901) 333-3521 Fax (901) 333-3576

From: John Solomon [mailto:Solomon.John@doc.state.sc.us]

Sent: Monday, December 20, 2010 9:29 AM

To: Halpenny, Susan M **Cc:** David Tatarsky

Subject: Delay of Shipment

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John

Copy to David Tatarsky – General Counsel for the Department of Corrections

John P. Solomon, Ph.D., MBA
Director of Health Services
South Carolina Department of Corrections
4444 Broad River Rd.
Columbia, SC 29210
(Tele) 803-896-1995
(Fax) 803-896-1999

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5 Notice Number: 1

January 7, 2011

Filer:

Arizona Customs Brokers

2153 East Jones Ave

Phoenix, AZ 85040

Attention:

Broker Box:

>

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: Arizona State Prison Complex, Florence, AZ 85232

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 Notice Number: 1

Entry Number: 574-0251126-5 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

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5 Notice Number: 1

January 7, 2011

Importer:

Arizona Department Of Correction 1601 W Jefferson St Phoenix, AZ 85007-3002

>

Port of Entry: 2605, Phoenix, AZ
Carrier: (b) (4)
Date Received: October 25, 2010
Arrival Date: October 26, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040

Consignee: Arizona State Prison Complex, Florence, AZ 85232

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

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@ = Consignee ID

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CORRESPONDENCE

Line ACS/FDA Product Description

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Entry Number: 574-0251126-5 Page: 2

San Pedro, CA 90731

LINES RELEASED

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

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5 Notice Number: 1

January 7, 2011

Consignee:

Arizona State Prison Complex 1305 Butte Ave Florence, AZ 85232

>

Port of Entry: 2605, Phoenix, AZ
Carrier: (b) (4)
Date Received: October 25, 2010
Arrival Date: October 26, 2010

Filer of Record: Arizona Customs Brokers, Phoenix, AZ 85040

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

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

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

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@ = Consignee ID

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CORRESPONDENCE

Line ACS/FDA Product Description

001/001 THIOPENTAL SODIUM, POWDER

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U.S. Food and Drug Administration
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Entry Number: 574-0251126-5 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



Food and Drug Administration New Orleans District Import Operations 959 Ridgeway Loop, Suite 100 Memphis, Tn. 38120

Telephone: (901) 333-3520

FAX: (901) 333-3579

January 7, 2011

UNITED PARCEL SERVICE Delivery Signature Requested

John P. Solomon, PhD, MBA
Director of Health Services
South Carolina Department of Corrections
Kirkland Correctional Institution-Pharmacy
4344 Broad River Road
Columbia, South Carolina 29210-4010

RE: Entry Number 112-673446-4

Dear Mr. Solomon:

This letter provides the status of Entry Number 112-9673446-4, consisting of (b) (4) vial packets, each vial containing 500 mg of Thiopental Sodium. FDA received documentation for this shipment and verified it is destined for a state correctional facility.

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.

Sincerely,

Patricia K. Schafer / Acting District Director

New Orleans District Office

Enclosure: FDA Notice of Action

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 Memphis 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. Jeffrey Timothy Landrigan, CR-90-0323 AP).
- 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 FA2203571.

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: Solis, 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

New Orleans District Office

Notice of FDA Action

Entry Number:

112-9938358-2

Notice Number:

2

January 6, 2011

Importer:

Port of Entry:

2095, FedEx - Memphis, Memphis, TN

Carrier:

(b) (4)

Arrival Date:

Date Received: November 24, 2010 November 19, 2010

Filer of Record:

FEDEX Trade Networks Transport and Brokerage, Memphis, TN 38125

Consignee:

(b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA		Product Description	Quantity	Current Status	
*	001/001	688760418962 THIOPENTAL	(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 112-9938358-2. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA

Product Description

001/001

688760418962 THIOPENTAL

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.

Randy N. Boling, Compliance Officer (Region/District)

U.S. Food and Drug Administration 959 Ridgeway Loop Road, Suite 100

Memphis, TN 38120-4042

(901) 333-3537 (901) 333-3579 (FAX) RANDY.BOLING@FDA.HHS.GOV

Notice of FDA Action

Entry Number: 112-9938358-2

Notice Number: 2

Page: 2

LINES RELEASED

Line ACS/FDA

Product Description

001/001

688760418962 THIOPENTAL

Randy N. Boling, Compliance Officer (Region/District)
U.S. Food and Drug Administration

(901) 333-3537 (901) 333-3579 (FAX) RANDY.BOLING@FDA.HHS.GOV

959 Ridgeway Loop Road, Suite 100

Memphis, TN 38120-4042

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

DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

Form Approved OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

FEDEX TRADE NETWORKS
TRANSPORT & BROKERAGE, INC.

AIR EXPRESS

TEL: (901) 752-3000

	ener:	19 CFR 142.3. 14	2.16, 142.22, 142.24		
1. ARRIVAL DA	ATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	_	4. ENTRY NUMBER
111910	0		01		112-9938358-2
5. PORT		6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE N	UMBER	l.
2095			(b) (4)		•
	·	B. CONSIGNEE NUMBER		i	9. IMPORTER NUMBER
		(b) (4)	100		(b) (4)
10. ULTIMATE	CONSIGNEE NAME		11. IMPORTER OF RECORD N	AME.	
	(b) (4)		(t	o) (4)	
12. CARRIER	CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CO	DE(S)/NAME(S)	
(b) (4)		(b) (4)	(b) (·	4)	
15. VESSEL C	ODE/NAME				
16. U.S. PORT	OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER		19. TOTAL VALUE
2095					15575
20. DESCRIPT	TION OF MERCHANDISE				
	ACEUTICALS NOT RE	ESTRICTED			
21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
	TOTAL	(0) (4)	3004.90.9190) GB	GBDREPHA176LON
M H	(b) (4)				
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	_				
	*		4		
	27. CERTIFICATION	ON		28. CUSTOMS US	E ONLY
informatio	make application for entry/immediate on is accurate, the bond is sufficient, ents of 19 CFR Part 142 have been r	valid, and current, and that all	OTHER AGENCY	action required,	NAMELY:
SIGNATURE	E OF APPLICANT (b) (6)				
PHONE NO		DATE	1		
(I	b) (4)	11/24/10	CUSTOMS EXAMI	NATION REQUIRED.	
	29. BROKER OR OTHER GOV		1		
			ENTRY REJECTE	D, BECAUSE:	
					*
			, I OLONIATI		- DATE
			DELIVERY AUTHORIZED:	JHE	DATE
					,
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					,
	•				
			1		

Paperwork Reduction Act Notice: This information is needed 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.

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: 2727INV

Address:

VAT no: Purchase Order: Date: 19-11-2010

Delivery Address:

Currency: USD - US Dollar

Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's	(b) (4)		14700
Batch No: AW6022 EXP: 05/14			

Statement Details

Goods Total: 14700.00 Subtotal: 15575.00 Discount (%): 0 VAT (World Zero): 0.00 Delivery: 875 Previous Balance: 0 Insurance: 0 Total: 15575.00 USD - US Dollar Payment Method: Prepayment Thank You

Shipping Details

Packing: (b) (4)	Gross Weight (Kg).(b) (4) Net Weight (Kg):(b) (4)
Tariff: 30049099	Carrier (b) (4)
Declarations: We certify that this invoice is true and correct.	Matt Alavi, for Dream Pharmatida R M
	Acton, London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

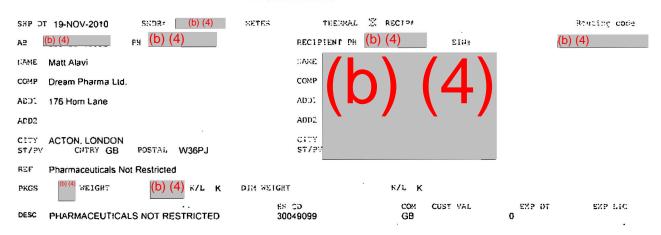
Damage, shortage or leakage must be notified in writing to ourselves within 3 days. Non-Delivery within 14 days. Goods remain the property of Dream Pharma Ltd. Until full payment has been received. Subject to our standard conditions of sale. E&OE

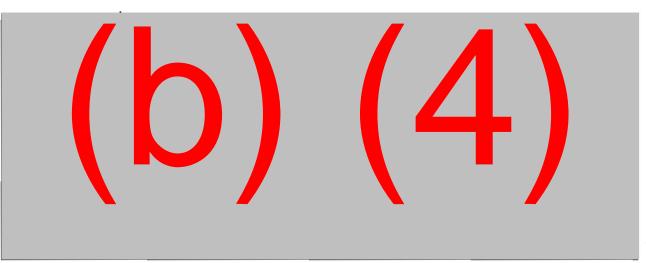
Company Registration Number: (b) (4) VAT No.

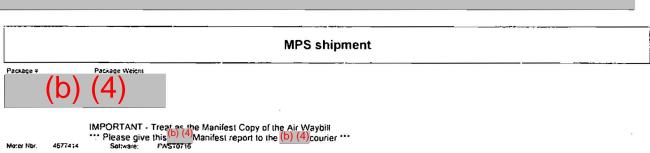
Director: M. Alavi

Page 1 of 1

Manifest report







46774;4

FDA_08.18.11_000137

ENT# 112-9938358-2 LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY NAME MATT ALAVI NAME COMP DREAM PHARMA LTD. COMP ADD1 176 HORN LANE ADD2 ADD2 CITY ACTON, LONDON CITY ST/PV ST/PV CNTRY GB POSTAL W36PJ WEIGHT COM CURR CARR VAL CUSTOMS VAL EX LIC HDLG UNITS (b) (4) GB USD 15575.00 DESC: PHARMACEUTICALS NOT RESTRICTED

(b) (4) T-859 P.001/001 v-22-2010 12:00pm From-F-698 Approved Prough 12/31/95, OMB NO isis-algi See back of form for Paperwork Reduction Act Notice. DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE 1. TYPE OF ACTION (mark all applicable) Monfication of mporters number Change of address IMPORTER ID Check here it you also want your address updated in the Fines, Penalties, and Forfatures Office Change of name* INPUT RECORD NOTE-It a constructed bond is on file, a bond order must accompany this change document FILL 2A OR 2B 19 CFR 24 5 2 IMPORTER NUMBER (Fill in one format). 2 B. Social Security Number 2A IR S Number Check here if requesting a Customs Assemed higher and indicate reason (a). [Check all that apply] I have not applied for either number. I am not a I have no Social Security No. I have no IRS No 2C. U.S. resident RETURN TO:. 2D, Customs-Assigned Number AWB REF #: n 5. DIVI AKAY DBA Name 4 DIV AKA DBA DBA U.S. Government Other Corporation Sole Proprietorship Partnership Individual

7	(b) (4)	ACCOL	JNT	
	13 (b) (4)	14 State Code (b) (4)	(b) (4)	
	(b) (4)			
17.	Hea importer ever been usughed a Customs Importer Number using the same name as in Bluck 3.7. 17	p Has unbottel eve peen sezighed a	Customs importer Number using a name	different from that in Block 37
7	Yes (List number(s) and or name(s) in Block 17 c-)	No	Yes (List number) and a name(s)	in Block (7 c.)

norter Mailina Address (2 12

(b) (4)

17 c. If Yes to 17a and/or 17 b, is immine(s) and/or name(s)
NOTE: If the namer or altimate consignee is a corporation this form must be signed by the president, vice president, secretary, or treasurer of the corporation, or by any employee or any agent of the corporation who holds a power of attorney and a certificate by the curporation that such employee or agent has or will have knowledge of the pertinent facts.

ICERTIFY: That the information presented herein is corporation that if my Social Security Number is used it is because I have no IRS Employer Number is used it is because I have no IRS Employer Number is used it is because I have no including a social Security Number in or an IRS Employer Number, and my signature constitutes a request to assignment of a number by Customs.

20

21 Date

11 - 22 - 201 D

22 Broker Use Only

FDA_08.18.11_000139

CUSTOMS FORM 5106 (012293)

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			Park Park	





Arkansas Department of Correction

Wendy Kelley
Deputy Director of Health &
Correctional Programs
P.O. Box 8707
Pine Bluff, Arkansas 71611-8707
Phone: (870) 267-6361
Fax: (870) 267-6363
WENDY KELLEY @ARKANSAS.GOV

FAX COVER SHEET

SEND TO: Gaguelyn FROM: Wendy Kelleyn FAX#: 901.333.3579 DATE: 9.27.10

TOTAL PGS (INCLUDING COVER): 3

Comments:

PLEASE NOTE: This facsimile and any attachments is the property of the State of Arkansas and may be protected by state and federal laws governing disclosure of private information. It is for the Intended recipient only. If an addressing or transmission error has misdirected this facsimile, please notify the sender. If you are not the intended recipient you may not use, disclose, distribute, copy, print or rely on this facsimile. You are notified that the document(s) provided may contain health information that is legally privileged, confidential and protected by law from disclosure. Copying or distributing this information except as required for the direct care and treatment of the designated patient, without the express authorization of the Arkansas Department of Correction, Office of the Administrator of Mental Health or Medical Services, is prohibited.



Arkansas Department of Correction

Wendy Kelley
Deputy Director of Health &
Correctional Programs
P.O. Box 8707
Pine Bluff, Arkansas 71611-8707
Phone: (870) 267-6361
Fax: (870) 267-6363
WENDY.L.KELLEY@ARKANSAS.GOV

September 10, 2010

Dream Pharma Ltd. ATTN: Matt Alavi 176 Horn Lane Action, London W3 6PJ

SUBJECT: Thiopental Injection Purchase

Dear Mr. Alavi,

The Arkansas Department of Corrections (GDC) uses Thiopental Injection to carry out Capital Punishment in Arkansas. In accordance Arkansas State Law, A.C.A. § 5-4-617, "The sentence of death is to be carried out by intravenous lethal injection of one (1) or more chemicals, as determined in kind and amount in the discretion of the Director of the Department of Correction. The chemical or chemicals injected may include one (1) or more of the following substances: one (1) or more ultra-short-acting barbiturate, one (1) or more chemical paralytic agents, potassium chloride, or any other chemical or chemicals, including but not limited to saline solution." The Director of the Arkansas Department of Correction by Administrative Directive has ordered that sodium pentothal or Thiopental sodium be used for the first chemical.

The Arkansas Department of Correction placed an order earlier this year with a manufacturer in the United States, but has been advised that they have none in stock, nor is any expected this year. In order to carry out the State of Arkansas' constitutional mandates in death penalty cases, we desire to make the following purchase:

Name/Description Quantity	Quantity	Price (ea)	Total
Thiopental Injection, power for reconstitution, thiopental sodium, 500mg vial packs of 25's	(b) (4)	(b) (4) GBP	590.25 GBP

Shipping Location:

Arkansas Department of Correction Central Administration Office ATTN: Wendy Kelley, Deputy Director 6814 Princeton Pike Pine Bluff, AR 71602-9411 Telephone: 870-550-7307

United States Drug Enforcement Agency Number (DEA): FA1835199

Our Federal Express account is (b) (4)

I understand the expiration date of the chemical currently available is February 2014. I can be reached by telephone at 001-870-550-7307 or by e-mail: wendy.kelley@arkansas.gov

Sincerely,

Wendy L. Kelley,

Deputy Director for Health & Correctional Programs

Arkansas Department of Corrections

Trepagnier, Timothy

From: Thomas, David

Sent: Monday, September 27, 2010 2:08 PM

To: Schafer, Patricia; Halpenny, Susan M; Dixon, Ruth P; Boling, Randy N

Cc: Strickland, Evanguel; Solis, Daniel; 'cflanag@azcorrections.gov'; 'michael.dean@dhs.gov'

Subject: RE: Lethal Injection Pharmacology

Patricia:

Correspondence received, thank you. I will email your staffing the Entry number once transmitted.

Respectfully,

David Thomas, DCM FDA Investigations Phoenix, Office

From: Schafer, Patricia

Sent: Monday, September 27, 2010 10:02 AM

To: Thomas, David; Halpenny, Susan M; Dixon, Ruth P; Boling, Randy N

Cc: Strickland, Evanguel; Solis, Daniel; 'cflanag@azcorrections.gov'; 'michael.dean@dhs.gov'

Subject: Re: Lethal Injection Pharmacology

Susan, Ruth and Randy-- please read this email.

David Thomas- thank you for your email. I will be out of the office for about 2.5 weeks. Please keep my staff aware of this shipment and others.

Thanks, Patt Schafer Patricia Schafer,

Director, Compliance Branch and Import Operations

New Orleans District Office

From: Thomas, David To: Schafer, Patricia

Cc: Strickland, Evanguel; Solis, Daniel; 'CHARLES FLANAGAN' <cflanag@azcorrections.gov>; 'DEAN, MICHAEL K'

<michael.dean@dhs.gov>

Sent: Mon Sep 27 12:03:04 2010 Subject: Lethal Injection Pharmacology

Ms. Schafer:

FDA Supervisor SCSO:

Memphis, TN

RE: Lethal Injection Pharmacology arrival

These drugs will be coming in on a (b) (4) flight from U.K. tomorrow, with destination Port of Entry Phoenix, 2605. At this writing, the Entry has not been made by filer 575, Arizona Customs Brokerage, 602-273-0912. I will advise you of the Entry number once it has been transmitted ABI.

<u>Please do not detain this entry</u>. The product is scheduled for immediate delivery to Arizona Corrections Department upon arrival and examination at Phoenix, Port of Entry, 2605.

Should you have any questions, please notify me immediately at the contact information below.

Respectfully,

David Thomas, DCM FDA Investigations Phoenix, Office 480-829-7396 x 12

-----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 Memphis 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

<<Thomas, David - FDA Investigations (London Shipment) 2010-09-24.pdf>> <<DOC092310_1.pdf>> <<DEA Registration.pdf>>

Trepagnier, Timothy

From: Schafer, Patricia

Sent: Monday, September 27, 2010 12:02 PM

To: Thomas, David; Halpenny, Susan M; Dixon, Ruth P; Boling, Randy N

Cc: Strickland, Evanguel; Solis, Daniel; 'cflanag@azcorrections.gov'; 'michael.dean@dhs.gov'

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Thanks, Patt Schafer Patricia Schafer,

Director, Compliance Branch and Import Operations New Orleans District Office

From: Thomas, David To: Schafer, Patricia

Cc: Strickland, Evanguel; Solis, Daniel; 'CHARLES FLANAGAN' <cflanag@azcorrections.gov>; 'DEAN, MICHAEL K'

<michael.dean@dhs.gov>

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Ms. Schafer:

FDA Supervisor SCSO:

Memphis, TN

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David Thomas, DCM FDA Investigations Phoenix, Office

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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

<<Thomas, David - FDA Investigations (London Shipment) 2010-09-24.pdf>> <<DOC092310_1.pdf>> <<DEA Registration.pdf>>