

## 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,

A handwritten signature in black ink, appearing to read "Ben T Rice", written over a horizontal line.

BENJAMIN T. RICE  
General Counsel

cc: John McAuliffe

**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

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**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](mailto:Ruth.Dixon@FDA.HHS.gov)

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

**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 Chemique Pharmaceuticals, Inc. 13306 East Whittier Boulevard, Whittier, CA. 90602-3200 by FED-EX. (Barbara Taffy is the FED-EX 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

**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,

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Scott Kernan  
Undersecretary  
California Department of Corrections  
And Rehabilitation

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**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](mailto:Ruth.Dixon@FDA.HHS.gov)

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

**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

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**From:** McAuliffe, John@CDCR  
**Sent:** Thursday, December 09, 2010 12:10 PM  
**To:** McCleave, Kelly@CDCR  
**Subject:** FW: Letter to Ms. Dixon

FYI

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**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.

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Sincerely,

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Undersecretary  
California Department of Corrections  
And Rehabilitation

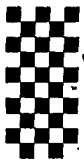
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**From:** Gaddi, Kathy@CDCR  
**Sent:** Thursday, December 09, 2010 11:58 AM  
**To:** Kernan, Scott@CDCR  
**Subject:** Letter to Ms. Dixon

[Ruth.Dixon@FDA.HHS.gov](mailto:Ruth.Dixon@FDA.HHS.gov)

*Kathy Gaddi*  
*Executive Assistant to Scott Kernan*

*Undersecretary, Operations*  
*(916) 341-7015*



#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**

# Fax

Faxed  
8/10/10  
JR 2:28 P.M.

To:

(b) (6)

From:

C. SMITH

Fax:

701.333.3577

Pages:

3 (INCLUDING COVER PAGE)

Phone:

Date:

TRBLICW6 # 688760417429

Re:

ENTRY # 112-7818637-8

CC:

☐ Urgent☐ For Review☐ Please Comment☐ Please 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

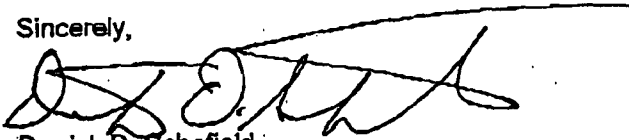
**Shipping Location:**

**Wilson's Pharmacy**  
**1142 Main Street**  
**Forest Park, GA 30297**  
**Phone: 404.366.4271**  
**US DEA Number AW3495961**

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.

Sincerely,



Derrick D. Schofield,  
Assistant Commissioner, Chief of Staff  
Georgia Department of Corrections

## 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:

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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) 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 (b) (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,

A handwritten signature in black ink, appearing to read "Ben T Rice", is written over a horizontal line.

BENJAMIN T. RICE  
General Counsel

cc: John McAuliffe

**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  
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Thank you,

*Christopher Boulmay*  
Consumer Safety Officer  
US Food & Drug Administration  
NOL-DO: Memphis R.P.  
**Phone:** (901) 333-3528  
**Fax:** (901) 333-3577

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John McAuliffe  
California Department of Corrections and Rehabilitation

**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. Dixon*

Supervisory Investigator  
New Orleans District  
Import Operations

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Undersecretary  
California Department of Corrections  
And Rehabilitation

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**Subject:** Letter to Ms. Dixon

[Ruth.Dixon@FDA.HHS.gov](mailto:Ruth.Dixon@FDA.HHS.gov)

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

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**Subject:** FW: Letter to Ms. Dixon

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New Orleans District  
Import Operations

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Sincerely,

Scott Kernan  
Undersecretary  
California Department of Corrections  
And Rehabilitation

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**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:** 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

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**From:** McAuliffe, John@CDCR  
**Sent:** Thursday, December 09, 2010 12:10 PM  
**To:** McCleese, Kelly@CDCR  
**Subject:** FW: Letter to Ms. Dixon

FYI

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**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

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Sincerely,

Scott Kernan  
Undersecretary  
California Department of Corrections  
And Rehabilitation

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**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](mailto:Ruth.Dixon@FDA.HHS.gov)

*Kathy Gaddi*  
*Executive Assistant to Scott Kernan*

*Undersecretary, Operations*  
*(916) 341-7015*

**Trepagnier, Timothy**

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**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  
**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 being transmitted. Also we would be able to track the shipment thru Federal Express. I appreciate any information you can provide. Thanks in advance.

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

-----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: 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.

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

**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-----

**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  
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information related to this shipment.

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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: Budweg, Greta L  
Subject: FW: Lethal Injection Pharmacology  
Importance: High

Dave Thomas  
FDA Imports  
Phoenix, AZ

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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](mailto:cflanag@azcorrections.gov)



JANICE K. BREWER  
GOVERNOR

# Arizona Department of Corrections

1601 WEST JEFFERSON  
PHOENIX, ARIZONA 85007  
(602) 542-5497  
[www.azcorrections.gov](http://www.azcorrections.gov)



CHARLES L. RYAN  
DIRECTOR

September 24 2010

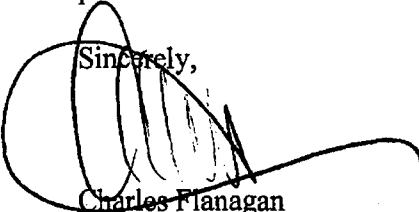
David Thomas, DCM  
FDA Investigations  
Food and Drug Administration  
Division of Import Operations and Policy  
4605 East Elwood Street, Suite 402  
Phoenix, Arizona 85040-1948

Dear Mr. Thomas:

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

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

Sincerely,

  
Charles Flanagan  
Deputy Director

cc: File

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



JANICE K. BREWER  
GOVERNOR

# Arizona Department of Corrections

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



CHARLES L. RYAN  
DIRECTOR

September 24, 2010

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

Re: Execution by Lethal Injection of Arizona Inmate  
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



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA2203571	06-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232-0000		

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

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.**

Form DEA-223 (4/07)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FA2203571	06-30-2013	FEE EXEMPT
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010
ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232-0000		

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<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">DEA REGISTRATION NUMBER</th> <th style="text-align: left;">THIS REGISTRATION EXPIRES</th> <th style="text-align: left;">FEE PAID</th> </tr> <tr> <td>FA2203571</td> <td>06-30-2013</td> <td>FEE EXEMPT</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="text-align: left;">SCHEDULES</th> <th style="text-align: left;">BUSINESS ACTIVITY</th> <th style="text-align: left;">ISSUE DATE</th> </tr> <tr> <td>3.3N.4.5.</td> <td>HOSPITAL/CLINIC</td> <td>08-25-2010</td> </tr> </table> <p>ARIZONA STATE PRISON - FLORENCE, CARSON WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232-0000</p>	DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID	FA2203571	06-30-2013	FEE EXEMPT	SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE	3.3N.4.5.	HOSPITAL/CLINIC	08-25-2010	<div style="text-align: center;"> <p><b>CONTROLLED SUBSTANCE/REGULATED CHEMICAL REGISTRATION CERTIFICATE</b></p> <p>UNITED STATES DEPARTMENT OF JUSTICE DRUG ENFORCEMENT ADMINISTRATION WASHINGTON D.C. 20537</p> </div> <p>This registration is only for use at Federal or State Institutions.</p> <p>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.</p> <p><b>THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.</b></p>
DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID											
FA2203571	06-30-2013	FEE EXEMPT											
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE											
3.3N.4.5.	HOSPITAL/CLINIC	08-25-2010											

<div style="display: flex; align-items: center;"> <div style="writing-mode: vertical-rl; transform: rotate(180deg); font-size: small; padding: 5px;">Form DEA-223/511 (4/07)</div> <div style="text-align: center; flex-grow: 1;"> <p><b>REPORT CHANGES PROMPTLY</b></p> </div> </div>	<div style="text-align: center;"> <p><b>REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE</b></p> </div> <p>To request a change to your registered name, address, the drug schedule or the drug codes you handle, please</p> <ol style="list-style-type: none"> <li>1. visit our web site at <a href="http://deaddiversion.usdoj.gov">deaddiversion.usdoj.gov</a> - or</li> <li>2. call our customer Service Center at 1-(800) 882-8539 - or</li> <li>3. submit your change(s) in writing to:</li> </ol> <div style="text-align: center;"> <p><b>Drug Enforcement Administration</b> P.O. Box 28083 Washington, DC 20083</p> </div> <p>See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

----- 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

# Fax

**To:** Matt Alavi **From:** Karen Ingram, Contracts Manager

**Company/  
Institution:** Dream Pharma, LTd  
176 Horn Lane  
Acton, London W3 6PJ

**Pages:** 1

**Fax:** 44 208-992-7001 **Date:** 9/23/10

**Phone:** 44-208-992-7000 **Re:** Urgent Order USA

☐ **Urgent** ☐ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

● **Comments:** THIS ORDER MUST BE RECEIVED BY THE DEPARTMENT NO LATER THAN OCTOBER 1, 2010.

Based on previous conversations between the Arizona Department of Corrections, we are placing the following order:

1. **THIOPENTAL INJECTION** (powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's)  
Item Cost: (b) (4) (pounds Sterling)  
Quantity: (b) (4)
2. **PANCURONIUM INJECTION** (pancuronium bromide 2 mg/ml, 2-ml amp)  
Item Cost: Awaiting cost from Vendor – please confirm the price once obtained  
Quantity: (b) (4)
3. **POTASSIUM CHLORIDE** (1.5gm, 10ml, injection packs of 10)  
Item Cost: (b) (4)  
Quantity: (b) (4)

Payment for this order will be by credit card, to be provided via telephone. Please contact me for additional information.

*Karen Ingram*  
p: 602-364-3791



<b>DEA REGISTRATION</b> NUMBER		<b>THIS REGISTRATION</b> EXPIRES		<b>FEE</b> PAID
<b>FA2203571</b>		<b>06-30-2013</b>		<b>Exempt</b>
<b>SCHEDULES</b>	<b>BUSINESS ACTIVITY</b>	<b>DATE ISSUED</b>		
<b>2,2N,3 3N,4,5</b>	<b>HOSPITAL/CLINIC</b>	<b>08-25-2010</b>		
<b>ARIZONA STATE PRISON - FLORENCE, CARSON A., WARDEN 1305 BUTTE AVE. P.O. BOX 629 FLORENCE, AZ 85232 0000</b>				

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

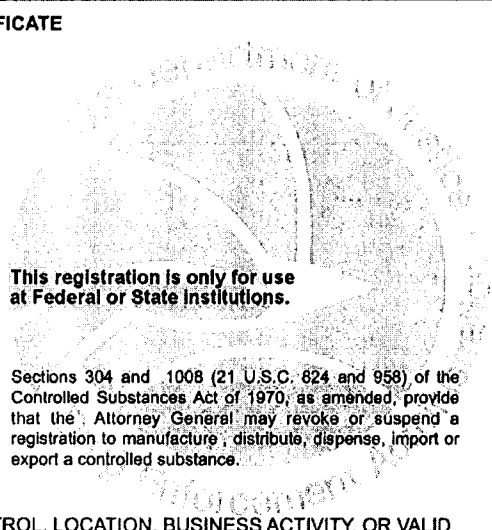
**This registration is only for use at Federal or State Institutions.**

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<b>FA2203571</b>		<b>06-30-2013</b>		<b>Exempt</b>
<b>SCHEDULES</b>	<b>BUSINESS ACTIVITY</b>	<b>DATE ISSUED</b>		
<b>2,2N,3 3N,4,5</b>	<b>HOSPITAL/CLINIC</b>	<b>08-25-2010</b>		
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Form DEA-223 (05/04)



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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,

*Patricia K. Schafer*  
Patricia K. Schafer  
Acting District Director  
New Orleans District Office

# 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:

(b) (4)

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

112-7818637-8

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

Consignee:

(b) (4)

>

<

Port of Entry: (b) (4) — 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

Importer of Record: (b) (4)

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

Hi Michael,

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

LEX  
completed  
7-1-2010

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.*

Detained  
Rsa  
7-15-2010

✓

DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEForm Approved  
OMB No. 1515-0069

## ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL:

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

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE 062810	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 11	4. ENTRY NUMBER 112-7818637-8
5. PORT 2095	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER NAME/ADDRESS		9. IMPORTER NUMBER (b) (4)
10. ULTIMATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS-CODE(SYN/NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE (b) (4)
20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS NOT RESTRICTED			
21. HTS/LAWB CODE	22. HTS/LAWB NO. TOTAL	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER (b) (4)
M	02358388481		25. COUNTRY OF ORIGIN GB
H	688760417429		26. MANUFACTURER ID GBDREPHAL76LON

## 27. CERTIFICATION

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.

SIGNATURE OF APPLICANT

(b) (6)

PHONE NO.

(b) (4)

DATE

06/28/10

28. BROKER OR OTHER GOVT. AGENCY USE

## 28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:☐ CUSTOMS EXAMINATION REQUIRED.☐ ENTRY REJECTED, BECAUSE:DELIVERY  
AUTHORIZED:

SIGNATURE

DATE

FEES

DRLS

→ Compounding

LEX - for pharm  
Compding  
only?

NO Det 7/15

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

(b) (4)

Released 8/12/10

Customs Form 3461 (010189)



# 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.

Date: 24-06-2010

Address:

(b) (4)

Delivery Address:

(b) (4)

VAT no:

Purchase Order:

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS

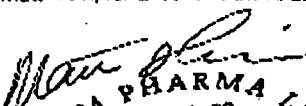
## Order Details

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)		
Admin fee for orders below £250			

## Statement Details

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

## Shipping Details

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

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

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

Director: M. Alavi

ENTRY NUMBER: 112 7818637 8

AWB/BL NBR : (b) (4)

INVOICE #  
LINE CONSOL. WORKSHEET

PAGE: 1

06/28/2010

07:49 PM

ITEMS MARKED 1 C/O- GB

TARIFF # (b) (4)

QTY 1: KG  
(b) (4)

LINE VALUE- GBP

(b) (4)

\*\* 1

\*\*

\*\*\*\*

\*\*\* END OF REPORT \*\*\*

ENTRY NUMBER: 112 7818637 8

AWB/BL NBR : (b) (4)

INVOICE #

SHIPPER : DREAM PHARMA LTD

ITEM MARKED REFERENCE

PAGE: 1

06/28/2010

07:49 PM

INVOICE ITEM  
LINE# MARK

TARIFF  
NUMBER

COUNTRY  
OF ORIG.

RATE OF DUTY

VALUE-GBP

1

1

(b) (4)

GB

Q:

(b) (4) KG

(b) (4)

\*\*\* END OF REPORT \*\*\*

(b) (4) Manifest report

SHP DT 28-JUN-2010 SNDR# (b) (4) METER THERMAL ☒ RECIPI 280722820  
(b) (4)

NAME Matt Alavi  
COMP Dream Pharma Ltd.  
ADD1 178 Horn Lane  
ADD2  
CITY ACTON, LONDON  
ST/PV CNTRY GB POSTAL W38PJ

NAME  
COMP  
ADD1  
ADD2  
CITY  
ST/PV

(b) (4)

REF Pharmaceuticals Not Restricted

PKGS (b) (4) WEIGHT (b) (4) K/L K DIM WEIGHT

1 K/L K

DESC PHARMACEUTICALS NOT RESTRICTED

HS CD  
(b) (4)

COM CUST VAL  
GB

EXP DT EXP LTC  
0

(b) (4)

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-7818637-8

(b) (4)

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

NAME ATT: ALAN A. ADAMS  
COMP WILSONS PHARMACY  
ADD1 1142 MAIN STREET  
ADD2 FOREST PARK  
CITY FOREST PARK  
ST/PV GA CENTRY US POSTAL 30297

(b) (4)

PKGS K/L  
K

WEIGHT COM CURR  
(b) (4) GB UKL

CARR VAL CUSTOMS VAL EX LIC HDLG UNITS  
(b) (4)

DESC: PHARMACEUTICALS NOT RESTRICTED

# United States Food and Drug Administration

New Orleans District Office

## Notice of FDA Action

Entry Number: 112-8992979-0

Notice Number: 2

September 28, 2010

Importer:

(b) (4)

>

<

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

FD&CA Section 505(a), 801(a)(3); UNAPPROVED NEW DRUG

The article appears to be a new drug without an approved new drug application. Unapproved drug w/o written

112-8992979-0

TABS:

DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEForm Approved  
OMB No. 1515-0069

## ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL:

(b) (4)

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE 091710	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 11	4. ENTRY NUMBER 112-8992979-0
5. PORT 2095	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER NAME/ADDRESS	9. IMPORTER NUMBER (b) (4)	
10. ULTIMATE CONSIGNEE NAME ARKANSAS DEPARTMENT OF C  6814 PRINCETON PIKE PINE BLUFF AR		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS CODE(S)/NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.I. NUMBER	19. TOTAL VALUE (b) (4)
20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS/THIOPENTAL			
21. IT/BLAWB CODE	22. IT/BLAWB NO. TOTAL	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER (b) (4)
M	02358486234		25. COUNTRY OF ORIGIN GB
H	688760418241		26. MANUFACTURER ID. GBDREPHA176LON

## 27. CERTIFICATION

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.

SIGNATURE OF APPLICANT

(b) (6)

PHONE NO.

(b) (4)

DATE

09/20/10

28. BROKER OR OTHER GOVT. AGENCY USE

## 28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:

SIGNATURE

DATE

DTE - AAP/REG

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.

09/20/10 17:50:54 (b) (4)

Customs Form 3461 (010189)

**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

Date: 17-09-2010

**Address:**

Arkansas Department of Correction  
Central Administration Office  
6814 Princeton Pike  
Pine Bluff, AR 71602-9411  
Fedex: 4512-1458-6  
Tel: 870-550 - 7307

**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

VAT no:

Purchase Order:

**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)		590.25

**Statement Details**

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

**Shipping Details**

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

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

Company Registration Number: (b) (4) VAT No: (b) (4)  
Director: M. Alavi



ENTRY NUMBER: 112 8992979 0

AWB/BL NBR : (b) (4)

INVOICE #

LINE CONSOL. WORKSHEET

PAGE: 1

09/20/2010

05:55 PM

ITEMS MARKED 1 C/O- GB

TARIFF # (b) (4)

QTY 1: KG

(b) (4)

LINE VALUE- GBP

590.25

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590.25

\*\*\*\*

590.25

\*\*\* END OF REPORT \*\*\*

ENTRY NUMBER: 112 8992979 0

AWB/BL NBR : (b) (4) INVOICE #

SHIPPER : DREAM PHARMA LTD

ITEM MARKED REFERENCE

PAGE: 1

09/20/2010

05:55 PM

INVOICE ITEM  
LINE# MARK

TARIFF  
NUMBER

COUNTRY  
OF ORIG.

RATE OF DUTY

VALUE-GBP

1

1

(b) (4) GB

Q:

(b) (4) KG  
590.25

\*\*\* END OF REPORT \*\*\*



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

**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?

010 mfg info  
Archimedes

A11 (b) (7)(C)

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

## Thiopental injection

(b) (4)

### 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 Therapeutic Indications

1. Thiopental is used for the induction of general anaesthesia and is also used as an adjunct to provide hypnosis during balanced anaesthesia with other anaesthetic agents, including analgesics and muscle relaxants.
2. Thiopental is also used as an adjunct 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 controlled ventilation is provided.

#### 4.2 Posology and method 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.

**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 (8mls to 12mls 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**

Intermittant 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 toxemia, 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, toxemia, 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

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 prilocaline 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 intracranial 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 thrombophlebitis.

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.

## 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 ganglia 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 Preclinical 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 Shelf 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 upright position and use within 7 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 Pharmaceuticals Limited, Bishops Weald House, Abblon Way, Horsham, West Sussex RH12 1AH, UK

**8. MARKETING AUTHORISATION NUMBER(S)**

PL 12406/0014

**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

(b) (4) Manifest report

SEP DT 17-SEP-2010

SIGN# (b) (4)

METER

THERMAL IS RECIP# (b) (4)

Serial by code

(b) (4)

(b) (4)

NAME Matt Alavi

NAME Att: Wendy Kelly, Deputy Director

COMP Dream Pharma Ltd.

COMP Arkansas Department of Correction

ADD1 176 Horn Lane

ADD1 Central Administration Office

ADD2

ADD2 6814 Princeton Pike

CITY ACTON, LONDON

CITY PINE BLUFF

ST/PR CTRY GB POSTAL W36PJ

ST/PR AR CTRY US POSTAL 71602

REF Pharmaceuticals Not Restricted

PAGE (b) (4) WEIGHT

(b) (4)

N/L K

DEM WEIGHT

(b) (4)

(b) (4)

(b) (4)

LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY ENT# 112-8992979-0  
FLT/TRK FX001 FTDT 17SEP10 BCH MTR CLC CHKR AB OF  
ROUTE FX001 DOC/NC N CO CONT BAG

(b) (4)

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

(b) (4)

(b) (4)

RECIPIENT PH (870)550-7307  
NAME ATT: WENDY KELLY, DEPUTY DIRECTO  
COMP ARKANSAS DEPARTMENT OF CORRECTIO  
ADD1 CENTRAL ADMINISTRATION OFFICE  
ADD2 6814 PRINCETON PIKE  
CITY PINE BLUFF  
ST/PV AR CNTRY US POSTAL 71602

(b) (4)

(b) (4)

PKGS K/L

(b) (4) K

WEIGHT COM CURR

(b) (4)

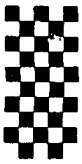
GB UKL

CARR VAL CUSTOMS VAL EX LIC HDLG UNITS

(b) (4)

DESC: PHARMACEUTICALS NOT RESTRICTED





09-27-10:15:32 ;

(b) (4)

# i/ 3



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: *Jaquelyn  
Bradford*

FROM: *Wendy Kelley*

FAX #: *901.333.3579* DATE: *9.27.10*

TOTAL PGS (INCLUDING COVER): *3*

Comments:

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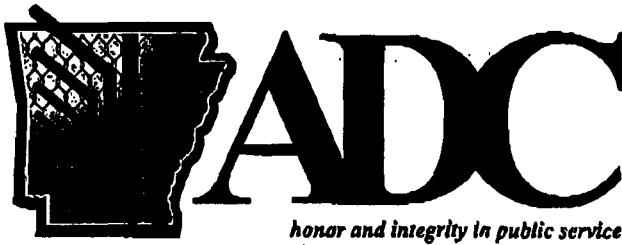
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PLEASE NOTE: This facsimile and any attachments is the property of the State of Arkansas and may be protected by state and federal laws governing disclosure of private information. It is for the intended recipient only. If an addressing or transmission 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**

**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  
**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 being transmitted. Also we would be able to track the shipment thru Federal Express. I appreciate any information you can provide. Thanks in advance.

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

-----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: 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.

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



DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEForm Approved  
OMB No. 1515-0069

## ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL :

(b) (4)

19 CFR 142.3, 142.10, 142.22, 142.24

1. ARRIVAL DATE 100610	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 11	4. ENTRY NUMBER 112-9247186-3
5. PORT 2095	6. SINGLE TRANS BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
8. CONSIGNEE NUMBER NAME/ADDRESS (b) (4)		9. IMPORTER NUMBER (b) (4)	
10. IMMEDIATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS CODE(S) NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE (b) (4)
20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS NOT RESTRICTED			
21. ITB/LAWB CODE M H	22. ITB/LAWB NO. TOTAL 02358508380 688760418425	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER (b) (4)
			25. COUNTRY OF ORIGIN GB
			26. MANUFACTURER ID GBDREPHA176LON

## 27. CERTIFICATION

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.

SIGNATURE OF APPLICANT

(b) (6)

PHONE NO.

(b) (4)

DATE

10/07/10

28. BROKER OR OTHER GOVT. AGENCY USE

## 28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:
DELIVERY  
AUTHORIZED:

SIGNATURE

DATE

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.

10/07/10 15:12:49

(b) (4)

Customs Form 3481 (010189)

**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

Address:

**(b) (4)**

Delivery Address:

**(b) (4)**

VAT no:

Purchase Order:

Currency: GBP - Pounds sterling

Heading: PHARMACEUTICALS NOT RESTRICTED

**Order Details**

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AW6022 EXP: 05/14	(b) (4)	(b) (4)	(b) (4)
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: one box	Gross Weight (Kg): (b) (4)
Tariff: (b) (4)	Net Weight (Kg): (b) (4)
Declarations: We certify that this invoice is true and correct.	Carrier: (b) (4)
	Matt Alavi, for Dream Pharma Ltd. 176 Horn Lane Acton, London W3 6PJ Tel: 020-8992-7000 Fax: 020-8992-7001

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

Company Registration Number: (b) (4) VAT No. (b) (4)  
Director: M. Alavi

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 #

(b) (4)

QTY 1: KG

(b) (4)

\*\*

LINE VALUE- GBP

(b) (4)

\*\*

\*\*\*\*\*

\*\*\* END OF REPORT \*\*\*

ENTRY NUMBER: 112 9247186 3

AWB/BL NBR : (b) (4) INVOICE #

SHIPPER : DREAM PHARMA LTD

ITEM MARKED REFERENCE

PAGE: 1

10/07/2010

05:38 PM

INVOICE LINE#	ITEM MARK	TARIFF NUMBER	COUNTRY OF ORIG.	RATE OF DUTY
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VALUE-GBP

1	1	(b) (4)	GB	
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Q:

(b) (4)

\*\*\* END OF REPORT \*\*\*

(b) (4) Manifest report

SUP DT 06-OCT-2010    ADDR (b) (4)    ENTER    THERMAL ST RECP (b) (4)    Loading cont  
AD (b) (4)    DE (b) (4)    RECP:ENT AS (b) (4)    LTR (b) (4)  
NAME Mall Alavi    NAME (b) (4) (4)  
COMP Dream Pharma Ltd.    COMP (b) (4) (4)  
ADDR 176 Horn Lane    ADDR (b) (4) (4)  
ADDR (b) (4) (4)  
CITY ACTON, LONDON    CITY (b) (4) (4)  
ST/RY GORE GB    POSTAL W38PJ    ST/RY (b) (4) (4)  
REF Pharmaceuticals Not Restricted  
PKGS (b) (4) WEIGHT (b) (4) R/L K    STX WEIGHT (b) (4) R/L K  
DESC PHARMACEUTICALS NOT RESTRICTED    HS CD 30049000    ORY GB    CURT VAL 0    EXP DT    EXP DTG

(b) (4) (4)

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-9247186-3

(b) (4)

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

NAME  
COMP  
ADD1  
ADD2  
CITY  
ST/PV

(b) (4)

(b) (4)

PKGS K/L  
(b) (4) K

WEIGHT COM CURR  
(b) (4) GB UKL

CARR VAL CUSTOMS VAL EX LIC HDLG UNITS  
(b) (4)

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: 2

January 6, 2011

**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  
(Region/District)

(901) 333-3520  
(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)  
U.S. Food and Drug Administration  
959 Ridgeway Loop Road, Suite 100  
Memphis, TN 38120-4042

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



TABS:

DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEForm Approved  
OMB No. 1515-0069

## ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL:

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

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE 110510	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 11	4. ENTRY NUMBER 112-9673446-4
5. PORT 2095	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER NAME/ADDRESS		9. IMPORTER NUMBER (b) (4)
10. ULTIMATE CONSIGNEE NAME KIRKLAND CORRECTIONAL IN 4344 BROAD RIVER RD COLUMBIA SC		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS-CODE(S)/NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE 1034
20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS NOT RESTRICTED			
21. IT/BLAWB CODE	22. IT/BLAWB NO. TOTAL	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER (b) (4)
M	02358543833		25. COUNTRY OF ORIGIN GB
H	688760418804		26. MANUFACTURER ID. GBDREPHA176LON

## 27. CERTIFICATION

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.

SIGNATURE OF APPLICANT

(b) (6)

PHONE NO.

(b) (4)

DATE

11/05/10

29. BROKER OR OTHER GOVT. AGENCY USE

## 28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:
DELIVERY  
AUTHORIZED:

SIGNATURE

DATE

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.

11/05/10 20:15:51 (b) (4)

Customs Form 3461 (010189)

# 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: 2718INV

Date: 05-11-2010

### Address:

South Carolina Department of Corrections  
Kirkland Correctional Institution- Pharmacy  
4344 Broad River Road  
Columbia, South Carolina 29210  
United States

Tel: 803 - 896-1995

### 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

VAT no:

Purchase Order:

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 Batch No: AW6022 EXP: 05/14	(b) (4)		1033.5

## Statement Details

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%)(b) (4)	VAT (World Zero):(b) (4)
Delivery (b) (4)	Previous Balance (b) (4)
Insurance: (b) (4)	Total: (b) (4) USD - US Dollar
	Payment Method: Prepayment Thank You

## Shipping Details

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

176 Horn Lane  
Acton, London W3 6PJ  
Tel: 020-8992-7000  
Fax: 020-8992-7001

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

Company Registration Number: (b) (4) VAT No: (b) (4)  
Director: M. Alavi

ENTRY NUMBER: 112 9673446 4

AWB/BL NBR : (b) (4)

INVOICE #

LINE CONSOL. WORKSHEET

PAGE: 1

11/05/2010

08:19 PM

ITEMS MARKED

1 C/O- GB

TARIFF #

(b) (4)

QTY 1: KG

(b) (4)

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LINE VALUE- USD

1,033.50

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1,033.50

\*\*\*\*

1,033.50

\*\*\* END OF REPORT \*\*\*

ENTRY NUMBER: 112 9673446 4

AWB/BL NBR : (b) (4) INVOICE #

SHIPPER : DREAM PHARMA LTD

PAGE: 1

11/05/2010

08:19 PM

ITEM MARKED REFERENCE

INVOICE LINE#	ITEM MARK	TARIFF NUMBER	COUNTRY OF ORIG.	RATE OF DUTY
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VALUE-USD

1	1	(b) (4)	GB	
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Q:

(b) (4) KG  
1,033.50

\*\*\* END OF REPORT \*\*\*

(b) (4) Manifest report

SAP DT 05-NOV-2010	SACF# (b) (4)	METER	INTERNAL IS RECEIPT	Rolling code
AS (b) (4)	PH 0208-992-7000	RECEIPT# PH 803 896 1995	ETH#	XH - USCA
NAME Matt Alavi		OWN John Solomon and Rose Mayer		
COMP Dream Pharma Ltd.		COMP South Carolina Department of Correc		
ADDR 176 Horn Lane		ADDR Kirkland Correctional Institution-		
ADDR		ADDR 4344 Broad River Road		
CITY ACTON, LONDON		CITY COLUMBIA		
ST/PR CTRY GB POSTAL W36PJ		ST/PR SC CTRY US POSTAL 29210		
REF Pharmaceuticals Not Restricted				
PKGS (b) (4) WEIGHT (b) (4) N/L K DIM WEIGHT (b) (4) N/L (b) (4)				
DBSC PHARMACEUTICALS NOT RESTRICTED	(b) (4)	COH GB	COH VAL	EXP MT
				EXP LJC

(b) (4)

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-9673446-4

(b) (4)

(b) (4)

NAME MATT ALAVI  
COMP DREAM PHARMA LTD.  
ADD1 176 HORN LANE  
ADD2  
CITY ACTON, LONDON  
ST/PV CENTRY 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 CENTRY US POSTAL 29210

(b) (4)

PKGS K/L

(b) (4)

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

**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  
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**Subject:** Na Thiopental

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Columbia, SC 29210  
(Tele) 803-896-1995  
(Fax) 803-896-1999

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4444 Broad River Rd.  
Columbia, SC 29210  
(Tele) 803-896-1995  
(Fax) 803-896-1999

**From:** Halpenny, Susan M  
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**To:** 'John Solomon'  
**Subject:** RE: Na Thiopental  
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*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]  
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**To:** Halpenny, Susan M  
**Subject:** Na Thiopental

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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, 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

**From:** Halpenny, Susan M  
**Sent:** Wednesday, December 01, 2010 2:35 PM  
**To:** 'John Solomon'  
**Subject:** RE: shipment delay FDA entry # 112967344464  
Good afternoon,

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*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,

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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:** 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:** 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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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:** Monday, December 20, 2010 9:29 AM  
**To:** Halpenny, Susan M  
**Cc:** David Tatarsky  
**Subject:** Delay of Shipment  
Good morning Susan,

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

Good morning Susan,

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



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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*  
Patricia K. Schafer  
Acting District Director  
New Orleans District Office

Enclosure: FDA Notice of Action

# United States Food and Drug Administration

New Orleans District Office

## Notice of FDA Action

Entry Number: 112-9938358-2

Notice Number: 2

January 6, 2011

Importer:

(b) (4)

>

<

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

Carrier: (b) (4)

Date Received: November 24, 2010

Arrival Date: 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)	(901) 333-3537
U.S. Food and Drug Administration	(901) 333-3579 (FAX)
959 Ridgeway Loop Road, Suite 100	RANDY.BOLING@FDA.HHS.GOV
Memphis, TN 38120-4042	

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) (901) 333-3537 U.S. Food and Drug Administration (901) 333-3579 (FAX) 959 Ridgeway Loop Road, Suite 100 RANDY.BOLING@FDA.HHS.GOV 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  
Notice Prepared By: LPW

DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEForm Approved  
OMB No. 1515-0069

## ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL:

(b) (4)

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE 111910	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME 01	4. ENTRY NUMBER 112-9938358-2
5. PORT 2095	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
8. CONSIGNEE NUMBER (b) (4)		9. IMPORTER NUMBER (b) (4)	
10. ULTIMATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS-CODE(S)/NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE (b) (4)
20. DESCRIPTION OF MERCHANDISE PHARMACEUTICALS NOT RESTRICTED			
21. IT/BLAWB CODE	22. IT/BLAWB NO. TOTAL	23. MANIFEST QUANTITY (b) (4)	24. H.S. NUMBER (b) (4)
M	02358560751		25. COUNTRY OF ORIGIN GB
H	688760418962		26. MANUFACTURER ID. GBDREPHA176LON

## 27. CERTIFICATION

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.

SIGNATURE OF APPLICANT

(b) (6)

PHONE NO.

(b) (4)

DATE

11/24/10

29. BROKER OR OTHER GOVT. AGENCY USE

## 28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:
DELIVERY  
AUTHORIZED:

SIGNATURE

DATE

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.

11/24/10 12:56:42 (b) (4)

Customs Form 3461 (010189)

**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

Date: 19-11-2010

## Address:

(b) (4)

## Delivery Address:

(b) (4)

Tel: (b) (4)

(b) (4)

VAT no:

Currency: USD - US Dollar

Purchase Order:

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)	

**Statement Details**

Goods Total: (b) (4)	Subtotal: (b) (4)
Discount (%): (b) (4)	VAT (World Zero): (b) (4)
Delivery: (b) (4)	Previous Balance: (b) (4)
Insurance: (b) (4)	Total: (b) (4) USD - US Dollar
	Payment Method: Prepayment Thank You

**Shipping Details**

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

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

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

Company Registration Number: (b) (4) VAT No. (b) (4)  
Director: M. Alavi

(b) (4) Manifest report

SHP DT 19-NOV-2010 SHDR# (b) (4) METER THERMAL ☒ RECIP#  
AR (b) (4) PH (b) (4) RECIPIENT PH (b) (4) STH# (b) (4)  
NAME Matt Alavi NAME (b) (4)  
COMP Dream Pharma Ltd. COMP (b) (4)  
ADD1 176 Horn Lane ADD1 (b) (4)  
ADD2 ADD2 (b) (4)  
CITY ACTON, LONDON CITY (b) (4)  
ST/PV CTRY GB POSTAL W36PJ ST/PV (b) (4)  
REF Pharmaceuticals Not Restricted  
PKGS (b) (4) WEIGHT (b) (4) K/L K DIM WEIGHT K/L K  
DESC PHARMACEUTICALS NOT RESTRICTED EN CD COM CUST VAL EXP DT EXP LIC  
(b) (4) GB 0

(b) (4)

MPS shipment

Package # Package Weight  
(b) (4)

IMPORTANT - Treat as the Manifest Copy of the Air Waybill  
\*\*\* Please give this (b) (4) Manifest report to the (b) (4) courier \*\*\*

Merch Nbr. 4577414 Software: FAST0718



LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-9938358-2

(b) (4)

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

NAME  
COMP  
ADD1  
ADD2  
CITY  
ST/PV

(b) (4)

(b) (4)

PKGS K/L  
(b) (4) K

WEIGHT COM CURR  
(b) (4) GB USD

CARR VAL CUSTOMS VAL EX LIC HDLG UNITS  
(b) (4)

DESC: PHARMACEUTICALS NOT RESTRICTED



04-22-2010 12:00pm

From (b) (4)

(b) (4)

T-859 P.001/001 F-698

(b) (4)

Approved through 12/31/95. OMB NO. 1545-0047  
See back of form for Paperwork Reduction Act Notice.DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICEIMPORTER ID  
INPUT RECORD

FILL 2A OR 2B

19 CFR 24.5

2. IMPORTER NUMBER (Fill in one format):

(b) (4)

2A. IRS Number

(b) (4)

2B. Social Security Number

2C. ☐ Check here if requesting a  
Customs Assigned number and  
Indicate reason on pt. (Check all that apply)☐ I have no IRS No.☐ I have no  
Social Security No.☐ I have not applied  
for either number.☐ I am not a  
U.S. resident

2D. Customs Assigned Number

RETURN TO :

AWB REF #:

3. Importer Name

(b) (4)

(b) (4)

4. DIV AKA DBA

☐ DIV☐ AKA☐ DBA

5. DIV AKA DBA Name

6. Type

☒ Corporation☐ Partnership☐ Sole Proprietorship☐ Individual☐ U.S. Government☐ Other

7. Importer Mailing Address (232-character lines maximum)

(b) (4)

(b) (4)

(b) (4)

11. Country ISO Code (Non-U.S. Only)

(b) (4)

12. Importer Physical Location Address (232-character lines maximum; see instructions)

(b) (4)

ACCOUNT

13. City (b) (4)

14. State Code (b) (4)

15. ZIP

(b) (4)

16. Country ISO Code (Non-U.S. Only)

(b) (4)

17a. Has importer ever been assigned a Customs Importer Number using the same name as in Block 3? ☒ No ☐ Yes (Last number(s) and/or name(s) in Block 17 c.)17b. Has importer ever been assigned a Customs Importer Number using a name different from that in Block 3? ☒ No ☐ Yes (Last number(s) and/or name(s) in Block 17 c.)

17c. If Yes to 17a and/or 17b, list number(s) and/or name(s)

NOTE: If the owner or ultimate 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 corporation that such employee or agent has or will have knowledge of the pertinent facts.

I CERTIFY That the information presented herein is correct, that if my Social Security Number is used it is because I have no IRS Employer Number, that if my Customs Assigned number is used it is because I have neither a Social Security Number nor an IRS Employer Number, that if none of these numbers is used, it is because I have none, and my signature constitutes a request for assignment of a number by Customs.

18. Printed or Typed Name and Title

(b) (7)(C)

19. Telephone No. including Area Code

PH

FAX

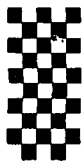
(b) (4)

21. Date

11-22-2010

22. Broker Use Only

CUSTOMS FORM 5106 (012293)



09-27-10;15:32 ;

919013333579 ;

# 1/ 3

**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:

*Jaquelyn  
Biddford*

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) 267-6381  
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. § 5-4-817, "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:**

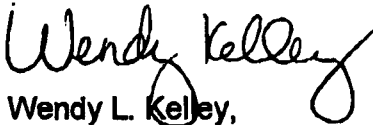
**Arkansas Department of Correction  
Central Administration Office  
ATTN: Wendy Kelley, Deputy Director  
6814 Princeton Pike  
Pine Bluff, AR 71602-9411  
Telephone: 870-550-7307**

**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

2/4/2011

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.

Please do not detain this entry. 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

2/4/2011

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'  
**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 tiler 575, Arizona Customs Brokerage, 602-273-0912. I will advise you of the Entry number once it has been transmitted ABI.

Please do not detain this entry. 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

2/4/2011

-----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

2/4/2011

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**

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**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 being transmitted. Also we would be able to track the shipment thru Federal Express. I appreciate any information you can provide. Thanks in advance.

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

Fax (901) 333-3576

-----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: 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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David Thomas, DCM  
FDA Investigations  
Phoenix, Office

Charles:

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David Thomas, DCM  
FDA Investigations  
Phoenix, Office

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

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To: Thomas, David

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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

**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:** 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,

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

**To:** Halpenny, Susan M

**Cc:** David Tatarsky

**Subject:** Delay of Shipment

Good morning Susan,

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

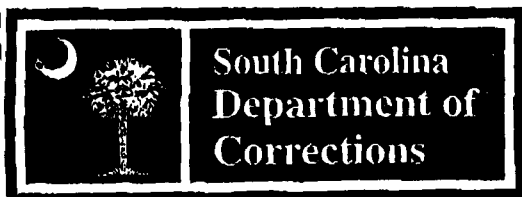
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John

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

**ATTENTION SUSAN**MARK SANFORD, Governor  
JON OZMINT, Director

October 29, 2010

United States Customs Department

**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 Maycr  
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](mailto:solomon.john@doc.state.sc.us).

Sincerely,

  
John 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