CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that John Verbeten, Director of the Operations and Policy Branch, Division of Import Operations and Policy, Office of Regional Operations, Office of Regulatory Affairs, United States Food and Drug Administration, whose declaration is attached, has custody of official records of the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provision of Title 42, United States Code, Section 3505, and FDA Staff Manual Guide 1410.23, hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 20th day of April, 2011.

Karen Kennard

Karen Kennard, Acting Director
Division of Dockets Management
Office of Public Information and Library Services
Office of Shared Services
Office of Management

By direction of the Secretary of
Health and Human Services

DECLARATION OF JOHN VERBETEN

John Verbeten, being first duly sworn, declares as follows:

1. I am the Director of the Operations and Policy Branch, Division of Import Operations and Policy, Office of Regional Operations, Office of Regulatory Affairs, United States Food and Drug Administration.

2. In this capacity, I have custody of official records of the United States Food and Drug Administration.

3. Attached is a certified and authentic copy of the following records of the Food and Drug Administration:

Administrative record relating to Beaty v. FDA et al., No. 11-00289 RJL (D.D.C.)

4. Copies of the attached administrative record are part of the official records of the United States Food and Drug Administration.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 18, 2011.

John Verbeten

Administrative Record Index

Description	Date	Bates Number
Letter from Charles Ryan, Director, Arizona Department of Corrections, to David Thomas, FDA Investigations re: Execution by Lethal Injection of Arizona Inmate Jeffrey Timothy Landrigan #082157	9/24/2010	000001
Letter from Charles Flanagan, Deputy Director, Arizona Department of Corrections, to David Thomas, FDA Investigations, enclosing Controlled Substance Registration Certificate	9/24/2010	000002-000003
Notice of FDA Action	9/29/2010	000004
Department of Treasury, U.S. Customs Service Entry/Immediate Delivery Form	10/7/2010	000005-00006
FDA's Operational and Administrative System for Import Support (OASIS) Screenshot for Entry # 112-9247186-3	n/a	000007
Letter from Dale Baich, Supervisor, Capital Habeas Unit, Office of the Federal Public Defender for the District of Arizona, to Ralph Tyler, Chief Counsel, FDA	10/23/2010	000008-000012
Department of Homeland Security, U.S. Customs and Border Protection Entry/Immediate Delivery Form	10/25/2010	000013-000015
FDA's OASIS Screenshot for Entry # 574-0251126-5	n/a	000016
Email from Patrick Bowen, FDA, to Distribution re: Import Bulletin #60-B08	10/27/2010	000017-000018
Email from Nima Abbaszadeh, U.K. Desk Officer, U.S. Department of State, to Ilisa Bernstein re: assistance on sodium thiopental question raised by UK Embassy, enclosing Letter from Ian Bond, Political Counsellor, British Embassy Washington, to Elizabeth Dibble, Deputy Assistant Secretary of State	11/4/2011	000019-000020
Email from Clare Bloomfield, British Embassy, to Murray Lumpkin, FDA, re: UK request for information on sodium thiopental	11/4/2010	000021
Email from Tom Smith, Department for Business, Innovation and Skills, to Murray Lumpkin re: Sodium Thiopental	11/5/2010	000022
Email from Murray Lumpkin to Tom Smith cc JM Sharfstein and Margaret Hamburg re: Substantive response from US FDA re: Sodium Thiopental	11/16/2010	000023-000024
Letter from Charles Ryan, Director, Arizona Department of Corrections, to Deborah Autor, Director, Office of Compliance, CDER, re: Entry #574-0251126-5 Thiopental Sodium	11/10/2010	000025-000026

Administrative Record Index

Letter from Charles Ryan, Director, Arizona Department of Corrections, to David Thomas, FDA Investigations, re: Inspection and Release of Entry #574-0251126-5, Thiopental Sodium	11/10/2010	000027
Letter from Dale Baich, Supervisor, Capital Habeas Unit, Office of the Federal Public Defender for the District of Arizona, to Thomas Emerick, Assistant Special Agent in Charge, FDA	11/17/2010	000028-000029
Department of Treasury Entry/Immediate Delivery Form	11/24/2010	000030-000031
FDA's OASIS Screenshot for Entry # 112-9938358-2	n/a	000032
Letter from Benjamin Rice, General Counsel, State of California, to Ruth Dixon, FDA	12/9/2010	000033
Sodium Thiopental Statement, Key Messages	12/29/2010	000034-000035
Email from Shelly Burgess to Nathan Koppel	1/4/2011	000036-000037
Letter from Coleen Klasmeier, Bradford Berenson (Sidley Austin), and Dale Baich (Office of the Federal Public Defender for the District of Arizona), to Margaret Hamburg, Commissioner, FDA	1/4/2011	000038-000050
Guidance for handling pending and future shipments of Sodium Thiopental	1/5/2011	000051-000057
Notice of FDA Action	1/6/2011	000058-000059
Notice of FDA Action	1/7/2011	000060-000061
Letter from Patricia Shafer, Acting District Director, New Orleans District Office, to Benjamin Rice, Chief Counsel, California Department of Corrections & Rehabilitation	1/7/2011	000062-000063
Letter from Alonza Cruse, District Director, Los Angeles District, to Carson McWilliams, Warden, Arizona State Prison Complex	n/a	000064
Miscellaneous		
FDA Establishment Inspection Report for Sandoz - Endorsement Excerpt	7/8/2009	000065
FDA Establishment Inspection Report for Sandoz - Summary Excerpt	7/29/2010	000066-000069
Form FDA 483 - Inspectional Observations for Sandoz	7/29/2010	000070

Arizona Department of Corrections

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

JANICE K. BREWER
GOVERNOR

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: (b) (7)(E) and it expires June 30, 2013. The execution is set by the court for October 26, 2010, and our agency is mandated to advise the court that it possesses the necessary chemicals for the lethal injection protocol as approved, no later than October 1, 2010.

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

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

Sincerely,

Charles L. Ryan
Director

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

Arizona Department of Corrections

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

JANICE K. BREWER
GOVERNOR

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

(b) (4)

(b) (4)

(b) (4)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (7)(E)	06-30-2013	FEE EXEMPT

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010

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

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

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

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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

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

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
(b) (7)(E)	06-30-2013	FEE EXEMPT

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4,5,	HOSPITAL/CLINIC	08-25-2010

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

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.

Form DEA-223 (4/07)

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

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1

Notice Number: 1
September 29, 2010

Consignee:
Arizona State Prison Complex
1305 Butte Ave
Florence, AZ 85232

>

<

Port of Entry: [redacted] Phoenix, AZ
Carrier: [redacted]
Date Received: September 29, 2010
Arrival Date: September 28, 2010

Filer of Record: [redacted]
Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

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

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

@ = Consignee ID

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

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

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

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

TABS

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form 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	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
100610		(b)	112-9247186-3
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
2095		(b) (4)	
	8. CONSIGNEE NUMBER		**9. IMPORTER NUMBER**
	NAME/ADDRESS		(b) (4)
10. ULTIMATE CONSIGNEE NAME		**11. IMPORTER OF RECORD NAME**	
(b) (4) PHARMACY (b) (4) (b) (4) GA		(b) (4)	
12. CARRIER CODE	**13. VOYAGE/FLIGHT/TRIP**	**14. LOCATION OF GOODS-CODE(S)/NAME(S)**	
(b) (4)	(b) (4)	(b) (4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	**17. MANIFEST NUMBER**	**18. G.O. NUMBER**	**19. TOTAL VALUE**
2095			1269

20. DESCRIPTION OF MERCHANDISE

PHARMACEUTICALS NOT RESTRICTED

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
	TOTAL	(b) (4)	(b) (4)	GB	GBDREPHA176LON
M	02358508380				
H	688760418425				

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) (7)(C) W37

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 3461 (010189)

FDA 000005

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

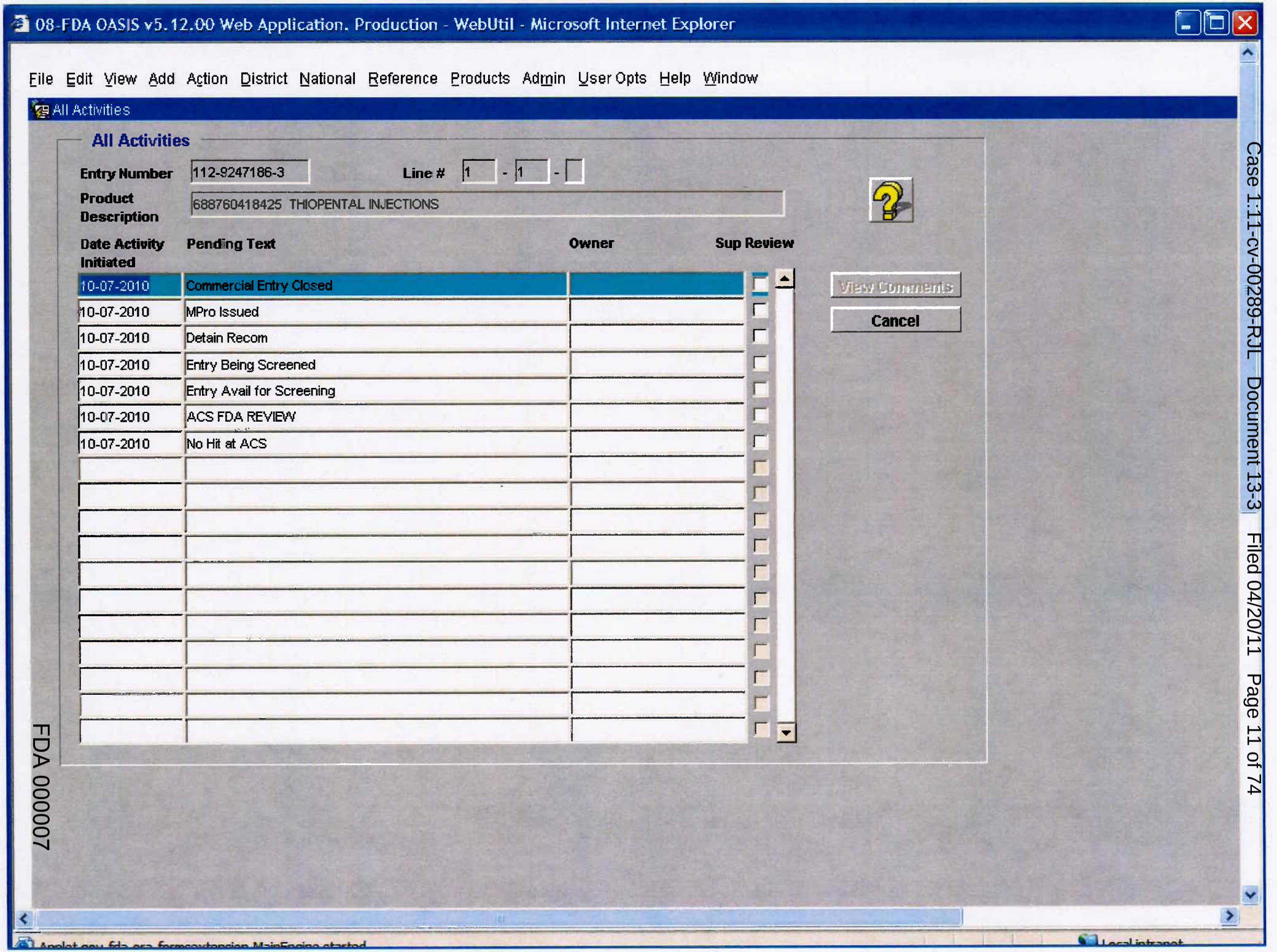
Shipping Details

Packing: one box	Gross Weight (Kg): (b) (4) Net Weight (Kg): (b) (4)
Tariff: (b) (4)	Carrier: (b) (4)
Declarations: We certify that this invoice is true and correct.	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


08-FDA OASIS v5.12.00 Web Application. Production - WebUtil - Microsoft Internet Explorer
File Edit View Add Action District National Reference Products Admin User Opts Help Window
All Activities
All Activities
Entry Number 112-9247186-3
Line # 1 - 1 -
Product Description 688760418425 THIOPENTAL INJECTIONS
Date Activity Initiated
Pending Text
Owner
Sup Review
10-07-2010 Commercial Entry Closed
10-07-2010 MPro Issued
10-07-2010 Detain Recom
10-07-2010 Entry Being Screened
10-07-2010 Entry Avail for Screening
10-07-2010 ACS FDA REVIEW
10-07-2010 No Hit at ACS
View Comments
Cancel
FDA 000007
Case 1:11-cv-00289-RJL Document 13-3 Filed 04/20/11 Page 11 of 74

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
Federal Public Defender

direct 602.382.2816
800.758.7053
facsimile 602.889.3960
e-mail dale_baich@fd.org

October 23, 2010

via email ralph.tyler@fda.hhs.gov

Ralph S. Tyler, Chief Counsel
United States Department of Health & Human
Services, Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, Maryland 20993-0002

Dear Mr. Tyler,

I am writing you concerning an urgent matter in the State of Arizona pertaining to potential violations of the Food, Drug, and Cosmetic Act, which may result in immediate harm to an Arizona citizen.

Recently I learned that the Arizona Department of Corrections ("ADOC") may have obtained a quantity of non-FDA-approved sodium thiopental that it intends to use on a human being. The State of Arizona intends to use the non-FDA-approved sodium thiopental as one of the drugs in the planned execution of Jeffrey Landrigan, scheduled to take place at 1:00 p.m. Eastern Daylight Time on Tuesday, October 26. As discussed below, Assistant Attorney General Kent Cattani admitted to the Arizona Supreme Court that the sodium thiopental ADOC obtained for use in Mr. Landrigan's execution is not a Hospira product (which, as you know, is the only FDA-approved manufacturer of thiopental).

I am requesting that you expeditiously investigate whether the State of Arizona and its agencies are in possession of a non-FDA-approved drug, and whether the State intends to use it on a human being.

As you are undoubtedly aware, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

On September 21, 2010, the Arizona Supreme Court scheduled Mr. Landrigan's execution. A few days later, Assistant Attorney General Kent Cattani stated to the press that the ADOC did not have sodium thiopental, and that he was not overly optimistic about securing the drug.[2] Mr. Cattani also stated that the ADOC had been looking not only to other states, but also to other countries, to obtain sodium thiopental.[3] On September 30, the ADOC filed a letter with the Arizona Supreme Court, reporting that it had acquired the drug, but the ADOC did not reveal its source. On October 20, Mr. Cattani admitted to the Arizona Supreme Court that the sodium thiopental the ADOC had obtained was not manufactured by Hospira.

Because we know that Hospira is the only manufacturer of sodium thiopental in the United States, and that its product is the only sodium thiopental approved for use in the United States, Mr. Cattani's admission to the Arizona Supreme Court suggests to us that the thiopental the ADOC obtained was made by a foreign manufacturer.

The FDA controls manufacture and distribution of thiopental in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any

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[1]See entry for "Pentothal (thiopental) Injection," http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

[2]Paul Davenport, *Ariz. Death Row Inmate to be Executed in October*, the Associated Press, Sept. 23, 2010, http://www.trivalleycentral.com/articles/2010/09/23/casa_grande_dispatch/around_arizona/doc4c9b81d4a0fc9230808604.txt.

[3]Michael Kiefer, *Arizona Obtains Drug Supply for Oct. Execution*, Arizona Republic, Oct. 1, 2010, http://www.azcentral.com/arizonarepublic/local/articles/2010/10/01/20101001deathdrugs1001.html.

firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[4] I have received the name of a local customs broker through an anonymous phone call, which was identified as the source of the sodium thiopental.[5] If this information is accurate, then ADOC's acquisition of sodium thiopental through a customs broker, would appear to be different than the FDA's understanding as expressed through the statement by Ms. Burgess.

We believe that the ADOC may violate federal law if it administers sodium thiopental that has not been approved by the FDA to Mr. Landrigan. We further believe that the ADOC, by acquiring sodium thiopental from a foreign source, directly or indirectly, may have violated the Food, Drug and Cosmetic Act ("FDCA") and the Controlled Substances Act ("CSA").[6]

The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless approval of an application . . . is effective with

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[4]Michael Kiefer, *Judge asks Arizona for execution-drug source*, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021arizona-execution-court-blocks-2nd-request.html.

[5]In the event the FDA is interested in pursuing this matter, I will provide you with the name of the local customs broker.

[6]We understand the FDA has no authority to enforce the CSA. However, a referral to the Drug Enforcement Administration may be appropriate.

If a controlled substances is imported into the United States "for medical, scientific or other legitimate uses" (here it was not), the registered importer must file a controlled substance import declaration not later than 15 calendar days prior to importation. 21 C.F.R. 1312.18(a) & (b). The declaration must include the DEA registration number of the importer and import broker, a complete description of the controlled substances, the quantity of controlled substance, DEA registration number of the recipient, date and foreign port of exportation, and the name and address of the consignor in the foreign country of exportation, and any registration or license numbers the consignor may be required to have by if the country of exportation or under U.S. law. 21 C.F.R. 1312.18(c).

respect to each drug."[7] Furthermore, the FDCA requires "foreign establishments" that manufacture drugs imported into the United States to register with the FDA.[8] To date, we have seen no indication that the ADOC applied to import sodium thiopental, or that its source of the drug is registered with the FDA.

It is our position that an execution is not a "legitimate use" that would justify importation of a non-FDA approved form of thiopental. Sodium thiopental is used to anesthetize the prisoner so that he is insensate to the pancuronium bromide and potassium chloride just as it is used in medical procedures, and the execution would be inhumane if it sodium thiopental did not work as planned.

I believe that my concerns, which pertain to matters such as drug misbranding and drug adulteration, fall under the authority of two divisions within the Office of Compliance (OCI): the Division of New Drugs and Labeling Compliance (responsible for, *inter alia*, concerns about misbranding), and the Division of Manufacturing and Product Quality (responsible for, *inter alia*, concerns about adulteration). Accordingly, I ask that you immediately refer this matter to those divisions for an emergency investigation. If those investigations demonstrate that the ADOC intends to use a non-FDA-approved product, I ask that the appropriate personnel consider obtaining a temporary restraining order ("TRO") against—at a minimum—ADOC staff, to enjoin those individuals who intend to administer the non-FDA-approved thiopental to a human being—Jeffrey T. Landrigan. *See* FDA Regulatory Procedures Manual § 6-2-3 ("FDA Recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately."). I also ask that the Office of Compliance take any further action deemed necessary under the Food, Drug, and Cosmetic Act, or any other relevant authority to prevent this and future occurrences of any violations that OCI finds.

---

[7] 21 U.S.C. § 355(a).

[8] 21 U.S.C. § 360(i). At the time of registration, the foreign establishment must file with the Secretary a list of all drugs that are being "manufactured, prepared, propagated, compounded, or processed" for commercial distribution. 21 U.S.C. § 360(j)(1). If a foreign establishment lists "new drugs," in its filing, it must also provide "a reference to the authority for the marketing of such drug" and provide a copy of the labeling. 21 U.S.C. § 360(j)(1)(A).

Again, this matter is urgent. I appreciate your expeditious consideration and review of my request. You may reach me by email at dale_baich@fd.org or on my mobile at 602-625-2111 should you need any additional information.

Very truly yours,

Dale A. Baich

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/kls

cc: Jeffrey T. Landrigan

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

Form Approved
OMB No. 1651-0024
Exp. 01-31-2012

ENTRY/IMMEDIATE DELIVERY

DI [redacted]

000 BOX #
574-0251126-5
ABI CERTIFIED

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
102610		11 INFORMAL -	574-0251126-5
5. PORT	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER	
2605	X891	[redacted]	
[redacted]			8. IMPORTER NUMBER [redacted]

10. ULTIMATE CONSIGNEE NAME	11. IMPORTER OF RECORD NAME
ARIZONA STATE PRISON COMPLEX 1305 BUTTE AVE FLORENCE, AZ 85232	ARIZONA DEPARTMENT OF CORRECTIONS 1601 W. JEFFERSON ST PHOENIX, AZ 85007-3002

12. CARRIER CODE	13. VOY/FLT/TRIP	[redacted]
[redacted]	[redacted]	
15. VESSEL CODE/NAME		

16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL [redacted]
2605			

20. DESCRIPTION OF MERCHANDISE
MEDICAL EQUIPMENT

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.
M	12562148505	1	3004909130	GE	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

[redacted]

DATE [redacted] 10/25/2010

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:	SIGNATURE	DATE

29. BROKER OR OTHER GOVT. AGENCY USE

AZ DOC PIU
11:37
[redacted]
AZ DOC

Exam Site [redacted]

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

FX/3461 (1/10) PART 1 CBP Form 3461 (10/09)

[redacted] 8:17AM 26 2010

FDA 000013

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: [redacted]

Date: 22-10-2010

Address: [redacted]

Delivery Address: [redacted]

VAT No:

Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS NOT RESTRICTED

Order Details

Name/Description	Quantity	Price	Total
Shipping charges for invoice number [redacted]	[redacted]	[redacted]	[redacted]

Statement Details

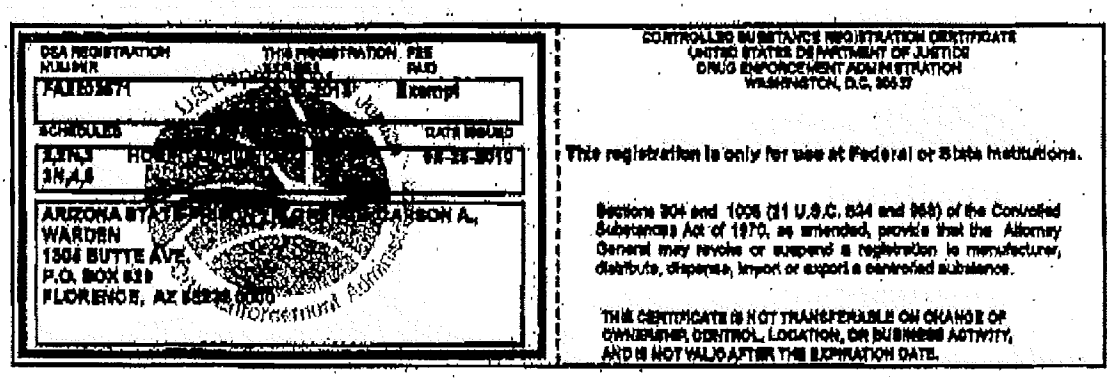
Goods Total: [redacted]	Subtotal [redacted]
Discount (%): 0	VAT (World Zero): 0.00
Delivery: 0	Previous Balance: 0
Insurance: 0	Total [redacted] GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

Packing:	Gross Weight (Kg): Net Weight (Kg): 0
Tariff: 30049099	Carrie[redacted]
Declarations: We certify that this invoice is true and correct.	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

p.3 [redacted] Oct 26 2010 8:17AM



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

DEA REGISTRATION NUMBER | THIS REGISTRATION EXPIRES | FEE PAID
(b) (7)(E) | 09-30-2013 | Exempt

SCHEDULES | BUSINESS ACTIVITY | DATE ISSUED
2,2N,3 3N,4,5 | HOSPITAL/CLINIC | 09-28-2010

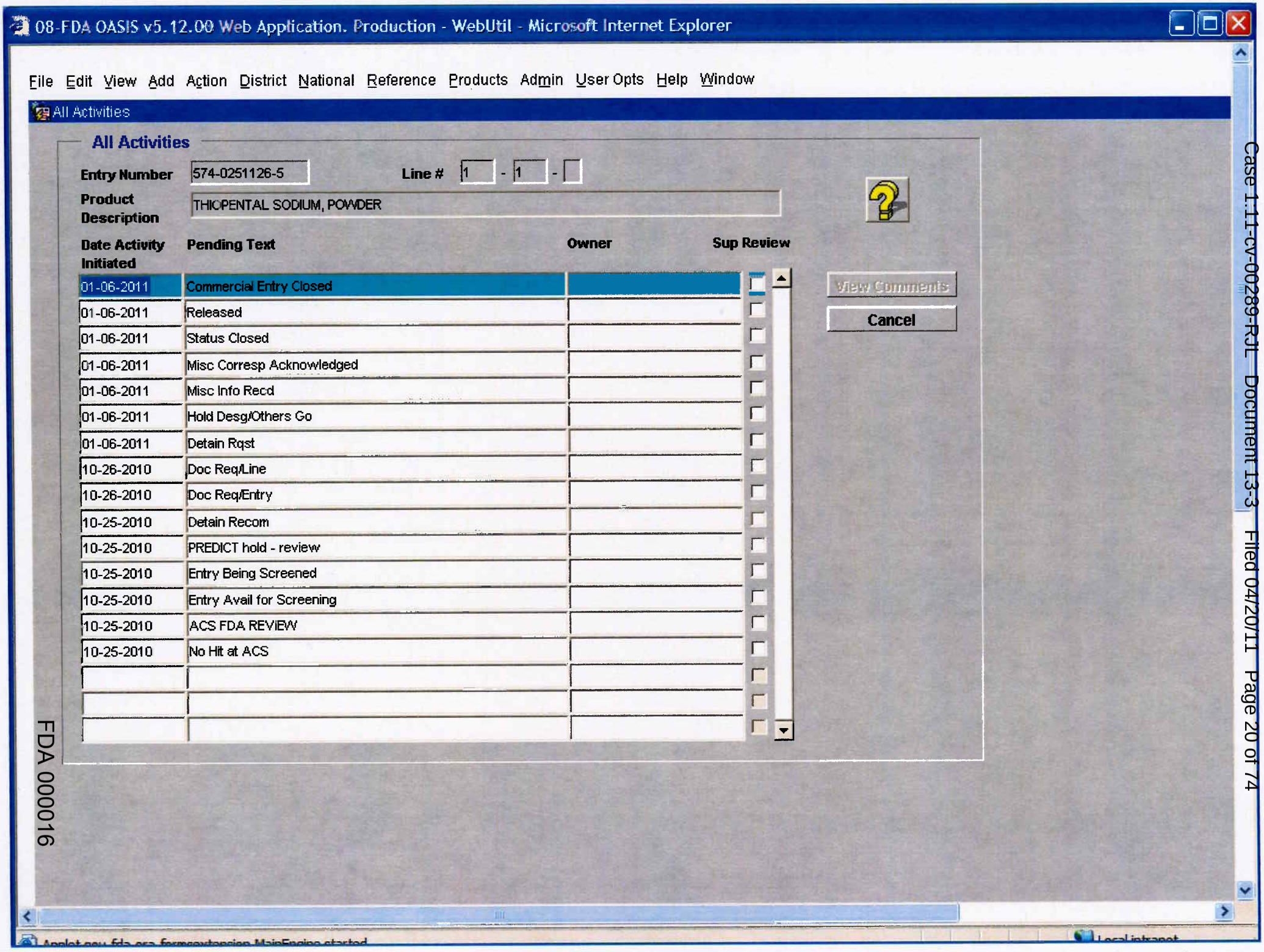
ARIZONA STATE PRISON - FLORENCE, CARSON A.,
WARDEN
1305 BUTTE AVE.
P.O. BOX 629
FLORENCE, AZ 85232-0000

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

Sections 304 and 1008 (21 U.S.C. 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 IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (REV04)



Dohm, Julie

From: Bowen, Patrick A
Sent: Wednesday, October 27, 2010 3:22 PM
To: ORA HQ DIOP IPM; ORA HQ DIOP Employees
Cc: ORA RFDDs; ORA DIBs; ORA DCBs; ORA DDs; ORA Lab Directors; Elder, David K.; Batista, Huascar R
Subject: IMPORT BULLETIN #60-B08

Date: 10/27/2010

From: DIRECTOR, DIVISION OF IMPORT OPERATIONS & POLICY (HFC-170)

SUBJ: IMPORT BULLETIN #60-B08, "SHORTAGE OF SODIUM PENTATHOL AKA SODIUM THIOPENTAL"

TO: IMPORT PROGRAM MANAGERS

* * * * * IMPORT BULLETIN * * * * *

NOTE: THIS IS A PRIVILEGED INTERNAL FDA DOCUMENT AND NOT INTENDED FOR RELEASE TO THE PUBLIC.

BACKGROUND: Sodium Pentathol is not being produced in the United States and is currently unavailable. It is not scheduled to be available until the first quarter of 2011.

GUIDANCE: Districts receiving shipments of Sodium Pentathol or Sodium Thiopental are asked to contact CDR Domenic Veneziano, Director of FDA's Division of Import Operations and Policy at (240)888-9316 for further instructions.

Appropriate OASIS screening criteria has been set.

MANUFACTURER:	ALL
COUNTRY:	ALL
PRODUCT(S):	Sodium Pentathol Sodium Thiopental
PRODUCT CODES:	60Q[][]28
PAF:	(AAP) Approvals (REG) Registrations & Listing
PAC:	56008H
EXPIRATION DATE:	90 days from date of issuance
RECOMMENDED BY:	DIOP, HFC-170
FOI:	No purging required
KEY WORDS:	Anesthetic, sodium pentathol
PREPARED BY:	Stella Notzon, DIOP, 301-594-3851

DATE
PUBLISHED: October 27, 2010

Under the Authority of
Domenic J. Veneziano, CDR USPHS

Dohm, Julie

From: Bernstein, Ilisa
Sent: Friday, April 15, 2011 12:08 PM
To: Dohm, Julie
Subject: FW: assistance on sodium thiopental question raised by UK Embassy
Attachments: 101101deathpenaltyletter.doc

From: Abbaszadeh, Nima [mailto:AbbaszadehN@state.gov]
Sent: Thursday, November 04, 2010 2:52 PM
To: Bernstein, Ilisa
Subject: assistance on sodium thiopental question raised by UK Embassy

Ilisa,

I'm writing to you from the UK desk at the State Department at the suggestion of Susie Boggess. I appreciate that you're probably not the right contact for this question, but we're hoping you can point us in the right direction. The attached letter from the British Embassy was sent to our Deputy Assistant Secretary yesterday complaining about the import of sodium thiopental from the UK for use in lethal injections in the United States. The letter claims that UK-sourced sodium thiopental is not FDA-approved. This issue has also received some prominent press attention in the UK (link to article below). I understand a lawsuit has now been filed in London to prevent the drug from being exported to the United States.

At this point, we're just trying to find the appropriate POC at FDA, including someone who can verify the letter's claim that "that Sodium Thiopental sourced from the UK is not FDA-approved for use in the U.S." Any suggestions for who we should be talking to would be greatly appreciated.

http://www.guardian.co.uk/world/2010/nov/02/death-penalty-campaigners-execution-drug

Thanks very much,
Nima

Nima Abbaszadeh
U.K. Desk Officer
U.S. Department of State
Tel: (202) 647-5674
AbbaszadehN@state.gov

This email is UNCLASSIFIED.

British Embassy
Washington

Foreign and Security Policy Group
British Embassy
3100 Massachusetts Ave NW
Washington, DC 20008

Tel: +1 202 588 6524
Fax: +1 202 588 7870
Email: ian.bond@fco.gov.uk
www.ukinusa.fco.gov.uk

Elizabeth L Dibble
Deputy Assistant Secretary of State
Bureau of European and Eurasian Affairs
Department of State

08 April 2011

Dear DAS Dibble

DEATH PENALTY – IMPORT OF SODIUM THIOPENTAL FROM THE UK

As you know, the UK firmly opposes the death penalty in all circumstances as a matter of principle. I am aware that the UK and US governments do not see eye to eye on this. It is nonetheless deeply concerning to hear reports that US States may be importing Sodium Thiopental (a drug which has legitimate therapeutic uses but can also be used in executions) from the UK in order to put convicted persons to death. This follows problems in obtaining this substance from the sole US manufacturer, Hospira, a company which has in the past made clear that it does not support the use of any of its products in capital punishment procedures.

We were especially dismayed to hear about the execution of Jeffrey Landrigan in Arizona on 26 October, given reports that he suffered from severe mental health problems; the 9th US Circuit Court of Appeals had previously stayed his execution because of the lack of clarity about the provenance of the Sodium Thiopental to be used.

We are also very concerned about the possibility of UK drugs being used in future executions in the US, such as the case of Edmund Zagorski in Tennessee. Our understanding is that Sodium Thiopental sourced from the UK is not FDA-approved for use in the US. We would therefore be grateful for any steps the Federal Government can take to prevent it being used here , especially in order to harm rather than heal.

Yours sincerely

Ian Bond

Ian Bond
Political Counsellor

Dohm, Julie

From: Clare.Bloomfield@fco.gov.uk
Sent: Thursday, November 04, 2010 4:06 PM
To: Lumpkin, Murray
Subject: UK request for information on sodium thiopental

Dear Mr Lumpkin,

With apologies for contacting you out of the blue, I am writing with a request from one of my colleagues in London, Tom Smith, Head of our Export Controls Organisation (part of the Department of Business, Innovation and Skills).

Tom is currently involved in a legal case in the UK revolving around a UK company supplying sodium thiopental to the US, which was then subsequently used for carrying out the death penalty. He is trying to find someone on good authority in the FDA who will be able to answer a question on US general usage of the drug. I believe he thinks it is licensed for use here but is more interested in knowing whether it is in general use.

Sadly this is not my area of expertise but know Tom well which is why he came to me to see if I could help point him in the right direction.

I wonder if it would be ok for me to pass on your contact details and ask him to get in touch with you directly (or one of your colleagues), in order to help him supply an answer to Secretary of State for Business by the end of the week?

I look forward to hearing from you,
Clare

Clare Bloomfield | *Foreign and Security Policy Group | British Embassy | 3100 Massachusetts Avenue NW | Washington DC 20008 |*

Email: Clare.Bloomfield@fco.gov.uk | Tel: (202) 588 6998 | Cell: (202) 213 8460 | FTN: 8430 6998 | www.ukinusa.fco.gov.uk

Help save paper - do you need to print this email?

Dohm, Julie

From:	Smith Tom (ITID) [tom.smith@bis.gsi.gov.uk]
Sent:	Friday, November 05, 2010 11:27 AM
To:	Lumpkin, Murray
Cc:	Jenkins Russell (ITID); Martinez-Soto Jose (LEGAL B); Chew Christopher (ITID); Clare.Bloomfield@fco.gsi.gov.uk
Subject:	Sodium Thiopental
Follow Up Flag:	Follow up
Flag Status:	Red

Dear Mr Lumpkin,

Thank you very much for speaking to me just now.

To confirm, we are interested in obtaining an authoritative view from the FDA on the current usage of sodium thiopental for medical reasons within the United States. I note your comment that it is an old drug and that new drugs have since come onto the market. The question is whether, nevertheless

a) it continues to be licensed for use within the US (and, if so, for what purposes);
b) it does in practice continue to be used. Even relatively low levels of usage (as a percentage of anaesthetic procedures) would be relevant information to us.

You kindly agreed to seek to find out this information for me from your experts.

If you were able to give me an answer early next week, that would be extremely helpful.

Regards,

Tom Smith
Head, Export Control Organisation
Department for Business, Innovation and Skills
3rd Floor, "Orchard 3", 1 Victoria Street
London SW1H 0ET
Tel: 0207 215 4355
Email: tom.smith@bis.gsi.gov.uk

Ramos, Merly

From: Lumpkin, Murray
Sent: Tuesday, November 16, 2010 2:03 PM
To: 'tom.smith@bis.gsi.gov.uk'
Cc: Sharfstein, JM; Hamburg, Margaret
Subject: Substantive response from US FDA re: Sodium Thiopental

Dear Mr. Smith,

Thank you for your understanding and for your original inquiry. I do now have information that I hope will still be responsive to your time frame.

You asked for the "authoritative view from the FDA on the current usage of sodium thiopental for medical reasons within the United States.". Currently there is no sodium thiopental for sale in the United States, because the domestically manufactured supply has been unavailable for more than a year. There are no approved or permitted foreign sources of sodium thiopental. As a result, there is currently little to no current usage of sodium thiopental for medical reasons.

To your specific questions:

a) The question is whether it continues to be licensed for use within the US (and, if so, for what purposes);

There is no FDA-approved sodium thiopental for human use in the United States. Although the domestically manufactured supply is not approved, the product has been marketed and commercially available without FDA approval pursuant to FDA's Compliance Policy Guide on Marketed Unapproved Drugs. This document is available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf.

b) The question is whether it does in practice continue to be used. Even relatively low levels of usage (as a percentage of anaesthetic procedures) would be relevant information to us.

Currently, sodium thiopental's use is very limited due to the shortage described above. When there is no shortage, there is minimal use of sodium thiopental for medical reasons. Experts consulted by FDA have stated that sodium thiopental would be used in well under 5% of patients presenting for a general anesthetic. There is one scenario where the use of sodium thiopental would likely increase: if there were to be another shortage of propofol, an anesthetic agent. If propofol is in shortage, sodium thiopental would most likely find increased use as an induction agent for general anesthesia. Propofol is not currently in shortage in the United States.

Again, I hope this is responsive to your request

Sincerely,

Murray M. Lumpkin, M.D., M.Sc.
Deputy Commissioner
International Programs
US Food and Drug Administration.

----- Original Message -----
From: Smith Tom (ITID) [mailto:tom.smith@bis.gsi.gov.uk]
Sent: Tuesday, November 16, 2010 09:01 AM
To: Lumpkin, Murray
Subject: RE: Apologies: Sodium Thiopental

Dear Mr Lumpkin,

Thank you. I do understand and appreciate your efforts.

Tom Smith
Head, Export Control Organisation
Department for Business, Innovation and Skills
3rd Floor, "Orchard 3", 1 Victoria Street

London SW1H 0ET
Tel: 0207 215 4355
Email: tom.smith@bis.gsi.gov.uk

The Department for Business, Innovation & Skills (BIS) is building a dynamic and competitive UK economy by creating the conditions for business success; promoting innovation, enterprise and science; and giving everyone the skills and opportunities to succeed. To achieve this we will foster world-class universities and promote an open global economy. BIS - Investing in our future

-----Original Message-----
From: Lumpkin, Murray [mailto:Murray.Lumpkin@fda.hhs.gov]
Sent: 16 November 2010 11:45
To: Smith Tom (ITID)
Cc: Sharfstein, JM; Hamburg, Margaret
Subject: Apologies: Sodium Thiopental

Dear Mr Smith,
I am writing today to offer my sincerest apologies that the US FDA has been unable to supply you with the information you requested in time to be of help in your UK exporting agency's trial tomorrow. I know it is now afternoon in London, and your trial starts tomorrow morning (London time). Even checking on an almost daily basis, as of this morning, I still have not received departmental clearance on a communication to you that would be responsive to your request. I know we have been singularly unhelpful, and, for that, I am truly sorry. I do wish we could have been more helpful to you. Again, many sincere apologies.

If I do happen to receive clearance later today our time, I will, of course, send you what is cleared in the hopes it might be of help, even at that late hour.

Best regards,
Murray Lumpkin

Murray M. Lumpkin, MD, MSc
Deputy Commissioner
International Programs
US Food and Drug Administration.

Arizona Department of Corrections

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

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

November 10, 2010

Deborah M. Autor
Director, Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Ave, Bldg. 51- Room 5270
Silver Spring, Maryland 20993

Re: Entry #574-0251126-5 Thiopental Sodium

Dear Director Autor:

The Arizona Department of Corrections (ADC) has been awaiting, for over two weeks, the inspection and release of chemicals purchased legally from a company located outside of the United States. We have the shipment in proper storage at our Florence, Arizona facility. Other than a message last week advising us to expect a decision by week's end, and a call on November 9, 2010, from Michael Levey (subsequent to repeated unreturned messages) advising a decision would be made at some undetermined point in the future, my staff have not had success in gaining information regarding the justification of the Food and Drug Administration (FDA) in holding this shipment and preventing the release to ADC. This is contrary to the precedent set by the FDA in releasing a prior shipment.

Given that a much larger shipment of this chemical was successfully entered and released with authorization from the United States Customs Department and the FDA, we respectfully request that you expedite the necessary inspection and release. The delay in this matter is wholly inconsistent with the timely and thorough inspection previously conducted on a much larger shipment of this and other chemicals in September. It is ADC's understanding that the FDA's responsibility in this process extends only to the inspection of the shipment to ensure the labeling and contents are consistent with the information on the bill of lading.

In addition to the previous successful processing through your agency, our legal acquisition of these chemicals was scrutinized extensively in the courts, up to and including the Supreme Court

of the United States of America. Clearly, our actions were approved and we were allowed to successfully utilize these chemicals as a result.

I look forward to your timely and positive response as well as your agency's release of this shipment.

Sincerely,

Charles L. Ryan
Director

cc: Charles Flanagan, Deputy Director
Robert Patton, Division Director, Operations
Karyn Klausner, General Counsel
Kent Cattani, Assistant Attorney General, Capital Appeals Section
Michael Levy, Division of New Drugs and Labeling Compliance
Daniel Solis, Director, Imports Operations Branch
Evanguel Strickland, Import Supervisor
David Thomas, DCM FDA Investigations, Phoenix Office

Arizona Department of Corrections

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

JANICE K. BREWER
GOVERNOR

CHARLES L. RYAN
DIRECTOR

November 10, 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: Inspection and Release of Entry #574-0251126-5, Thiopental Sodium

Dear Mr. Thomas:

The purpose of this correspondence regards our latest receipt of pharmaceutical products from Dream Pharma, Ltd. of London, England. We placed the order with this company for the purpose of securing the necessary drugs for carrying out prospective execution warrants to be issued by the Arizona Supreme Court.

In order to proceed with the executions we must have the product ordered through Dream Pharma. Our DEA Registration number is: (b) (7)(E) and it expires June 30, 2013. Our agency is mandated to possess the necessary chemicals for the lethal injection protocol as approved. This chemical is not currently available in the United States and will most likely not be available in time for our pending executions.

As you are aware, our prior order was successfully processed following your agency's procedure, and there is a precedent set which we expect will be followed. Any and all steps your agency can take in attending to this shipment expeditiously would be of great assistance to our agency. 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
Deborah M. Autor, Director, Office of Compliance
Michael Levey, Division of New Drugs and Labeling Compliance

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
Federal Public Defender

direct 602.382.2816
800.758.7053
facsimile 602.889.3960
e-mail dale_baich@fd.org

November 17, 2010

via email, original by Federal Express

Thomas Emerick, Assistant Special Agent in Charge
United States Department of Health & Human
Services, Food and Drug Administration
Office of Criminal Investigations
201 Avenida Fabricante, Suite 200
San Clemente, California 92672

Dear Mr. Emerick,

I am writing to report the importation into the United States of non-FDA-approved sodium thiopental for sale and distribution in the state of Arizona. I have information that an Arizona importer obtained the drugs from a distributor in Britain and then sold them to the Arizona Department of Corrections ("ADOC") for use in at least one execution. I am writing to request that your office initiate an investigation into this importation of non-FDA-approved sodium thiopental for sale and distribution.

As you may know, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

---

[1] *See* entry for "Pentothal (thiopental) Injection,"http://www/fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

On October 25, Arizona Attorney General Terry Goddard told a reporter that the sodium thiopental the state intended to use during the upcoming execution of Jeffrey Landrigan was imported from Great Britain.[2] State officials previously confirmed that the sodium thiopental the state intended to use in the Landrigan execution was not a Hospira product. Arizona subsequently used this non-FDA-approved drug to anesthetize Mr. Landrigan in his execution on October 26, 2010.

As stated above, my understanding is that foreign-made thiopental is not approved for use on humans in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[3]

I am willing to assist your investigation in any way that I can, and if you initiate an investigation and find that non-FDA-approved sodium thiopental has been imported illegally into the United States, I ask that you work with federal law enforcement to take all appropriate measures, particularly to prevent future violations of the law.

I appreciate your consideration and review of my request. You may reach me by email at dale_baich@fd.org or at 602-382-2816 should you need any additional information.

Very truly yours,

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/nar

---

[2]Michael Kiefer, U.S. Supreme Court Clears Way for Execution, Arizona Republic, Oct. 26, 2010, http://www.azcentral.com/news/articles/2010/10/25/20101025 arizona-execution-temporary-halt.html

[3]Michael Kiefer, Judge asks Arizona for execution-drug source, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021 arizona-execution-court-blocks-2nd-request.html.

TABS:

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form Approved
OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TE [redacted]

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
111910		[redacted]	112-9938358-2
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
2095		[redacted]	
	8. CONSIGNEE NUMBER [redacted]		**9. IMPORTER NUMBER** [redacted]

10. ULTIMATE CONSIGNEE NAME	11. IMPORTER OF RECORD NAME.
CHEMIQUE PHARMACEUTICALS INC 13306 E WHITTIER BLVD WHITTIER CA 90602	[redacted]

12. CARRIER CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(S)/NAME(S)
[redacted]	[redacted]	[redacted]

15. VESSEL CODE/NAME	

16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE
2095			[redacted]

20. DESCRIPTION OF MERCHANDISE

PHARMACEUTICALS NOT RESTRICTED

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
	TOTAL	[redacted]	[redacted]	GB	GBDREPHA176LON
M	02358560751				
H	688760418962	[redacted]			

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.

[redacted]

PHONE NO. [redacted]

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 [redacted]

Customs Form 3461 (010189)

FDA 000030

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:

[redacted]

Delivery Address:

[redacted]

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	[redacted]	[redacted]	[redacted]

Statement Details

Goods Total: [redacted]	Subtota[redacted]
Discount (%): [redacted]	VAT (World Zero): [redacted]
Delivery: [redacted]	Previous Balance: [redacted]
Insurance: [redacted]	**Total** [redacted] USD - US Dollar
	Payment Method: Prepayment Thank You

Shipping Details

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

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

Company Registration Number: [redacted] VAT No. [redacted]
Director: M. Alavi

08-FDA OASIS v5.12.00 Web Application. Production - WebUtil - Microsoft Internet Explorer

File Edit View Add Action District National Reference Products Admin User Opts Help Window

All Activities

All Activities

Entry Number 112-9938358-2 **Line #** 1 - 1 -

Product Description 688760418962 THIOPENTAL

Date Activity Initiated	Pending Text	Owner	Sup Review
01-06-2011	Commercial Entry Closed		
01-06-2011	Released		
01-06-2011	Status Closed		
01-06-2011	Misc Corresp Acknowledged		
01-06-2011	Misc Info Recd		
12-30-2010	Misc Info Recd		
12-30-2010	Misc Info Recd		
11-24-2010	Hold Desg/Others Go		
11-24-2010	Detain Rqst		
11-24-2010	Priority Rev Recom		
11-24-2010	Entry Being Screened		
11-24-2010	Entry Avail for Screening		
11-24-2010	ACS FDA REVIEW		
11-24-2010	No Hit at ACS		

View Comments

Cancel

FDA 000032

STATE OF CALIFORNIA —DEPARTMENT OF CORRECTIONS AND REHABILITATION ARNOLD SCHWARZENEGGER, GOVERNOR

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 521 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 521 grams of sodium thiopental. If you have any questions, concerns or any changes arise, please contact me at (916) 323-6001 or Mr. McAuliffe at (707) 480-6766.

Sincerely,

BENJAMIN T. RICE
General Counsel

cc: John McAuliffe

Sodium Thiopental Statement, Key Messages
December 29, 2010

First, we would confirm the shipments are imported on or behalf of state correctional authorities.

Second, we would release the shipments with the following comment:

"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."

Third, we would use the following key messages and Q and A to respond to inquiries from the news media and other interested parties.

Key Messages

*The U.S. Food and Drug Administration (FDA) is charged by Congress with protecting the public health. Ensuring the safety and effectiveness of pharmaceuticals used for medical purposes is a core part of FDA's mission.

*Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role. FDA does not verify the identity, potency, safety, or effectiveness of substances imported for this purpose. FDA exercises similar enforcement discretion when these drugs are manufactured and purchased within the United States.

*Accordingly, FDA chooses to continue to defer to law enforcement on all matters involving lethal injection, consistent with the U.S. Supreme Court's ruling in Heckler v. Chaney (1985).

Q and A

1.) What has happened so far this year with the imports of sodium thiopental?

In 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law enforcement in the use of substances for lethal injection, which is consistent with the agency's longstanding policy. The agency did not conduct any review of these products for safety, effectiveness or quality.

2.) What has changed?

Two things. In the context of two death penalty cases in the fall of 2010, it was suggested that FDA "approves" the importation of these drugs for use in lethal injections and/or reviews them for safety, effectiveness, and quality. In actuality, the FDA neither approves nor reviews these drugs for use in lethal injections and feels it necessary to clear up any confusion. Also, FDA reviewed its procedures for the importation of sodium thiopental in concert with CBP. The agencies decided that since FDA does not conduct a review of pharmaceuticals intended for lethal injection, FDA will continue to exercise its enforcement discretion and defer to CBP's system for processing importations. The agencies are working together to develop a system for future shipments that avoids any confusion about whether FDA evaluates shipments of drugs intended for lethal injection.

3.) Is the importation of unapproved sodium thiopental for lethal injection illegal?

In deferring to law enforcement on matters involving pharmaceuticals for lethal injection, FDA is exercising enforcement discretion. This approach by the agency was upheld by the Supreme Court in Heckler v. Chaney (1985). Among the reasons cited by the Court for its decision not to review FDA's non-enforcement against lethal injection drugs is that agencies are responsible for prioritizing their enforcement resources to most effectively achieve their statutory missions. Again, FDA similarly defers to law enforcement with respect to transport of these substances within the United States.

4.) What will happen to any shipments that are currently pending?

FDA is releasing these with the comment: "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."

Dohm, Julie

From: Burgess, Shelly
Sent: Tuesday, January 04, 2011 9:50 AM
To: 'Koppel, Nathan'
Subject: FW: update
Importance: High

Nathan - As discussed, the following is the latest FDA position on sodium thiopental.

The U.S. Food and Drug Administration (FDA) is charged by Congress with protecting the public health. Ensuring the safety and effectiveness of pharmaceuticals used for medical purposes is a core part of FDA's mission.

Reviewing substances imported or used for the purpose of state-authorized lethal injection clearly falls outside of FDA's explicit public health role. FDA does not verify the identity, potency, safety, or effectiveness of substances imported for this purpose. FDA exercises similar enforcement discretion when these drugs are manufactured and purchased within the United States.

Accordingly, FDA chooses to continue to defer to law enforcement on all matters involving lethal injection, consistent with the U.S. Supreme Court's ruling in Heckler v. Chaney (1985).

Following is information that addresses the import of sodium thiopental -

So far this year with the imports of sodium thiopental , inn 2009 and 2010, FDA permitted the importation of several shipments of sodium thiopental to state Departments of Correction. In doing so, FDA deferred to law enforcement in the use of substances for lethal injection, which is consistent with the agency's longstanding policy. The agency did not conduct any review of these products for safety, effectiveness or quality.

In the context of two death penalty cases in the fall of 2010, it was suggested that FDA "approves" the importation of these drugs for use in lethal injections and/or reviews them for safety, effectiveness, and quality. In actuality, the FDA neither approves nor reviews these drugs for use in lethal injections and feels it necessary to clear up any confusion. Also, FDA reviewed its procedures for the importation of sodium thiopental in concert with CBP. The agencies decided that since FDA does not conduct a review of pharmaceuticals intended for lethal injection, FDA will continue to exercise its enforcement discretion not to review these shipments and allow processing through CBP's automated system for importations. The agencies are working together to develop a system for future shipments that avoids any confusion about whether FDA evaluates shipments of drugs intended for lethal injection.

Is the importation of unapproved sodium thiopental for lethal injection illegal?

In deferring to law enforcement on matters involving pharmaceuticals for lethal injection, FDA is exercising enforcement discretion. This approach by the agency was upheld by the Supreme Court in Heckler v. Chaney (1985). Among the reasons cited by the Court for its decision not to review FDA's non-enforcement against lethal injection drugs is that agencies are responsible for prioritizing their enforcement resources to most effectively achieve their statutory missions. Again, FDA similarly defers to law enforcement with respect to transport of these substances within the United States.

What will happen to any shipments for correctional facilities that are currently pending?

*FDA is releasing these with the comment: "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."

I will try to find someone to speak with you. I hope this is helpful.

Best,
Shelly

SIDLEY AUSTIN LLP
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FOUNDED 1866

January 4, 2011

By Email and Federal Express

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Sodium Thiopental

Dear Dr. Hamburg:

We write on behalf of clients of the Firm regarding sodium thiopental, a rapid-onset short-acting barbiturate general anesthetic. Sodium thiopental is not generally recognized as safe and effective (GRAS/E), and it is not a "grandfathered" drug. It is, rather, an unapproved new drug, and therefore cannot be introduced, or delivered for introduction, into interstate commerce. 21 U.S.C. § 355(a). Nor can sodium thiopental presented for United States importation lawfully be admitted into domestic commerce. Id. § 381(a). Moreover, because sodium thiopental is unapproved, its safety and efficacy, whether intended for use in anesthesia induction or for other, non-medical purposes, cannot be assured. Indeed, there are ample grounds to suspect the purity and potency of sodium thiopental, based on reports of good manufacturing practice violations affecting at least one important foreign source of the product. Unapproved sodium thiopental has been associated with adverse events including anesthesia awareness (being conscious notwithstanding the administration of an anesthetic) from failure of expected pharmacological activity and tissue necrosis from improper administration technique.

Our clients are incarcerated individuals awaiting administration of sodium thiopental as part of three-drug lethal injection protocols in various States, including California, Arizona, and Tennessee. In October and November, respectively, our co-counsel Dale Baich of the Capital Habeas Unit of the Office of the Federal Public Defender for the District of Arizona sent letters to the Office of the Chief Counsel and to the Los Angeles District Office on behalf of another individual in Arizona, who has since been executed. *See* Enclosure A (Baich letters). The purpose of those letters was to encourage appropriate FDA personnel to investigate and take action to assure that ex-U.S. sources of sodium thiopental were not permitted to enter the country illegally.

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We are not aware that any action has been taken in response to Mr. Baich's requests. Indeed, FDA has announced that it lacks the statutory authority to regulate sodium thiopental for this purpose, and certain agency representatives appear to have determined that the drug can be allowed into the United States as an exercise in "enforcement discretion." *See* Enclosure B (notice of FDA action reflecting agency decision to release sodium thiopental to the State of Arizona Corrections Department). We understand that additional sodium thiopental—a much larger quantity than the Arizona shipment—more recently was released upon an FDA determination to allow the drug to proceed into domestic commerce for use in lethal injection procedures in California.

We have been engaged to evaluate potential claims against FDA on behalf of our clients. Based upon our preliminary review, we believe that FDA decisions allowing the importation of sodium thiopental violate the clear terms of the FDCA. The decision whether to allow unapproved new drugs to be imported into the United States is not a matter of enforcement discretion for FDA but has instead been made by Congress itself. It is reflected directly in the text of the FDCA. Where there is no reasonable dispute that a new drug is unapproved, as is the case with sodium thiopental, FDA acts unlawfully if it allows the drug to be imported for any purpose.

In contrast to the situation in *Heckler v. Chaney*, 470 U.S. 821 (1985), which involved a petition that FDA regulate off-label use of approved drugs, here a court would have a statutory standard against which to review the agency's action (*i.e.*, 21 U.S.C. § 381(a)). *See Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 69 n.8 (D.D.C. 2010) (FDA argument that "import decisions are committed to agency discretion" went "much too far" because 21 U.S.C. § 381(a) provided "a meaningful standard" under *Heckler*), *aff'd sub nom. Sottera, Inc. v. FDA*, 2010 U.S. App. LEXIS 24883 (D.C. Cir. Dec. 7, 2010). Further, *Heckler* itself held that review would be available if FDA's decision were based on an erroneous interpretation of the scope of its statutory authority or amounted to a complete abdication of its responsibilities under the FDCA.

In litigation, our requested relief would include a court order directing FDA to forbid illegal U.S. importation of sodium thiopental. In an effort to resolve the status of sodium thiopental without resorting to litigation, we intend to seek a meeting with you and other appropriate representatives of the agency to discuss our conclusions as to the viability of our clients' claims and any potential defenses. We expect that we will be prepared to have that meeting as early as the middle of January.

In the interim, we ask that the agency decline to authorize the release into domestic commerce of any sodium thiopental, whether it is currently awaiting admission into the United States or is presented for such admission at some future time. If additional sodium thiopental were to be allowed into the country before any litigation were commenced, then it could present

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a number of challenges for agency personnel if a court were to direct recovery of the drug. We believe that it would be in FDA's interest to seek to preserve the status quo by declining to authorize the release into commerce of any sodium thiopental, at least until the agency has had the opportunity to assess the strength of the legal arguments we are now developing, or perhaps, if we fail to reach agreement on an appropriate way forward, until important questions regarding FDA's responsibilities with respect to the drug can be resolved by the courts.

We expect to contact you within a matter of days to seek a meeting regarding our clients' potential claims. In the meantime, if you have questions, please feel free to contact us. Thank you for your attention to this important matter.

Very truly yours,

Coleen Klasmeier

Bradford A. Berenson/ech

Bradford A. Berenson

Dale A. Baich/ech

Dale A. Baich
Supervisor, Capital Habeas Unit
Office of the Federal Public Defender for the
District of Arizona

Enclosures

cc (w/encls.): Ralph Tyler
Rick Blumberg

DC1 1886673v.1

A

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
Federal Public Defender

direct 602.382.2816
800.758.7053
facsimile 602.889.3960
e-mail dale_baich@fd.org

October 23, 2010

via email ralph.tyler@fda.hhs.gov

Ralph S. Tyler, Chief Counsel
United States Department of Health & Human
Services, Food and Drug Administration
10903 New Hampshire Avenue
Silver Springs, Maryland 20993-0002

Dear Mr. Tyler,

I am writing you concerning an urgent matter in the State of Arizona pertaining to potential violations of the Food, Drug, and Cosmetic Act, which may result in immediate harm to an Arizona citizen.

Recently I learned that the Arizona Department of Corrections ("ADOC") may have obtained a quantity of non-FDA-approved sodium thiopental that it intends to use on a human being. The State of Arizona intends to use the non-FDA-approved sodium thiopental as one of the drugs in the planned execution of Jeffrey Landrigan, scheduled to take place at 1:00 p.m. Eastern Daylight Time on Tuesday, October 26. As discussed below, Assistant Attorney General Kent Cattani admitted to the Arizona Supreme Court that the sodium thiopental ADOC obtained for use in Mr. Landrigan's execution is not a Hospira product (which, as you know, is the only FDA-approved manufacturer of thiopental).

I am requesting that you expeditiously investigate whether the State of Arizona and its agencies are in possession of a non-FDA-approved drug, and whether the State intends to use it on a human being.

As you are undoubtedly aware, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

On September 21, 2010, the Arizona Supreme Court scheduled Mr. Landrigan's execution. A few days later, Assistant Attorney General Kent Cattani stated to the press that the ADOC did not have sodium thiopental, and that he was not overly optimistic about securing the drug.[2] Mr. Cattani also stated that the ADOC had been looking not only to other states, but also to other countries, to obtain sodium thiopental.[3] On September 30, the ADOC filed a letter with the Arizona Supreme Court, reporting that it had acquired the drug, but the ADOC did not reveal its source. On October 20, Mr. Cattani admitted to the Arizona Supreme Court that the sodium thiopental the ADOC had obtained was not manufactured by Hospira.

Because we know that Hospira is the only manufacturer of sodium thiopental in the United States, and that its product is the only sodium thiopental approved for use in the United States, Mr. Cattani's admission to the Arizona Supreme Court suggests to us that the thiopental the ADOC obtained was made by a foreign manufacturer.

The FDA controls manufacture and distribution of thiopental in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any

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[1]See entry for "Pentothal (thiopental) Injection,"
http://www.fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

[2]Paul Davenport, *Ariz. Death Row Inmate to be Executed in October*, the Associated Press, Sept. 23, 2010,
http://www.trivalleycentral.com/articles/2010/09/23/casa_grande_dispatch/around_arizona/doc4c9b81d4a0fc9230808604.txt.

[3]Michael Kiefer, *Arizona Obtains Drug Supply for Oct. Execution*, Arizona Republic, Oct. 1, 2010,
http://www.azcentral.com/arizonarepublic/local/articles/2010/10/01/20101001deathdrugs1001.html.

firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[4] I have received the name of a local customs broker through an anonymous phone call, which was identified as the source of the sodium thiopental.[5] If this information is accurate, then ADOC's acquisition of sodium thiopental through a customs broker, would appear to be different than the FDA's understanding as expressed through the statement by Ms. Burgess.

We believe that the ADOC may violate federal law if it administers sodium thiopental that has not been approved by the FDA to Mr. Landrigan. We further believe that the ADOC, by acquiring sodium thiopental from a foreign source, directly or indirectly, may have violated the Food, Drug and Cosmetic Act ("FDCA") and the Controlled Substances Act ("CSA").[6]

The FDCA provides that "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless approval of an application . . . is effective with

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[4]Michael Kiefer, *Judge asks Arizona for execution-drug source*, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021arizona-execution-court-blocks-2nd-request.html.

[5]In the event the FDA is interested in pursuing this matter, I will provide you with the name of the local customs broker.

[6]We understand the FDA has no authority to enforce the CSA. However, a referral to the Drug Enforcement Administration may be appropriate.

If a controlled substances is imported into the United States "for medical, scientific or other legitimate uses" (here it was not), the registered importer must file a controlled substance import declaration not later than 15 calendar days prior to importation. 21 C.F.R. 1312.18(a) & (b). The declaration must include the DEA registration number of the importer and import broker, a complete description of the controlled substances, the quantity of controlled substance, DEA registration number of the recipient, date and foreign port of exportation, and the name and address of the consignor in the foreign country of exportation, and any registration or license numbers the consignor may be required to have by if the country of exportation or under U.S. law. 21 C.F.R. 1312.18(c).

respect to each drug."[7] Furthermore, the FDCA requires "foreign establishments" that manufacture drugs imported into the United States to register with the FDA.[8] To date, we have seen no indication that the ADOC applied to import sodium thiopental, or that its source of the drug is registered with the FDA.

It is our position that an execution is not a "legitimate use" that would justify importation of a non-FDA approved form of thiopental. Sodium thiopental is used to anesthetize the prisoner so that he is insensate to the pancuronium bromide and potassium chloride just as it is used in medical procedures, and the execution would be inhumane if it sodium thiopental did not work as planned.

I believe that my concerns, which pertain to matters such as drug misbranding and drug adulteration, fall under the authority of two divisions within the Office of Compliance (OCI): the Division of New Drugs and Labeling Compliance (responsible for, *inter alia*, concerns about misbranding), and the Division of Manufacturing and Product Quality (responsible for, *inter alia*, concerns about adulteration). Accordingly, I ask that you immediately refer this matter to those divisions for an emergency investigation. If those investigations demonstrate that the ADOC intends to use a non-FDA-approved product, I ask that the appropriate personnel consider obtaining a temporary restraining order ("TRO") against—at a minimum—ADOC staff, to enjoin those individuals who intend to administer the non-FDA-approved thiopental to a human being—Jeffrey T. Landrigan. *See* FDA Regulatory Procedures Manual § 6-2-3 ("FDA Recommends a TRO when the agency believes that the violation is so serious that it must be controlled immediately."). I also ask that the Office of Compliance take any further action deemed necessary under the Food, Drug, and Cosmetic Act, or any other relevant authority to prevent this and future occurrences of any violations that OCI finds.

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[7] 21 U.S.C. § 355(a).

[8] 21 U.S.C. § 360(i). At the time of registration, the foreign establishment must file with the Secretary a list of all drugs that are being "manufactured, prepared, propagated, compounded, or processed" for commercial distribution. 21 U.S.C. § 360(j)(1). If a foreign establishment lists "new drugs," in its filing, it must also provide "a reference to the authority for the marketing of such drug" and provide a copy of the labeling. 21 U.S.C. § 360(j)(1)(A).

Again, this matter is urgent. I appreciate your expeditious consideration and review of my request. You may reach me by email at dale_baich@fd.org or on my mobile at 602-625-2111 should you need any additional information.

Very truly yours,

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/kls

cc: Jeffrey T. Landrigan

Office of the
FEDERAL PUBLIC DEFENDER
for the District of Arizona
Capital Habeas Unit
850 West Adams Street, Suite 201
Phoenix, Arizona 85007

JON M. SANDS
Federal Public Defender

direct 602.382.2816
800.758.7053
facsimile 602.889.3960
e-mail dale_baich@fd.org

November 17, 2010

via email, original by Federal Express

Thomas Emerick, Assistant Special Agent in Charge
United States Department of Health & Human
Services, Food and Drug Administration
Office of Criminal Investigations
201 Avenida Fabricante, Suite 200
San Clemente, California 92672

Dear Mr. Emerick,

I am writing to report the importation into the United States of non-FDA-approved sodium thiopental for sale and distribution in the state of Arizona. I have information that an Arizona importer obtained the drugs from a distributor in Britain and then sold them to the Arizona Department of Corrections ("ADOC") for use in at least one execution. I am writing to request that your office initiate an investigation into this importation of non-FDA-approved sodium thiopental for sale and distribution.

As you may know, there is a shortage of sodium thiopental in the United States.[1] Hospira, Inc. ("Hospira") is the only manufacturer of sodium thiopental in the United States, and its product is the only sodium thiopental that the FDA has approved for use in this country. There are no FDA-approved manufacturers of sodium thiopental outside of the United States. Our research has revealed that Hospira manufactured its last lot of sodium thiopental in 2009.

[1] *See* entry for "Pentothal (thiopental) Injection,"http://www/fda.gov/drugs/drugsafety/drugshortages/ucm050792.htm.

On October 25, Arizona Attorney General Terry Goddard told a reporter that the sodium thiopental the state intended to use during the upcoming execution of Jeffrey Landrigan was imported from Great Britain.[2] State officials previously confirmed that the sodium thiopental the state intended to use in the Landrigan execution was not a Hospira product. Arizona subsequently used this non-FDA-approved drug to anesthetize Mr. Landrigan in his execution on October 26, 2010.

As stated above, my understanding is that foreign-made thiopental is not approved for use on humans in this country. According to Shelly Burgess, a spokesperson at the FDA, the agency "is not aware of any firm currently able to supply thiopental to the U.S. . . . A company would need to submit an application to the FDA in order to be considered for approval including approval for overseas manufacturers of a drug for U.S. markets."[3]

I am willing to assist your investigation in any way that I can, and if you initiate an investigation and find that non-FDA-approved sodium thiopental has been imported illegally into the United States, I ask that you work with federal law enforcement to take all appropriate measures, particularly to prevent future violations of the law.

I appreciate your consideration and review of my request. You may reach me by email at dale_baich@fd.org or at 602-382-2816 should you need any additional information.

Very truly yours,

Dale A. Baich, Supervisor
Capital Habeas Unit

DAB/nar

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[2]Michael Kiefer, U.S. Supreme Court Clears Way for Execution, Arizona Republic, Oct. 26, 2010, http://www.azcentral.com/news/articles/2010/10/25/20101025 arizona-execution-temporary-halt.html

[3]Michael Kiefer, Judge asks Arizona for execution-drug source, Arizona Republic, October 22, 2010, http://www.azcentral.com/community/pinal/articles/2010/10/21/20101021 arizona-execution-court-blocks-2nd-request.html.

B

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0250322-1

Notice Number: 1
September 29, 2010

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

Port of Entry: 2605, Phoenix, AZ
Carrier: FEDERAL EXPRESS;
Date Received: September 29, 2010
Arrival Date: September 28, 2010
Filer of Record: [redacted]
Consignee: Arizona State Prison Complex, Florence, AZ 85232

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	THIOPENTAL SODIUM 500 MG	6 BX	Released 09-29-2010
002/001	PANCURONIUM INJECTION	450 PC	Line Split
002/001A	PANCURONIUM BROMIDE	45 BX	Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE	18 BX	Released 09-29-2010

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

@ = Consignee ID

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

[redacted]

U.S. Food & Drug Administration [redacted] @FDA.HHS.GOV

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

Guidance for handling pending and future shipments of Sodium Thiopenthal

- **Pending shipments** (2 entries recommended for detention; 3 entries with documents requested):

A. 3 entries with documents requested:
- 112-9839758-3 (SWID)
- 574-0251126-5 (LOS-DO)
- M73-0106684-2 (SWID)

Entry Reviewers:

1. Entry reviewers should review the documents provided by the broker to determine if pending lines are destined for correctional facilities.

   a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

   b. If the document review indicates the shipment is going to a correctional facility, assign a Detention Request (DTR) to the line in order to move it to compliance branch.

Compliance Officers:

1. Select Misc Info Recd from the Next Steps (Log Receipt and Response) screen. Enter "entry documents received" in the Remarks field.

2. Select Miscellaneous Correspondence from the Next Steps (Log Receipt and Response) screen. Enter the following in the Narrative field:

   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.

3. Select release and immediately print out the Notice of FDA Action.

4. The Notice of FDA Action will be routed to the filer, importer of record, and consignee (if different from the importer).

5. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature.

6. Mail the CORRECTIONAL FACILITY LETTER to the correctional facility only along with the Notice of FDA Action. In instances where the correctional facility is not the importer or consignee, there will be no Notice of FDA Action for the correctional facility; send only the CORRECTIONAL FACILITY LETTER to the correctional facility.

7. A copy of the signed letter, the Notice of FDA Action, and the entry documentation will be kept in the district's files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the entry reviewer determines that any shipment of sodium thiopental is not destined for a correctional facility, per #1a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the Compliance Officer and will send a copy of the case file, including OASIS screen shots for the entry.

B. 2 current entries that have been recommended for detention:
   - 112-9673446-4 (NOL-DO)
   - 112-9938358-2 (NOL-DO)

Compliance Officers:

1. Request documents from the broker to determine if pending lines are destined for correctional facilities, if not already done by Investigations Branch (IB).

2. Review documents submitted by broker or IB to determine if pending lines are destined for correctional facilities.

   a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

b. If the document review indicates the shipment is going to a correctional facility, the Compliance Officer will:

i. Select Misc Info Recd from the Next Steps (Log Receipt and Response) screen. Enter "entry documents received" in the Remarks field.

ii. Select Miscellaneous Correspondence from the Next Steps (Log Receipt and Response) screen. Enter the following in the Narrative field:

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.

3. Select release and immediately print out the Notice of FDA Action.

4. The Notice of FDA Action will be routed to the filer, importer of record, and consignee (if different from the importer).

5. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature.

6. Mail the CORRECTIONAL FACILITY LETTER to the correctional facility only along with the Notice of FDA Action. In instances where the correctional facility is not the importer or consignee, there will be no Notice of FDA Action for the correctional facility; send only the CORRECTIONAL FACILITY LETTER to the correctional facility.

7. A copy of the signed letter, the Notice of FDA Action, and the entry documentation will be kept in the district's files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the shipment of sodium thiopental is not destined for a correctional facility, per #1a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the Compliance Officer and will send a copy of the case file, including OASIS screen shots for the entry.

- **Future entries effective January 5, 2011:**

DIOP Systems Branch:

1. Criteria will be placed in OASIS and MARCS ER to flag all shipments of Sodium Thiopental as a priority review.

Entry Reviewers:

1. When an entry of sodium thiopental is identified, do not search the agency's databases to verify manufactures registration and listing information or the approval status of the drug.

2. Request documents from the broker to determine if the line(s) are destined for correctional facilities.

3. Review documents submitted by broker to determine if pending lines are destined for correctional facilities.

    a. If they are not destined for a correctional facility, notify DIOP via e-mail and process the line in accordance with current operational procedures for making admissibility decisions on imported drugs. Also notify DIOP when the final admissibility determination is made.

    b. If the document review illustrates that it is going to a correctional facility, the Entry Reviewer will select May Proceed and enter the following narrative when prompted:

        "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"

4. Take a screen shot (print screen) of the language documented in the "Remarks" section. This document will be forwarded to DIOP as part of the HQ notification process.

5. The line will then be "May Proceeded".

6. Prepare the CORRECTIONAL FACILITY LETTER for the District Director's (or designee's) signature. Mail the letter to the correctional facility only.

7. A copy of the signed letter, the "Remarks" screen shot, and the entry documentation will be kept in the districts files. The entire file will also be scanned and emailed to DIOP as a .pdf file.

DIOP Operations Branch:

1. If the shipment of sodium thiopental is not destined for a correctional facility, per #3a above, DIOP will notify the Commissioner's office of said shipment. DIOP will also notify OC when the final admissibility decision has been made.

2. If destined for a correctional facility, DIOP will inform the Commissioner's Office when shipment is released by the District and will send a copy of the case file, including OASIS screen shots for the entry.

Additional actions that need to be completed:

1. Compliance Policy Guide needs to be written.

2. Conference call needs to be set up to notify import staff across the organization on the new guidance and answer questions that they may have.

3. Reports will be generated and used to assure that guidance is being followed uniformly and consistently across ORA and feedback provided in accordance with QMS policies.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

[DISTRICT LETTERHEAD]

CORRECTIONAL FACILITY LETTER template

[CORRECTIONAL FACILITY NAME & ADDRESS]

This letter provides the status of entry # XXX-XXXXX-X, which consists of [AMOUNT] of [PRODUCT DESCRIPTION]. 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,

[DISTRICT DIRECTOR SIGNATURE BLOCK]

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:
[redacted]

>

Port of Entry: [redacted] - Memphis, Memphis, TN
Carrier: [redacted]
Date Received: November 24, 2010
Arrival Date: November 19, 2010
Filer of Record: [redacted]
Consignee: Chemique Pharmaceuticals Inc, Whittier, CA 90602-3052

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COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	688760418962 THIOPENTAL	[redacted]	Released 01-06-2011

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

@ = Consignee ID

This is the final notice concerning entry 112-9938358-2. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA	Product Description
001/001	688760418962 THIOPENTAL

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

Randy N. Boling, Compliance Officer (Region/District)
U.S. Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120-4042

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

LINES RELEASED

Line ACS/FDA	Product Description
001/001	688760418962 THIOPENTAL

Randy N. Boling, Compliance Officer (Region/District)
U.S. Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120-4042

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

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

United States Food and Drug Administration

Los Angeles District Office

Notice of FDA Action

Entry Number: 574-0251126-5

Notice Number: 1
January 7, 2011

Consignee:
Arizona State Prison Complex
1305 Butte Ave
Florence, AZ 85232

>

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Port of Entry: [redacted] Phoenix, AZ
Carrier: [redacted]
Date Received: October 25, 2010
Arrival Date: October 26, 2010

Filer of Record: [redacted]
Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	THIOPENTAL SODIUM, POWDER	[redacted]	Released 01-06-2011

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

@ = Consignee ID

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

CORRESPONDENCE

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

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

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

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

San Pedro, CA 90731

LINES RELEASED

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

Ruben Delagarza, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
222 W. 6th St., Suite 700
San Pedro, CA 90731

(310) 971-2297
(310) 971-2363 (FAX)
RUBEN.DELAGARZA@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: RD

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 42, 25 vial packets, each vial containing 500 mg of Thiopental Sodium. FDA received documentation for this shipment and verified it is destined for a state correctional facility.

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

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District Office

bc: State of California – Department of Corrections File 112-9938358-2
Hard copy file
DIOP

(916) 323-6001

RNB/tlf

H:\Memphis\SHARED\General Compliance Letters FY 2011\State of California - Department of Corrections and Rehabilitation, Sacramento, CA 1_7_11.doc

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19900 MacArthur Blvd.
Suite 300
Irvine, CA 92612-2445

Telephone: 949-798-7600
FAX: 949-798-7690

Arizona State Prison Complex
Carson McWilliams, Warden
1305 Butte Avenue
P.O. Box 629
Florence, AZ 85232-0000

This letter provides the status of entry # 574-0251126-5, which consists of (100 packets; 4 box; 25 Packet; 500 Milligrams) of Thiopental Sodium Injection, Powder. 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,

Alonza Cruse, District Director
Los Angeles District

Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/24/2009 **Inspection Start Date:** 07/08/2009 **Inspection End Date:** 07/08/2009

Firm Name & Address: Sandoz GmbH , Biochemiestrasse 10 Kundl

Firm Mailing Address: Bachmann Strasse 7, Kundl ,1234, Austria

FEI: 3002806523 **JD/TA:** **County:** **Est Size:** 50,000,000 - and over

Phone: **District:** IOG **Profiled:** Yes

Conveyance Type: **% Interstate:** 100 **Inspectional Responsibility:**

Endorsement

This GMP inspection of the firm Kundl, Austria laboratory facilities was conducted concurrently with an inspection of the firms heparin USP manufacturing site in Schaftenau, Austria. This inspection was performed in accordance with CP 7356.002F, Active Pharmaceutical Ingredient Inspection and CP 7346.832 Drug Process Inspection. The was a limited systems inspection focused on the heparin API analysis. The cinspection covered in limitied aspects included Quality Assurance and Control, including Laboratory and Materials, and Facilities/Equipment systems. It was conducted as per the request of the CDER International Compliance Branch and Division of Field Investigations, International Operations Branch, (Trip No. 2009-116D).

The previous FDA inspection of this facility in Kundl, Austria was conducted in 2008 and was classified VAI. The purpose of that inspection was to conduct a pre-approval and general GMP inspection of Amoxicillin; Clavulanate Potassium (ANDA 90-227) and Cefpodoxime Proxetil (ANDA 90-031). Four observations were noted on a FDA Form 483 regarding raw material/component conformity testing, reserve sample selection, identity of drug product testing and component receipt procedures. Corrections made to the observations were verified during this inspection.

This inspection focused on the quality assurance and control of the following:
Heparin Sodium, USP for Enoxaparin Sodium API, DMF 18557; the applicant is Sandoz (USA)

During this inspection, no observations were noted on a FDA Form 483.
Please see separate memo generted by the OGD reviewer on the inspection. Memo dated 7/20/2009
o=CDER International Compliance Branch
F/U: concur with approval based on facility inspection

Endorsement Location: Turbo/DFI

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Kevin P Foley	01/13/2010 03:16 PM ET	Susan F Laska	01/13/2010 06:07 PM ET
Kevin P Foley	08/06/2009 04:49 PM ET		ET

Establishment Inspection Report	GGD/SMJ	FEI:	**3002806523**
Sandoz GmbH		EI Start:	07/19/2010
Kundl, Austria		EI End:	07/29/2010

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SUMMARY

(written by GGD)
This inspection was a routine GMP inspection conducted in accordance with the Compliance Programs (CPs) 7356.002, "Drug Process Inspections," 7356.002A, "Sterile Drug Process Inspections," 7356.002M, "Inspections of Licensed Therapeutic Drug Products," and 7356.002F, "Bulk Pharmaceutical Chemicals," and the Guidance for Industry Q7A, Good Manufacturing Practice Guidance for APIs. The most recent inspection of this firm was a directed inspection covering the quality control and quality assurance operations specific to Heparin Sodium USP. The inspection was conducted 06Jul – 10Jul2009 concurrently with the inspection of the Sandoz manufacturing facility in Schaftenau, Austria. Heparin Sodium USP is manufactured as described in the Drug Master File (DMF) 18557, at the Schaftenau site and is tested at this site in Kundl Austria. No FDA 483, Inspectional Observations, was issued at the conclusion of the prior inspection and no deficiencies were noted. The inspection was classified as No Action Indicated (NAI).

Establishment Inspection Report	GGD/SMJ	FEI:	**3002806523**
Sandoz GmbH		EI Start:	07/19/2010
Kundl, Austria		EI End:	07/29/2010

The current inspection was requested by the International Operations Branch, (HFC-130), to conduct a full GMP inspection covering the manufacturing processes for products shipped to the United States. The inspection was accomplished under FACTS Assignment ID # 1161698.

Sandoz GmbH (Kundl Austria) continues to manufacture sterile and non-sterile finished dosage form pharmaceutical and biopharmaceutical products, and sterile and non-sterile active pharmaceutical and biopharmaceutical ingredients. The products include cephalosporins, penicillins, and (b)(4) (b)(4) products. The profile classes for U.S. marketed products include SVS (aseptically processed small volume parenterals), LVP (large volume parenterals); POW (powders, includes non-sterile oral and topical); TCM (tablets – prompt release); TCT (tablets – delayed release); TTR (tablets – extended release); CHG (capsules – prompt release); CCS (chemical synthesis crude); CFN (non-sterile bulk by fermentation crude drug); CFS (sterile bulk by fermentation crude drug); CSN (non-sterile bulk by chemical synthesis crude); CSS (sterile bulk by chemical synthesis crude); and CBI (Biotechnology Crude).

The inspection was conducted concurrently with the inspection at the Sandoz GmbH site in Langkampfen, Austria, referred to as the Schaftenau site. Sandoz GmbH, Schaftenau also manufactures sterile and non-sterile finished dosage form pharmaceutical/biopharmaceutical products and active pharmaceutical/biopharmaceutical ingredients. All release and stability testing for products manufactured at the Schaftenau site is performed by at the Sandoz GmbH Kundl site. In light of the types of products and profiles classes, the time allotted for this inspection at both sites was insufficient to conduct a comprehensive cGMP inspection covering all profile classes. Five days was allotted for the inspection at the Kundl site and 4 days was allotted for the inspection at the Schaftenau site.

The current inspection at the Kundl site evaluated the quality, production, and laboratory-control systems, and to a limited extent the facilities-and-equipment, and packaging-and-labeling systems. Several deficiencies were noted and were listed on a FDA-483, Inspectional Observations, issued at the conclusion of the inspection to Mr. Ernst Meijnders, Chief Executive Officer and Head of Business Unit Anti-Infectives & API.

The deficiencies and recommendations noted during the inspection pertained to investigations and documentation of unusual events/occurrences; the personnel monitoring program and gowning practices; (b)(4) sterilization of equipment and supplies in the (b)(4), equipment cleaning and use logs; and the containment program. They included the following.

- The investigation related to the sterility failure of (b)(4); was poorly documented in that it did not include an evaluation of (b)(4) which was aseptically filled on the same day (09Apr2009) prior to (b)(4). The filling equipment/line was not dismantled and cleaned/sterilized between batches (b)(4) and (b)(4). Sterile (b)(4) products are aseptically filled on a campaign basis which consists of up to (b)(4) fill days. One of the possible causes of the sterility failure was attributed to a change of the

transport belts in the filling machine during the fill of (b)(4); however, this was performed successfully during a subsequent media fill. A second possible cause of the failure was a mix up of the vials sampled for sterility samples and machine adjustment vials after replacement of the belt. However, this could not conclusively be shown and product in the machine adjustment vials should be sterile. Additionally, environmental monitoring data collected during both fills including settling plates which are exposed on the fill line though out the aseptic fill revealed no problems. Only batch (b)(4) was rejected.

- Procedure 07.070 "Aseptic Filling of (b)(4)" was found deficient in that the change of a transport belt during an aseptic fill, which requires clearing the line of all vials, is not identified as a critical event. As such it would not be recorded in the production record documentation. Additionally, the procedure does not require operators to document unusual events at the time of occurrence. For example, during the aseptic fill of (b)(4), vials were falling over and problems were experienced with the transport belt, which had to be replaced. These occurrences were not recorded in the batch production record.

- Personnel responsible for cleaning the grade (b)(4) areas in the aseptic processing areas (including fill rooms) are not monitored except during their (b)(4) requalification. (b)(4) the cleaning personnel gown in sterile garb and enter the aseptic filling room to clean the grade (b)(4) areas outside the filling line while production activities are ongoing.

- The actual number of materials and equipment sterilized in the (b)(4) for each individual (b)(4) run/load are not documented to ensure that the maximum load established during validation is not exceeded.

- The sterile face mask and hood worn during aseptic filling operations does not always provide sufficient coverage. On 19Jul2010, during the aseptic fill of (b)(4) batch (b)(4), exposed skin was observed between the face mask and the hood of two aseptic filling operators caused by an inadequate fit of the mask. On 20Jul2010, this was again observed during the demonstration of the gowning procedure.

- Equipment cleaning and use logs are inadequate in that the product name, batch number, and cleaning times are not routinely recorded.

- The containment program does not include an adequate evaluation of personnel movement between the (b)(4) production plants in that personnel are not periodically monitored and personnel are not restricted from moving between the buildings where (b)(4) products are manufactured.

In addition, several deficiencies and/or recommendations were presented verbally during the close-out discussion. They included the following.

- The interventions during the worst case media fills for lines (b)(4) and (b)(4) do not adequately reflect the interventions during the fill. (b)(4) bags of (b)(4) are manually added to the hopper on the filling line per batch. However, only (b)(4) additions are simulated during a media fill. This concern was noted late in the inspection and as such was discussed verbally with management.

- Smoke studies to evaluate air flow patterns in the Grade (b)(4) areas outside the aseptic filling lines appear outdated in that they were performed with minimal equipment and supplies in the fill rooms. Currently a large rack with 7 to 8 shelves packed full of sterile equipment and supplies, trolleys (b)(4) with canisters containing sterile (b)(4), the (b)(4) conveyor/cart, the table containing the weigh area for the canisters and/or bags of product, a step ladder, and a chair, etc., are routinely located in the filling rooms during production activities.

- Not all aseptic fill lines are equipped with timers to ensure that personnel performing the (b)(4) control are changed after (b)(4) as required in procedure 02.016.

- Personnel working in controlled (Grade (b)(4) areas and non-sterile production areas are not required to wear socks.

Firm management corrected many of the deficiencies/recommendations prior to completion of the inspection and stated they would respond in writing to the observations.

ADMINISTRATIVE DATA

Inspected firm:	Sandoz GmbH
Location:	Biochemiestrasse 10 Kundl, Austria
Phone:	+43 (0) 5338 200 3400
FAX:	+43 (0) 5338 200 3650
Mailing address:	Biochemiestrasse 10 6250 Kundl, Austria
Dates of inspection:	7/19/2010, 7/20/2010, 7/21/2010, 7/22/2010, 7/23/2010, 7/27/2010, 7/29/2010
Days in the facility:	7
Participants:	Gwyn G. Dickinson, Investigator Susan M. Jackson, Microbiologist

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration, CDER/OC/DMPQ/ICT, HFD-325 10903 New Hampshire Avenue, Building 51, Room 4218 Silver Spring, Maryland 20993 USA Tel. No. 301 796-3334, Fax No. 301 847-8738	July 19-23, 27, & 29, 2010 FEI NUMBER 3002806523

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Ernst Meijnders, Head of Business Unit Anti-Infectives & API, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Sandoz GmbH	Biochemiestrasse 10
CITY, STATE AND ZIP CODE 6250 Kundl, Austria	TYPE OF ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer (Finished Dose & API)

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. The investigation related to the sterility failure of (b)(4) batch (b)(4) was poorly documented in that it did not include an evaluation of (b)(4), batch (b)(4) which was aseptically filled on the same day (09Apr2009) prior to (b)(4).

2. Procedure 07.070 "Aseptic Filling of (b)(4)" is deficient in that the change of a transport belt during an aseptic fill, which requires clearing the line of all vials, is not identified as a critical event. As such it would not be recorded in the production record documentation. Additionally, the procedure does not require operators to document unusual events at the time of occurrence. For example, during the aseptic fill of (b)(4), batch (b)(4), vials were falling over and problems were experienced with the transport belt, which had to be replaced. These occurrences were not recorded in the batch production record.

3. Personnel responsible for cleaning the grade (b)(4) and (b)(4) areas in the aseptic processing areas (including fill rooms) are not monitored except during their (b)(4) requalification.

4. The actual number of materials and equipment sterilized in the (b)(4) for each individual (b)(4) run/load are not documented to ensure that the maximum load established during validation is not exceeded.

5. Equipment cleaning and use logs are inadequate in that the product name, batch number, and cleaning times are not routinely recorded.

6. On 19Jul2010, during the aseptic fill of (b)(4), batch (b)(4), exposed skin was observed between the face mask and the hood of two filling operators caused by an inadequate fit of the mask. On 20Jul2010, this was again observed during the demonstration of the gowning procedure.

7. The Cross Contamination Protection program does not include an adequate evaluation of personnel movement between the (b)(4) and (b)(4) production plants in that personnel are not periodically monitored.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Gwyn G. Dickinson Susan M. Jackson	Gwyn G. Dickinson, Investigator Susan M. Jackson, Microbiologist	July 29, 2010