

U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:58:29 Sign-on Port: 9900 NATIONAL FINANCE CENTER date: 12/08/10

FLR/Entry#: 112/99383582 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2095

Entry type: 01 MOT: 40 Arr dt: 101119 (e) HTS#: 3004909190 FDA prod cd: 60QCZ28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: (b)(4) Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Rx/Single Ingredient;  
Desc: 688760418962 THIOPENTAL

Affirm. of compliance code/qualifier: / More? No

Brand name:	FDA	quantity	/	UOM
USCS qty/UOM : _____ / _____	(1)	(b)(4)	/	VI
USCS value : _____ (b)(4)	(2)	(b)(4)	/	MG
FDA line value: _____	(3)	0	/	_____
Estblshmnt ID : _____ Dmns (L): 0 " 0 /16ths	(4)	0	/	_____
Storage status: _ = _____ X (W): 0 " 0 /16ths	(5)	0	/	_____
BTA PN Confm No: _____ X (H): 0 " 0 /16ths	(6)	0	/	_____

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:57:35 Sign-on Port: 9900 NATIONAL FINANCE CENTER date: 12/08/10

FLR/Entry#: 112/96734464 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2095

Entry type: 11 MOT: 40 Arr dt: 101105 (e) HTS#: 3004909135 FDA prod cd: 60QCZ28

Importer of record: (b)(4) Name: (b)(4)
Ultimate consignee: (b)(4) Name: (b)(4)
FDA Act/Mfgr ID: (b)(4) Name: (b)(4)
FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Rx/Single Ingredient;
Desc: 688760418804/THIOPENTAL SODIUM

Affirm. of compliance code/qualifier: / More? No

Brand name: \_\_\_\_\_ FDA quantity / UOM
USCS qty/UOM : \_\_\_\_\_ / \_\_\_\_\_ USCS c/o : GB (1) (b)(4) / PK
USCS value : (b)(4) USCS c/e : \_\_\_\_\_ (2) / PA
FDA line value: \_\_\_\_\_ FDA c/prod: GB (3) / VI
Estblshmnt ID : \_\_\_\_\_ Dmns (L): 0 " 0 /16ths (4) / MG
Storage status: \_ = \_\_\_\_\_ X (W): 0 " 0 /16ths (5) 0 / \_\_\_\_\_
BTA PN Confm No: \_\_\_\_\_ X (H): 0 " 0 /16ths (6) 0 / \_\_\_\_\_

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;
7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02
Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:57:08 Sign-on Port: 9900 NATIONAL FINANCE CENTER date: 12/08/10

FLR/Entry#: 112/92471863 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2095

Entry type: 11 MOT: 40 Arr dt: 101006 (e) HTS#: 3004909190 FDA prod cd: 60QCY28

Importer of record: (b)(4) Name: (b)(4)
Ultimate consignee: (b)(4) Name: (b)(4)
FDA Act/Mfgr ID: (b)(4) Name: (b)(4)
FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Rx/Single Ingredient;
Desc: 688760418425 THIOPENTAL INJECTIONS

Affirm. of compliance code/qualifier: / More? No

Table with columns: Brand name, USCS qty/UOM, USCS value, FDA line value, Estblshmnt ID, Storage status, BTA PN Confm No, USCS c/o, USCS c/e, FDA c/prod, Dmns (L), X (W), X (H), FDA quantity, UOM. Includes redacted values (b)(4).

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;
7=Backwards; .8=Forwards; 9=FDSE; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02
Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:54:28

Sign-on Port: 9900 NATIONAL FINANCE CENTER

date: 12/08/10

FLR/Entry#: 112/78186378 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2095

Entry type: 11 MOT: 40 Arr dt: 100628 (e) HTS#: 3004909190 FDA prod cd: 60QCR28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: (b)(4) Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Rx/Single Ingredient;

Desc: 688760417429/THIPENTAL 500MG

Affirm. of compliance code/qualifier: /

More? No

Brand name: \_\_\_\_\_ FDA quantity / UOM

USCS qty/UOM : \_\_\_\_\_ / \_\_\_\_\_ USCS c/o : GB (1) (b)(4) / BX

USCS value : \_\_\_\_\_ (b)(4) USCS c/e : \_\_\_\_\_ (2) \_\_\_\_\_ / VI

FDA line value: \_\_\_\_\_ FDA c/prod: GB (3) \_\_\_\_\_ / MG

Estblshmnt ID : \_\_\_\_\_ Dmns (L): 0 " 0 /16ths (4) 0 / \_\_\_\_\_

Storage status: \_ = \_\_\_\_\_ X (W): 0 " 0 /16ths (5) 0 / \_\_\_\_\_

BTA PN Confm No: \_\_\_\_\_ X (H): 0 " 0 /16ths (6) 0 / \_\_\_\_\_

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line#

CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry  
time: 09:53:39 Sign-on Port: 9900 NATIONAL FINANCE CENTER date: 12/08/10

FLR/Entry#: UPS/90668615 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 4196

Entry type: 11 MOT: 40 Arr dt: 100724 (a) HTS#: 3004909130 FDA prod cd: 60QIY28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: (b)(4) Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Investigational; NEC

Desc: THIOPIENTAL/FOR LETHAL INJ/DEA#BG-7074761/LETTER ATTACHED

Affirm. of compliance code/qualifier: / More? No

Brand name: \_\_\_\_\_ FDA quantity / UOM

USCS qty/UOM : \_\_\_\_\_ / \_\_\_\_\_ USCS c/o : GB (1) (b)(4) / MG

USCS value : \_\_\_\_\_ (b)(4) USCS c/e : \_\_\_\_\_ (2) 0 / \_\_\_\_\_

FDA line value: \_\_\_\_\_ FDA c/prod: GB (3) 0 / \_\_\_\_\_

Estblshmnt ID : \_\_\_\_\_ Dmns (L): 0 " 0 /16ths (4) 0 / \_\_\_\_\_

Storage status: A = Ambient X (W): 0 " 0 /16ths (5) 0 / \_\_\_\_\_

BTA PN Confm No: \_\_\_\_\_ X (H): 0 " 0 /16ths (6) 0 / \_\_\_\_\_

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry  
time: 10:04:51 Sign-on Port: 9900 NATIONAL FINANCE CENTER date: 12/08/10

FLR/Entry#: 574/02511265 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2605

Entry type: 01 MOT: 40 Arr dt: 101026 (a) HTS#: 3004909130 FDA prod cd: 60QLK28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: (b)(4) Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/  
Desc: THIOPIENTAL INJECTION

Affirm. of compliance code/qualifier: / More? No

Brand name:	_____	FDA quantity / UOM
USCS qty/UOM:	_____ / _____	USCS c/o : GB (1) (b)(4) / BX
USCS value :	(b)(4)	USCS c/e : _____ (2) / PA
FDA line value:	_____	FDA c/prod: GB (3) / MG
Estblshmnt ID :	_____ Dms (L): 0 " 0 /16ths	(4) 0 / _____
Storage status: _ = _____	X (W): 0 " 0 /16ths	(5) 0 / _____
BTA PN Confm No: _____	X (H): 0 " 0 /16ths	(6) 0 / _____

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;  
7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02  
Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry

time: 10:18:17

Sign-on Port: 9900 NATIONAL FINANCE CENTER

date: 12/08/10

FLR/Entry#: 112/89929790 USCS line#: 001 FDA line#: 001 Total: 1 D/P: 2095

Entry type: 11 MOT: 40 Arr dt: 100917 (e) HTS#: 3004909140 FDA prod cd: 60QCN28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: Name:

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: Name:

FDA Product desc: Thiopental Sodium (Anesthetic); Human - Rx/Single Ingredient;

Desc: 688760418241/THIOPENTAL SODIUM

Affirm. of compliance code/qualifier: /

More? No

Brand name: \_\_\_\_\_ FDA quantity / UOM

USCS qty/UOM : \_\_\_\_\_ / \_\_\_\_\_ USCS c/o : GB (1) (b)(4) / PK

USCS value : (b)(4) USCS c/e : \_\_\_\_\_ (2) \_\_\_\_\_ / PCS

FDA line value: \_\_\_\_\_ FDA c/prod: GB (3) 0 / \_\_\_\_\_

Estblshmnt ID : \_\_\_\_\_ Dmns (L): 0 " 0 /16ths (4) 0 / \_\_\_\_\_

Storage status: \_ = \_\_\_\_\_ X (W): 0 " 0 /16ths (5) 0 / \_\_\_\_\_

BTA PN Confm No: \_\_\_\_\_ X (H): 0 " 0 /16ths (6) 0 / \_\_\_\_\_

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line# CMKY4C02

U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:58:59

Sign-on Port: 9900 NATIONAL FINANCE CENTER

date: 12/08/10

FLR/Entry#: 574/02503221 USCS line#: 001 FDA line#: 001 Total: 3 D/P: 2605

Entry type: 01 MOT: 40 Arr dt: 100928 (a) HTS#: 3004909130 FDA prod cd: 60QLK28

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: (b)(4) Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: (b)(4) Name: (b)(4)

FDA Product desc: Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/  
Desc: THIOPIENTAL INJECTION

Affirm. of compliance code/qualifier: DLS / FA2203571

More? No

Brand name:	FDA	quantity	/	UOM
USCS qty/UOM : _____ / _____	(1)	(b)(4)	/	PCS
USCS value : _____ (b)(4)	(2)	0	/	_____
FDA line value: _____	(3)	0	/	_____
Estblshmnt ID : _____ Dmns (L): 0 " 0 /16ths	(4)	0	/	_____
Storage status: _ = _____ X (W): 0 " 0 /16ths	(5)	0	/	_____
BTA PN Confm No: _____ X (H): 0 " 0 /16ths	(6)	0	/	_____

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line#

CMKY4C02



U.S. Food and Drug Administration - Form 701 Inquiry

time: 09:59:15

Sign-on Port: 9900 NATIONAL FINANCE CENTER

date: 12/08/10

FLR/Entry#: 574/02503221 USCS line#: 002 FDA line#: 001 Total: 3 D/P: 2605

Entry type: 01 MOT: 40 Arr dt: 100928 (a) HTS#: 2933394100 FDA prod cd: 65QLK25

Importer of record: (b)(4) Name: (b)(4)

Ultimate consignee: Name: (b)(4)

FDA Act/Mfgr ID: (b)(4) Name: (b)(4)

FDA Act/Shipper: Name: (b)(4)

FDA Product desc: Pancuronium Bromide (Relaxant); Animal (Food Producing) - Rx/  
Desc: PANCURONIUM INJECTION

Affirm. of compliance code/qualifier: DLS / FA2203571

More? No

Brand name: _____	FDA quantity / UOM
USCS qty/UOM : _____ / _____ USCS c/o : GB	(1) (b)(4) / PC
USCS value : _____ (b)(4) USCS c/e : _____	(2) _____ / ML
FDA line value: _____ FDA c/prod: GB	(3) 0 / _____
Estblshmnt ID : _____ Dmns (L): 0 " 0 /16ths	(4) 0 / _____
Storage status: _ = _____ X (W): 0 " 0 /16ths	(5) 0 / _____
BTA PN Confm No: _____ X (H): 0 " 0 /16ths	(6) 0 / _____

PF: 1=Scrn Help; 2=Fld Help; 3=FDEL; 4=Othr Optns; 5=ENAI; 6=SSAI;

7=Backwards; 8=Forwards; 9=FDES; 10=FDLL ; 11=FDGL; 12=FDHI CPPY4C02

Key: 1/Flr/Entry#/USCS line#/FDA line#

CMKY4C02

**United States Food and Drug Administration**

Los Angeles District Office

**Notice of FDA Action**

Entry Number: 574-0250322-1

Notice Number: 1  
September 29, 2010

Filer:  
Arizona Customs Brokers  
2153 East Jones Ave  
Phoenix, AZ 85040

Attention: SKIP  
Broker Box: 574

Port of Entry: 2805, Phoenix, AZ  
Carrier: FEDERAL EXPRESS;  
Date Received: September 29, 2010  
Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002  
Consignee: Arizona State Prison Complex, Florence, AZ 85232

**COMMERCIAL ENTRY CLOSED**

Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
001/001	THIOPENTAL SODIUM 800 MG	(b) (4)	Released 09-29-2010
002/001	PANCURONIUM INJECTION		Line Split
002/001A	PANCURONIUM BROMIDE		Released 09-29-2010
002/001B	POTASSIUM CHLORIDE INJECTIBLE		Released 09-29-2010

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

@ = Consignee ID

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

David C. Thomas, Investigator  
U.S. Food & Drug Administration  
51 W. 3rd Street, Suite E-285  
Tempe, AZ 85281

(480) 829-7399 ext. 12  
(480) 829-7877 (FAX)  
DAVID.THOMAS@FDA.HHS.GOV

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

B4

266298 - ROBERT

**United States Food and Drug Administration**  
Los Angeles District Office  
**Notice of FDA Action**

Entry Number: 574-0250322-1

Notice Number: 1  
September 29, 2010

Filer:  
Arizona Customs Brokers  
2153 East Jones Ave  
Phoenix, AZ 85040

Attention: SKIP  
Broker Box: 574

Port of Entry: 2605, Phoenix, AZ  
Carrier: FEDERAL EXPRESS;  
Date Received: September 29, 2010  
Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002  
Consignee: Arizona State Prison Complex, Florence, AZ 85232

**COMMERCIAL ENTRY CLOSED**

Summary of Current Status of Individual Lines

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

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

@ = Consignee ID

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

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

(480) 829-7388 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: DCT

**United States Food and Drug Administration**  
Los Angeles District Office  
**Notice of FDA Action**

Entry Number: 674-0250322-1

Notice Number: 1  
September 29, 2010

Filer:  
Arizona Customs Brokers  
2153 East Jones Ave  
Phoenix, AZ 85040

Attention: SKIP  
Broker Box: 574

Port of Entry: 2805, Phoenix, AZ  
Carrier: FEDERAL EXPRESS;  
Date Received: September 29, 2010  
Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002  
Consignee: Arizona State Prison Complex, Florence, AZ 85232

**COMMERCIAL ENTRY CLOSED**

Summary of Current Status of Individual Lines

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

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

@ = Consignee ID

This is the final notice concerning entry 674-0250322-1. 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-285  
Tempe, AZ 85284

(480) 829-7388 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: DCT

266298 - Robert

**United States Food and Drug Administration**

Los Angeles District Office

**Notice of FDA Action**

Entry Number: 574-0250322-1

Notice Number: 1  
September 29, 2010

**Filer:**

Arizona Customs Brokers  
2153 East Jones Ave  
Phoenix, AZ 85040

Attention: SKIP  
Broker Box: 574

> <  
Port of Entry: 2605, Phoenix, AZ  
Carrier: FEDERAL EXPRESS;  
Date Received: September 29, 2010  
Arrival Date: September 28, 2010

Importer of Record: Arizona Department Of Correction, Phoenix, AZ 85007-3002  
Consignee: Arizona State Prison Complex, Florence, AZ 85232

**COMMERCIAL ENTRY CLOSED**

Summary of Current Status of Individual Lines

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

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

@ = Consignee ID

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

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

(480) 820-7398 ext. 12  
(480) 820-7677 (FAX)  
DAVID.THOMAS@FDA.HHS.GOV

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

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, April 04, 2011 5:56 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: DEA seizure of sodium thiopental  
Not a problem. Have a good flight.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Mon Apr 04 05:20:17 2011  
**Subject:** Fw: DEA seizure of sodium thiopental

(b)(6) (b)(7)(C) could you draft a few bullets for Mr. Gina to use as talking points at this morning's 8:30a Intel brief. Please try to give him background (update the issue paper?) As well as current status, including DEA involvement.

I don't now whether he will be at 14L before going to RRB for Intel brief, so please provide hard copy of materials to (b)(6) (b)(7)(C) and blackberry readable material. Keep it simple!

Go ahead and send directly to him and cc me please (I'm on a plane at 8:20a)

Thanks very much. (b)(6) (b)(7)(C)

**From:** GINA, ALLEN  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Sun Apr 03 20:54:00 2011  
**Subject:** Re: DEA seizure of sodium thiopental

(b)(6) (b)(7)(C)

Can you please provide me several bullets that I can use in reporting this issue out at the Monday 0830 C1 brief.

In reading the emails I was not sure if CBP does or does not have an arrangement with FDA for allowing these shipments into the US. I am also perplexed as to the DEA issue with these shipments.

Thanks. AI

**From:** (b)(6) (b)(7)(C)  
**To:** BALDWIN, DAN (XD-CCS)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Sat Apr 02 18:43:34 2011  
**Subject:** Fw: DEA seizure of sodlum thiopental

Dan - this is the only sodium thiopental (ST) related email I have on my bb.

As you may recall, we worked out an approach with FDA that would allow us to flag this as a "may proceed" from FDA, requiring little intervention from CBP or FDA on shipments of ST, claiming a law

7/6/2011

enforcement exemption/purpose. FDA needed to provide us with legal analysis supporting this approach and instructions to the trade. At the last status check, neither had been produced.

My mobikey is acting up, so I don't have access to the original paper but will check with (b)(6) (b)(7)(C) (I believe (b)(6) is traveling). I should also be able to answer specific questions if you have them.

(b)(6) (b)(7)(C)

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**From:** (b)(6) (b)(7)(C)

**To:** (b)(6) (b)(7)(C)

**Sent:** Wed Mar 16 06:48:29 2011

**Subject:** DEA seizure of sodium thiopental

# US seizes key execution drug in Georgia

**DEA has questions about how stockpile was imported**

ATLANTA — The Drug Enforcement Administration confirmed Tuesday that the agency seized the state of Georgia's supply of a key lethal injection drug because of questions about how the stockpile was imported to the U.S.

DEA spokesman Chuvalo Truesdell said he didn't know if other states' supplies of sodium thiopental were being collected. The seizure comes less than two months after a convicted killer in Georgia was executed, despite raising questions about where the state had obtained the drug and whether or not it had expired.

Truesdell wouldn't elaborate on exactly what worried the DEA.

"We had questions about how the drug was imported to the U.S.," he said. "There were concerns."

Georgia's stockpile of the drug has been a target of death row inmates and capital punishment critics since corrections officials released documents this year that showed the state obtained the drug from Link Pharmaceuticals, a firm purchased five years ago by Archimedes Pharma

Limited. Both are British firms.

The drug was used in January to execute Emmanuel Hammond, 45-year-old man convicted for the 1988 shotgun slaying of an Atlanta preschool teacher. His attorneys sought a delay in the execution to gather more information on how the state obtained the drug, claiming in court documents it came from a "fly-by-night supplier operating from the back of a driving school in England." They said the drug could have been counterfeit.

The U.S. Supreme Court, as well as lower courts, rejected Hammond's argument.

Joan Heath, a spokeswoman for the Georgia Department of Corrections, said state officials were not concerned with the quality of the drug.

"We contacted the DEA and asked them for a regulatory review, and that's what we're doing," she said. "We're going to make sure we're in regulatory compliance with the DEA over how we handle controlled substances."

Sodium thiopental, a sedative that is part of a three drug cocktail used in executions, has been in short supply since the sole U.S. manufacturer decided to stop producing it.

The shortage has delayed executions in several states, and an Associated Press review found that at least five states — Arizona, Arkansas, California, Georgia and Tennessee — had to turn to England for their supply of the drug. Nebraska, meanwhile, secured a stockpile from an Indian firm.



(b)(6) (b)(7)(C)

**From:** BALDWIN, DAN (AC-OT)  
**Sent:** Friday, February 18, 2011 11:10 PM  
**To:** 'Todd.Park@hhs.gov'  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: CALL - CBP - HHS Next Steps

Thx. I will pass it on.

Dan

**From:** Park, Todd (HHS/IOS) <Todd.Park@hhs.gov>  
**To:** BALDWIN, DAN (AC-OT)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Fri Feb 18 23:07:04 2011  
**Subject:** Re: CALL - CBP - HHS Next Steps

(b) (5)

Cheers,  
Todd

**From:** BALDWIN, DAN (AC-OT) [mailto:daniel.baldwin@dhs.gov]  
**Sent:** Friday, February 18, 2011 06:25 PM  
**To:** Park, Todd (HHS/IOS)  
**Cc:** (b)(6) (b)(7)(C)@dhs.gov>  
**Subject:** Re: CALL - CBP - HHS Next Steps

Todd,

Could you tell me who your contact at WH has been? We have looped in our NSS contact, (b)(6) (b)(7)(C) and want to be sure there is connectivity at that level as well.

Thanks,

Daniel Baldwin  
Assistant Commissioner  
Office of International Trade  
U.S. Customs and Border Protection  
(202) 863-6000

**From:** Park, Todd (HHS/IOS) <Todd.Park@hhs.gov>  
**To:** (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC) <John.Taylor2@fda.hhs.gov>; Teeter, John (OS/ASA/OCIO) <John.Teeter@HHS.GOV>; Corrigan, Dara (FDA/ORA) <Dara.Corrigan@fda.hhs.gov>; Veneziano, Domenic J. (FDA/ORA) <Domenic.Veneziano@fda.hhs.gov>; Horowitz, David (HHS/OGC) <David.Horowitz@hhs.gov>; Smolonsky, Marc (HHS/IOS) <Marc.Smolonsky@hhs.gov>; (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)@dhs.gov' (b)(6) (b)(7)(C)@dhs.gov>; (b)(6) (b)(7)(C)  
<Laura.Petrou@hhs.gov>; Hughes, Dora (HHS/IOS) <Dora.Hughes@hhs.gov>; (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)@dhs.gov>; BALDWIN, DAN (AC-OT)  
**Cc:** (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORA)

7/7/2011

<Dara.Corrigan@fda.hhs.gov>  
**Sent:** Thu Feb 17 09:07:10 2011  
**Subject:** RE: CALL - CBP - HHS Next Steps

(b) (5)

(b)(6) (b)(7)(C)

**From:** Park, Todd (HHS/IOS)  
**Sent:** Thursday, February 17, 2011 2:30 AM  
**To:** (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORA); Veneziano, Domenic J. (FDA/ORA); Horowitz, David (HHS/OGC); Smolonsky, Marc (HHS/IOS); (b)(6) (b)(7)(C) dhs.gov'; (b)(6) (b)(7)(C) cbp.dhs.gov'; (b)(6) (b)(7)(C) @cbp.dhs.gov'; (b)(6) (b)(7)(C) cbp.dhs.gov'; (b)(6) (b)(7)(C) dhs.gov'; Petrou, Laura (HHS/OS); Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C) cbp.dhs.gov'; (b)(6) (b)(7)(C) dhs.gov'; (b)(6) (b)(7)(C) 'daniel.baldwin@dhs.gov'  
**Cc:** (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORA)  
**Subject:** CALL - CBP - HHS Next Steps

(b) (5)

Thanks very much,  
(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, November 19, 2010 8:22 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: FDA lethal injection drug importation issue

(b)(6) (b)(7)(C)

Check with me on this.

(b)(6) (b)(7)(C)

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**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, November 19, 2010 8:17 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: FDA lethal injection drug importation issue

(b)(6) (b)(7)(C)

Please see below. We will confer with our OIT counterparts on these issues.

(b)(6) (b)(7)(C)

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

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, November 19, 2010 7:21 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: FDA lethal injection drug importation issue

Hello, (b)(6) (b)(7)(C)

WE have been continuing to discuss this issue with DHS and FDA -- I wanted to ask some follow-up questions regarding the ACS inputs.

As I understand the issue from our previous discussions, in practice, CBP does not receive the information that is electronically transmitted directly to FDA -- which consists of more detailed information about the drug itself and the manufacturer (detailed beyond what is required by tariff codes and entry descriptions) -- so that FDA can make a determination whether to test and/or recall the merchandise. Also, CBP typically releases the merchandise for its purposes while FDA is still testing (unless the importation is perishable), and if there is a basis to recall, FDA will notify CBP that the drugs are in violation, and must be recalled for re-export or destruction.

The two messages that CBP gets from FDA are either "release" or "may proceed." The "release" message basically indicates that there are no admissibility issues while the "may proceed" message will allow CBP to go forward and let the shipment go, and then if it later needs to be recalled, CBP can issue a notice for redelivery. Also, as I understand it, if FDA sees an importation that must be tested or that is in violation prior to release by CBP, it will notify CBP at the port involved to detain the shipment. Yes - these are generally the messages CBP gets from FDA's system.

Apparently, FDA no longer wants to have to issue either message in ACS to CBP regarding these importations. DHS, therefore, has asked me to find out answer to the following two questions:

(b) (5)

(b) (5)

Is a notice for redelivery automatically generated after a certain period of time? No, only upon FDA's request is a redelivery notice generated by CBP personnel.

2) If CBP does need a message from FDA to "close out" the records on the importation, could the system be changed to have a message from FDA stating "FDA will not review," or something like, only for these importations. Changing the ACS/FDA interface system to accommodate a new message from FDA although probably possible, would require research to determine the systemic effects, would be time consuming and CBP's programming costs would need to be fully pre-paid by FDA. For the very limited amount of shipments involved, it would probably not be worth the effort, as the programming changes would not be completed in time to address the instant issue as U.S. domestic production of the commodity would be resumed long before any programming changes could be completed.

(b) (5)

(b) (5)  
(b) (5) I am not in the office today, but am available on bberry.

(b)(6) (b)(7)(C)

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

From: (b)(6) (b)(7)(C)  
Sent: Monday, November 15, 2010 12:25 PM  
To: (b)(6) (b)(7)(C)  
Cc: (b)(6) (b)(7)(C)  
Subject: RE: FDA lethal injection drug importation issue

Good afternoon (b)(6) (b)(7)(C)

Per your request, I have attached screen prints of the following entries for your review:

09/29/2010  
574-0250322-1 /1/1  
United Kingdom

Dream Pharma Ltd  
Arizona State Prison Complex  
Arizona Department Of Correction  
2605 - Phoenix

10/25/2010  
574-0251126-5 /1/1  
United Kingdom  
Dream Pharma Ltd  
Arizona State Prison Complex  
Arizona Department Of Correction  
2605 - Phoenix

Note: These were criteria hits for DEA Import Permit Requirements.

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202) (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) @dhs.gov

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

From: (b)(6) (b)(7)(C)

Sent: Monday, November 15, 2010 11:42 AM

To: (b)(6) (b)(7)(C)

Subject: FDA lethal injection drug importation issue

Hi, (b)(6) (b)(7)(C)

Thank you very much for your help this morning in explaining the information flow on entry between the importer/broker, FDA and CBP in the above types of importations. I explained the process to DHS counsel this morning and we had one follow-up question. Is there a way to get a print out of one of the entries of these importations that the broker would file with CBP? The purpose would be to examine the information that is submitted by the broker/importer. Thanks again.

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, November 23, 2010 10:26 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: Lethal Injection Drug Importations

(b)(6) (b)(7)(C)

Thank you very much, this is very helpful, and I think these systematic and cost issues have to be worked out. I will indicate that most of the POC's are out this week, and perhaps early next week would be best. Again, thanks for your help.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:**  
**Sent:** Tue Nov 23 10:16:38 2010  
**Subject:** RE: Lethal Injection Drug Importations

Good morning (b)(6) (b)(7)(C)

(b) (5)

This may not be a good time to proceed forward on this matter as several key players that need to be engaged in the discussions may be out on annual leave due to the upcoming Thanksgiving Holiday. I would recommend that we reconvene on this issue sometime after the holiday. The following is a list of the appropriate CBP points of contact that should be involved in future discussions:

(b)(6) (b)(7)(C) Office of International Trade/Interagency Requirements Branch  
(b)(6) (b)(7)(C) – Office of International Trade/Interagency Requirements Branch

(b)(6) (b)(7)(C) – Office of Field Operations/Trade Operations Division  
(b)(6) (b)(7)(C) – Office of Field Operations/Cargo Control and Release

(b)(6) (b)(7)(C) OIT/Cargo Control and Release  
(b)(6) (b)(7)(C) OIT/Cargo Control and Release

(b)(6) (b)(7)(C)  
International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, November 23, 2010 9:14 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: Lethal Injection Drug Importations

Hi (b)(6) (b)(7)(C)

FDA has asked for CBP operational and technical folks in order to set up a call with FDA counterparts on systems messages and related issues for these importations going forward. Would you be the op experts? Can you also give me OIT contacts for this? Thanks very much.

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Mon Nov 22 10:13:53 2010  
**Subject:** Lethal Injection Darug Importations

Hello, (b)(6) (b)(7)(C)

Just want you to know that the Chief Counsel had a call with FDA Chief Counsel on Friday. In an effort to resolve this issue, FDA agreed to put something in writing which states that it does not have to review these importations, and as a result, CBP can let the importations into the United States. Also, both agencies agreed that the systems people should work together to come up with a proper systems message for these importations for communication from FDA to CBP. I will need your help with that issue, either from you directly, or by identifying some OIT individuals that should be involved. Thank you very much for your help so far – I will keep you updated when I hear from FDA.

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 4:24 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: Conference call with FDA on importation of lethal injection drugs

Hi All:

Below is the call-in information for tomorrow's call with FDA at 10am--

When: Tuesday, November 30, 2010 10:00 AM-10:30 AM (GMT-05:00) Eastern Time (US & Canada).

Where: Call In: 877-934-5064, Code: 9492894

If you haven't already, can you let me know if you are available. Thanks very much.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Mon Nov 29 15:24:08 2010  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

Thanks to all of you. I will let you know the call-in details as soon as I get them.

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 3:20 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

(b)(6) (b)(7)(C)  
I will be willing to sit in on the conference call. Let me know what the number is. I am going to cop (b)(6) (b)(7)(C) on this reply, since (b)(6) (b)(7)(C) is involved with the FDA process.

(b)(6) (b)(7)(C)  
ACS Specialist  
Office of International Trade, ABO  
email: (b)(6) (b)(7)(C)@dhs.gov  
phone: 571 (b)(6) (b)(7)(C)  
fax: 571 (b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 3:07 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs



I am including (b)(6) (b)(7)(C) on this. I think this would fall under (b)(6) (b)(7)(C) umbrella.

I can make the 10am

(b)(6) (b)(7)(C)

Branch Chief - Cargo, Control and Release (CCR)  
ACE Business Office (ABO)  
Office of International Trade (OT)  
Customs and Border Protection (CBP)  
Department of Homeland Security (DHS)

Office Number (Beauregard) - (571) (b)(6) (b)(7)(C)  
Office Number (Tysons) - (b)(6) (b)(7)(C)  
Email: (b)(6) (b)(7)(C) @DHS.gov

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**From:** (b)(6) (b)(7)(C)

**Sent:** Monday, November 29, 2010 2:33 PM

**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Subject:** Conference call with FDA on importation of lethal injection drugs

Hello, All:

Can you all be available tomorrow morning at 10:00 am for a conference call with FDA regarding importation of lethal injection drugs? The focus would be what CBP would need from FDA to let these importations in. Other issues that relate to this matter that CBP wishes to raise could also be discussed at that time. Can you please let me know if you are available – if you are not available, can you please let me know when you will be available for this week. If most of you are available tomorrow morning, we will have the call.

FDA has also asked the following as an initial matter:

- 1) Would FDA have to notify CBP on a shipment-by-shipment basis that it will not review these shipments, and therefore, CBP can let release the shipments; or, would it be possible for FDA to provide one document setting forth why it will not review these shipments, a description of what the importations would look like, and instruct that if the importation fits under the description, CBP can release the shipment. If the second alternative would be acceptable, what would it take to implement this as a practical matter?
- 2) What happens in the system regarding shipments that have been conditionally released, but CBP does not hear from FDA within the 30 day period to demand redelivery of the merchandise? Does the system automatically change the status to "release?"

I really appreciate your help with this matter.

(b)(6) (b)(7)(C)

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**From:** (b)(6) (b)(7)(C)

**Sent:** Monday, November 29, 2010 9:58 AM

**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Subject:** Meeting with FDA re: Importation of Lethal Injection Drugs

Hello, All:

CBP is working with FDA to determine, from a legal as well as OIT standpoint, how CBP would be able to allow these importations to proceed into the country. FDA believes that it has the enforcement discretion to elect not to review these shipments, and as a result, would like to work with CBP to come up with a message that would be sufficient for CBP to release the shipments.

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While my office would be responsible for the legal issues, FDA has asked for the appropriate individuals to discuss the operational side of these issues, particularly systems issues related to these importations. You have been identified as one of those CBP representatives. I will be talking with FDA OCC this morning and you should be hearing from either FDA or me on possible times for further discussions on these issues. Thanks in advance for your help.

(b)(6) (b)(7)(C)

6/29/2011

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, November 30, 2010 10:59 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)

**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

All:

Thanks very much to all of you for your help on this. Obviously, there are some issues but I appreciate you taking the time to give input and work with FDA. I will let you know of any updates I receive from FDA. Thanks again.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 3:24 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

Thanks to all of you. I will let you know the call-in details as soon as I get them.

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 3:20 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

(b)(6) (b)(7)(C)

I will be willing to sit in on the conference call. Let me know what the number is. I am going to copy (b)(6) (b)(7)(C) on this reply, since (b)(6) (b)(7)(C) is involved with the FDA process.

(b)(6) (b)(7)(C)  
ACS Specialist  
Office of International Trade, ABO  
email: (b)(6) (b)(7)(C)@dhs.gov  
phone: 571 (b)(6) (b)(7)(C)  
fax: 571 (b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, November 29, 2010 3:07 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Conference call with FDA on importation of lethal injection drugs

I am including (b)(6) (b)(7)(C) on this. I think this would fall under (b)(6) (b)(7)(C) umbrella.

I can make the 10am

(b)(6) (b)(7)(C)

Branch Chief - Cargo, Control and Release (CCR)  
ACE Business Office (ABO)  
Office of International Trade (OT)  
Customs and Border Protection (CBP)  
Department of Homeland Security (DHS)

Office Number (Beauregard) - (571) (b)(6) (b)(7)(C)  
Office Number (Tysons) - (703) (b)(6) (b)(7)(C)  
Email: (b)(6) (b)(7)(C) @DHS.gov

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**From:** (b)(6) (b)(7)(C)

**Sent:** Monday, November 29, 2010 2:33 PM

**To:** (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

**Subject:** Conference call with FDA on importation of lethal injection drugs

Hello, All:

Can you all be available tomorrow morning at 10:00 am for a conference call with FDA regarding importation of lethal injection drugs? The focus would be what CBP would need from FDA to let these importations in. Other issues that relate to this matter that CBP wishes to raise could also be discussed at that time. Can you please let me know if you are available – if you are not available, can you please let me know when you will be available for this week. If most of you are available tomorrow morning, we will have the call.

FDA has also asked the following as an initial matter:

- 1) Would FDA have to notify CBP on a shipment-by-shipment basis that it will not review these shipments, and therefore, CBP can let release the shipments; or, would it be possible for FDA to provide one document setting forth why it will not review these shipments, a description of what the importations would look like, and instruct that if the importation fits under the description, CBP can release the shipment. If the second alternative would be acceptable, what would it take to implement this as a practical matter?
- 2) What happens in the system regarding shipments that have been conditionally released, but CBP does not hear from FDA within the 30 day period to demand redelivery of the merchandise? Does the system automatically change the status to "release?"

I really appreciate your help with this matter.

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)

**Sent:** Monday, November 29, 2010 9:58 AM

**To:** (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

**Subject:** Meeting with FDA re: Importation of Lethal Injection Drugs

Hello, All:

CBP is working with FDA to determine, from a legal as well as OIT standpoint, how CBP would be able to allow these importations to proceed into the country. FDA believes that it has the enforcement discretion to elect not to review these shipments, and as a result, would like to work with CBP to come up with a message that would be sufficient for CBP to release the shipments.

While my office would be responsible for the legal issues, FDA has asked for the appropriate individuals to discuss the operational side of these issues, particularly systems issues related to these importations. You have

6/29/2011

been identified as one of those CBP representatives. I will be talking with FDA OCC this morning and you should be hearing from either FDA or me on possible times for further discussions on these issues. Thanks in advance for your help.

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

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**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, December 13, 2010 8:46 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: sodium thiopental lethal injection follow up

Yes that is correct. My office has not heard back from FDA on this topic.

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, December 13, 2010 8:44 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: sodium thiopental lethal injection follow up

(b) (5)

(b)(6) (b)(7)(C)  
Acting Executive Director, Trade Policy and Programs  
Office of International Trade  
(202) (b)(6) (b)(7)(C) office  
(202) (b)(6) (b)(7)(C) blackberry

---

**From:** prvs=954bad018=(b)(6) (b)(7)(C)@who.eop.gov  
[mailto:prvs=954bad018=(b)(6) (b)(7)(C)@who.eop.gov] On Behalf Of (b)(6) (b)(7)(C)  
**Sent:** Friday, December 10, 2010 7:30 PM  
**To:** (b)(6) (b)(7)(C)@dhs.gov'  
**Subject:** sodium thiopental lethal injection follow up

(b)(6) (b)(7)(C)

I wanted to follow up with you on the issue of imported thiopental shipments. Both of you were part of our initial interagency call on this matter. (b)(5)

(b) (5)  
(b) (5)

would like to talk with you (or whomever is most appropriate) on this matter... hopefully we will be able to connect on Monday morning. My direct is below. Thanks and have a great weekend!

**Racquel S. Russell**  
Senior Policy Advisor for Health Care  
Domestic Policy Council  
The White House  
202 (b)(6) (b)(7)(C) direct)

(b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [Domenic.Veneziano@fda.hhs.gov]

**Sent:** Tuesday, December 14, 2010 9:20 AM

**To:** (b)(6) (b)(7)(C)

**Cc:** (b)(6) (b)(7)(C)

**Subject:** Conference call needed regarding Drug importation

Good Morning,

I apologize for the short notice, however, I have been asked to set up another conference call this afternoon regarding the importation of Sodium Thiopental to Correctional Facilities. The WH would like us to discuss and prepare a paper on how the process would work if CBP were required to screen shipments of Sodium Thiopental intended for Correctional Facilities and not send them to FDA.

The call is scheduled for 1:00pm today. The call in number is:

Conference number: 866-649-3301

Pass code: 9589150

Thank you

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy

Work: (301) 443-6553

FAX: (301) 594-0413

Cell: (240) 888-9316

6/29/2011

(b)(6) (b)(7)(C)

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**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 10:45 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

(b) (5)

(b)(6) (b)(7)(C)

*Program Manager  
U.S. Customs & Border Protection  
1300 Pennsylvania Avenue N.W.  
Room 2.3-45  
Washington, D.C. 20229*

202 (b)(6) (b)(7)(C) - Phone  
202 (b)(6) (b)(7)(C) - Fax  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 10:38 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

I don't have that information. My guess is that they just want this whole situation to "just go away."

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 10:34 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

*Program Manager  
U.S. Customs & Border Protection  
1300 Pennsylvania Avenue N.W.  
Room 2.3-45  
Washington, D.C. 20229*

202 (b)(6) (b)(7)(C) - Phone

6/29/2011



202 (b)(6) (b)(7)(C) - Fax  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 8:01 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: CBP Process

Good Morning!

Please review the attached and provide comments using track changes; and return to (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) for consolidation by noon today please!

Thanks!

(b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Tuesday, December 14, 2010 9:33 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** CBP Process

(b)(6) (b)(7)(C)

As discussed this afternoon, please find attached the (b) (5) process of Sodium Pentathol.

Please provide comments and edits.

Thank you

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 443-6553  
FAX: (301) 594-0413  
Cell: (240) 888-9316  
PNC hotline: (866) 521-2297

6/29/2011

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 11:55 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process  
**Attachments:** CBP process of Sodium Pentathol-OFO 12-15-10.doc  
See attached document with comments from OFO.

(b)(6) (b)(7)(C)

*Program Manager  
U.S. Customs & Border Protection  
1300 Pennsylvania Avenue N.W.  
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Washington, D.C. 20229*

202 (b)(6) (b)(7)(C) - Phone  
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(b)(6) (b)(7)(C) @dhs.gov

---

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**Sent:** Wednesday, December 15, 2010 10:38 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

I don't have that information. My guess is that they just want this whole situation to "just go away."

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 10:34 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)  
*Program Manager  
U.S. Customs & Border Protection  
1300 Pennsylvania Avenue N.W.  
Room 2.3-45  
Washington, D.C. 20229*

202 (b)(6) (b)(7)(C) Phone

202 (b)(6) (b)(7)(C) Fax  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 8:01 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: CBP Process

Good Morning!

Please review the attached and provide comments using track changes; and return to (b)(6) (b)(7)(C) (b)(6) (b)(7)(C) for consolidation by noon today please!

Thanks!

(b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Tuesday, December 14, 2010 9:33 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** CBP Process

(b)(6) (b)(7)(C)

As discussed this afternoon, please find attached the (b)(5) process of Sodium Pentathol.

Please provide comments and edits.

Thank you

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 443-6553  
FAX: (301) 594-0413  
Cell: (240) 888-9316  
PNC hotline: (866) 521-2297

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 1:19 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process  
We will put that in for sure!

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 1:18 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 1:17 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

Thank you. We will put as much of this in the response as we can.

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 1:15 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process

Here are my comments based upon what I believed we discussed at yesterday's meeting. Thanks for the opportunity to comment – please let me know if you have comments or questions.

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 8:01 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: CBP Process

Good Morning!

Please review the attached and provide comments using track changes; and return to (b)(6) (b)(7)(C) for consolidation by noon today please!

Thanks!

(b)(6) (b)(7)(C)

6/29/2011

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Tuesday, December 14, 2010 9:33 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) Poplawski, Ted J  
**Subject:** CBP Process

(b)(6) (b)(7)(C)

As discussed this afternoon, please find attached the (b)(5) process of Sodium Pentathol.

Please provide comments and edits.

Thank you

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 443-6553  
FAX: (301) 594-0413  
Cell: (240) 888-9316  
PNC hotline: (866) 521-2297

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, December 15, 2010 2:04 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C) Poplawski, Ted J; (b)(6) (b)(7)(C)  
**Subject:** RE: CBP Process  
**Attachments:** CBP Entry Process for Sodium Pentothal (REVISED).doc

Here it is.

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, December 15, 2010 1:41 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) Poplawski, Ted J  
**Subject:** RE: CBP Process

Thank you

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

---

**From:** (b)(6) (b)(7)(C)@dhs.gov]  
**Sent:** Wednesday, December 15, 2010 1:28 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C) Poplawski, Ted J  
**Subject:** RE: CBP Process

We just got the last of the comments and are consolidating them.

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, December 15, 2010 1:20 PM  
**To:** Veneziano, Domenic J.; (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) Poplawski, Ted J  
**Subject:** RE: CBP Process

Sorry

But the Department is getting a lot of pressure from the WH. Do we know how long?

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 443-6553

6/29/2011

FAX: (301) 594-0413  
Cell: (240) 888-9316

---

Domenic J.  
ember 14, 2010 9:33 PM

(b)(6) (b)  
(7)(C) Poplawski, Ted J  
ocess

(b)(6) (b)(7)(C)

As discussed this afternoon, please find attached the (b) (5) process of Sodium Pentathol.

Please provide comments and edits.

Thank you

<< File: CBP process of Sodium Pentathol.doc >>

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 443-6553  
FAX: (301) 594-0413  
Cell: (240) 888-9316  
PNC hotline: (866) 521-2297

6/29/2011

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, December 21, 2010 12:21 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: Conference call with WH at 1pm today on FDA lethal injection issue  
**Attachments:** FDA WH Thiopental Memo Revised 12 16 10.doc  
fyi

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, December 21, 2010 12:06 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: Conference call with WH at 1pm today on FDA lethal injection issue

This is an important junction we are at. You need to read the attached proposal.

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, December 21, 2010 11:42 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Conference call with WH at 1pm today on FDA lethal injection issue

Hello: Mike and Bob:

Here is the call in information for the FDA lethal injection meeting with the WH today. Just in case some technical operational questions arise, I wanted you both to be on the call, so thanks for your availability.

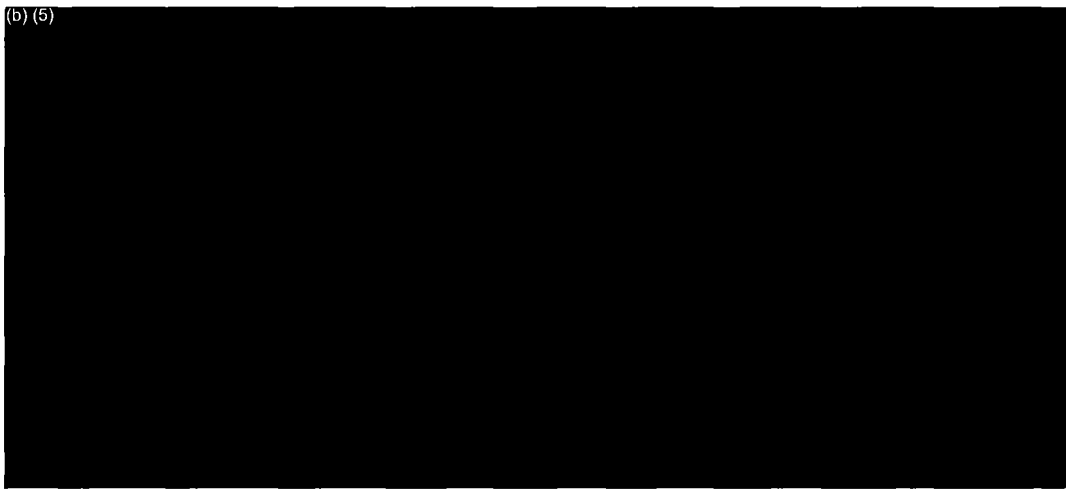
When: Tuesday, December 21, 2010 1:00 PM-2:00 PM (GMT-05:00) Eastern Time (US & Canada).

Where: 202-395-6392 passcode 9189695

I have also attached the revised paper that has been drafted. Also, these were the questions that apparently have been raised about the revised proposal that we sent.

- 1.
- 2.
- 3.
- 4.
- 5.

(b) (5)





(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, January 19, 2011 12:56 PM  
**To:** 'Ted.Poplawski@fda.hhs.gov'; (b)(6) (b)(7)(C) @dhs.gov'; (b)(6) (b)(7)(C)  
**Subject:** Re: Head of CBP IT

Hello Ted,  
Is there a specific number you needed from the list I provided? I would like to help you get to the correct person. Can you give me a general idea of the subject?

My division would also be happy to help facilitate in any way we can.

Take care,

---

**From:** Poplawski, Ted J <Ted.Poplawski@fda.hhs.gov>  
**To:** (b)(6) (b)(7)(C) @dhs.gov; (b)(6) (b)(7)(C)  
**Sent:** Wed Jan 19 10:37:54 2011  
**Subject:** FW: Head of CBP IT

(b)(6) (b)(7)(C)

(b) (5)

**Ted Poplawski**  
**FDA/ORI/DIOP**  
**301-796-6674**

---

**From:** Veneziano, Domenic J.  
**Sent:** Tuesday, January 18, 2011 1:03 PM  
**To:** (b)(6) (b)(7)(C) @dhs.gov; (b)(6) (b)(7)(C) @dhs.gov'  
**Cc:** Poplawski, Ted J  
**Subject:** Re: Head of CBP IT

Thank you.  
Domenic J. Veneziano  
CDR US Public Health Service  
Director, Division of Import Operations and Policy  
Office: (301) 443-6553  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) @dhs.gov]  
**Sent:** Tuesday, January 18, 2011 01:01 PM  
**To:** Veneziano, Domenic J.; (b)(6) (b)(7)(C) @dhs.gov>  
**Cc:** Poplawski, Ted J  
**Subject:** RE: Head of CBP IT

Hi Domenic,

6/29/2011

I am back on line. My apologies for the delay I was in a meeting with no cell/email access. Are you looking for the Assistant Commissioner of the Office of Information Technology – (b)(6) (b)(7)(C) or Deputy Assistant Commissioner of the Office of Information Technology – (b)(6) (b)(7)(C) or the Executive of the Cargo Systems Program Office (ACE and ACS) (b)(6) (b)(7)(C)? Let me know if you need anything further.  
Thank you,

(b)(6) (b)(7)(C)

Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Tuesday, January 18, 2011 11:43 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** Poplawski, Ted J  
**Subject:** Head of CBP IT

(b)(6) (b)(7)(C)

(b) (5)

Thank you

Domenic

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:53 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal  
Ok -- I will try to get something to you as soon as possible.

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:48:35 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
[@dhs.gov](mailto:(b)(6) (b)(7)(C)@dhs.gov)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:44 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:31:21 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
[@dhs.gov](mailto:(b)(6) (b)(7)(C)@dhs.gov)

6/29/2011

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:28 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:18:18 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)  
International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:12 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:05:52 2011  
**Subject:** OCC Position Paper: Sodium Pentothal

Good afternoon (b)(6) (b)(7)(C)

(b) (5)

(b) (5)



(b) (5)



(b) (5)



Thank you,

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202)

(b)(6) (b)(7)(C) @dhs.gov

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 8:57 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: OCC Position Paper: Sodium Pentothal  
(b)(6) (b)(7)(C)

I will try to get you something quickly, but it would have to be reviewed by my supervisors, so I am not certain I can get you something today.

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 8:55 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

Good morning (b)(6) (b)(7)(C)

(b) (5)

Thank you,

(b)(6) (b)(7)(C)  
*International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) [d.dhs.gov](http://d.dhs.gov)*

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Fri 1/28/2011 4:53 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

Ok – I will try to get something to you as soon as possible.

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:48:35 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

6/29/2011

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
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Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:44 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:31:21 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b) (5)

(b)(6) (b)(7)(C)  
International Trade Specialist  
Interagency Requirements Branch  
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Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:28 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:18:18 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

**From:** (b)(6) (b)(7)(C)

**Sent:** Friday, January 28, 2011 4:12 PM

**To:** (b)(6) (b)(7)(C)

**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)

**To:** (b)(6) (b)(7)(C)

**Sent:** Fri Jan 28 16:05:52 2011

**Subject:** OCC Position Paper: Sodium Pentothal

Good afternoon (b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b) (5)



(b) (5)

Thank you,

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202)

(b)(6) (b)(7)(C) @dhs.gov

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 10:25 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C) FYI- have sent a draft response to my supervisor to review, but I cannot control how long it will take to get reviewed....I have indicated that AC wants it today. (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 8:55 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

Good morning (b)(6) (b)(7)(C)

(b) (5)

Thank you,

(b)(6) (b)(7)(C)  
*International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov*

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**From:** (b)(6) (b)(7)(C)  
**Sent:** Fri 1/28/2011 4:53 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

Ok – I will try to get something to you as soon as possible.

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:48:35 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:44 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:31:21 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b) (5)

(b)(6) (b)(7)(C)  
International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Friday, January 28, 2011 4:28 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b) (5)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Fri Jan 28 16:18:18 2011  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202)

(b)(6) (b)(7)(C) @dhs.gov

---

**From:** (b)(6) (b)(7)(C)

**Sent:** Friday, January 28, 2011 4:12 PM

**To:** (b)(6) (b)(7)(C)

**Subject:** Re: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)

**To:** (b)(6) (b)(7)(C)

**Sent:** Fri Jan 28 16:05:52 2011

**Subject:** OCC Position Paper: Sodium Pentothal

Good afternoon (b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b) (5)

Thank you,

(b)(6) (b)(7)(C)

International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202)

(b)(6) (b)(7)(C) @dhs.gov

6/29/2011

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 11:09 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: OCC Position Paper: Sodium Pentothal

Thanks (b)(6) (b)(7)(C) has drafted the response for OT and submitted it for supervisory review. In order to ensure a response for (b)(6) (b)(7)(C) today we may need to push (b)(6) (b)(7)(C) for the response.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 10:39 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: OCC Position Paper: Sodium Pentothal

Please tell me who you're working with and exactly what you need

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Mon Jan 31 10:34:46 2011  
**Subject:** OCC Position Paper: Sodium Pentothal

Good Morning (b)(6) (b)(7)(C)

(b) (5)

Thank you.  
(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)  
Office of International Trade  
Import Safety Branch  
(202) (b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, January 31, 2011 9:48 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)

Thank you,

(b)(6) (b)(7)(C)

*International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
@dhs.gov*

---

**From:** (b)(6) (b)(7)(C)

**Sent:** Mon 1/31/2011 8:57 AM

**To:** (b)(6) (b)(7)(C)

**Subject:** RE: OCC Position Paper: Sodium Pentothal

(b)(6) (b)(7)(C)

I will try to get you something quickly, but it would have to be reviewed by my supervisors, so I am not certain I can get you something today.

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)

**Sent:** Monday, January 31, 2011 8:55 AM

**To:** (b)(6) (b)(7)(C)

**Subject:** RE: OCC Position Paper: Sodium Pentothal

Good morning (b)(6) (b)(7)(C)

(b) (5)

Thank you,

(b)(6) (b)(7)(C)

*International Trade Specialist  
Interagency Requirements Branch  
Office of International Trade  
Tel: (202) (b)(6) (b)(7)(C)  
Fax: (202) (b)(6) (b)(7)(C)  
@dhs.gov*

6/29/2011

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 02, 2011 11:40 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: FDA Issue Paper-Sodium Pentothal

**Importance:** High

Review OCC's comments below and provide me comments today.  
Thank you,

(b)(6) (b)(7)(C)

Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

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

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 02, 2011 11:38 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Fw: FDA Issue Paper-Sodium Pentothal

Are we ok with this?

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

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Wed Feb 02 10:31:55 2011  
**Subject:** FW: FDA Issue Paper-Sodium Pentothal

(b)(6) (b)(7)(C)

FYI.

(b)(6) (b)(7)(C)

This document, and any attachment(s), may contain information which is law enforcement sensitive, attorney-client privileged, attorney work-product, or U.S. Government information. It is not for release, review, retransmission, dissemination or use by anyone other than the intended recipient. Please consult with the CBP Office of Chief Counsel before disclosing any information contained in this message or any attachment(s).

---

**From:** ROBLES, ALFONSO  
**Sent:** Wednesday, February 02, 2011 10:26 AM  
**To:** BERSIN, ALAN D.  
**Cc:** BALDWIN, DAN (AC-OT); (b)(6) (b)(7)(C) AGUILAR, DAVID V; (b)(6) (b)(7)(C)  
**K;** (b)(6) (b)(7)(C)  
**Subject:** RE: FDA Issue Paper-Sodium Pentothal

Commissioner,



(b) (5)



(b) (5)



(b) (5)



(b) (5)



Please let us know if you have any further questions on this issue.

--Alfonso

Alfonso Robles  
Chief Counsel

U.S. Customs and Border Protection

(202) (b)(6) (b)(7)(C)

This communication might contain information that is confidential and/or subject to the attorney-client, attorney work product, and/or the deliberative process privileges. It might also contain U.S. Government information that is sensitive and not for release, review, retransmission, dissemination or use by anyone other than the intended recipient. Please notify the sender if this email has been misdirected and immediately destroy all originals and copies. Any disclosure of this communication must be approved by the Office of Chief Counsel, U.S. Customs and Border Protection.

---

From: BALDWIN, DAN (AC-OT)  
Sent: Tuesday, February 01, 2011 5:28 PM  
To: BERSIN, ALAN D.; (b)(6) (b)(7)(C) AGUILAR, DAVID V  
Cc: ROBLES, ALFONSO  
Subject: FDA Issue Paper-Sodium Pentothal

Sir,

Attached is a briefing paper regarding a brewing issue with FDA regarding imports of Sodium Pentothal. We have a conference call scheduled with FDA tomorrow afternoon to move the ball forward, and I suspect it will also come up during our Border Interagency Executive Council (BIEC) meeting on Thursday. Commissioner Hamburg came on the call personally last time. In addition, we have worked extensively with Alfonso's office and they are submitting a document under separate cover.

Please let me know if you would like to discuss further, perhaps at tomorrow's Intel.

Dan

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 03, 2011 11:42 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Please Review

**Importance:** High

Please Review the below for accuracy. I am writing up the long term option now. Thanks!


**Background Statistics:**

Total Entry Lines (FY10): 4,156  
Top 5 Ports by Entry Lines:  
2095 Fed Ex, Memphis – 1207 (29.04%)  
4601 Newark – 471 (11.33%)  
4701 JFK – 382 (9.19%)  
3901 Chicago – 319 (7.68%)  
3195 Fed Ex, Anchorage Alaska – 265 (6.38%)

\* Data derived with HTS# 2933.59.9500

**CBP Proposed Short Term Option:**

(b) (5)



(b)(6) (b)(7)(C)  
Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 09, 2011 1:01 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: ROM/Cost Estimates

fyi

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, February 09, 2011 12:54 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: ROM/Cost Estimates

OK.

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C)@dhs.gov  
**Sent:** Wednesday, February 09, 2011 12:53 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: ROM/Cost Estimates

Domenic,  
Lets go for 2pm today. I will get a conf. call bridge.  
Thanks for getting back to me,

(b)(6) (b)(7)(C)  
Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, February 09, 2011 12:25 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: ROM/Cost Estimates

(b)(6) (b)(7)(C)

If you are available at 2:00 today we would like to discuss this issue with you. If not then please provide

6/29/2011

another time. I have a meeting at 1:00-2:00 and 3-4.

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) @dhs.gov]  
**Sent:** Wednesday, February 09, 2011 7:12 AM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: ROM/Cost Estimates

Thanks Domenic,  
We will be on the ready.

---

**From:** Veneziano, Domenic J. <Domenic.Veneziano@fda.hhs.gov>  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) @dhs.gov>  
**Sent:** Wed Feb 09 06:42:57 2011  
**Subject:** RE: ROM/Cost Estimates

I am in the process of pulling staff away from other meetings. We should be able to meet with you this afternoon around 5 maybe earlier.

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) @dhs.gov]  
**Sent:** Tuesday, February 08, 2011 6:18 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** ROM/Cost Estimates

Hello Domenic,  
We are eager to begin costing the options presented by FDA. We will need additional details for Options 4 and 5.

(b) (5)

(b) (5)

A large black rectangular redaction box covers the majority of the page's content, starting below the header and ending above the closing text.

Please let me know your preference and soon we can start.

Thank you,

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 10, 2011 8:57 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
 (b)(6) (b)(7)(C)  
**Subject:** RE: ROM/Cost Estimates

(b) (5)

**Challenges:**

- 1) (b) (5)
- 2)

(b)(6) (b)(7)(C)

Director, Commercial Targeting  
 CBP, Office of International Trade  
 1400 L St NW, 11th Floor  
 Washington DC, 20229  
 Office: 202 (b)(6) (b)(7)(C)  
 Mobile: 202 (b)(6) (b)(7)(C)  
 Fax: 202 (b)(6) (b)(7)(C)  
 Email: (b)(6) (b)(7)(C)@dhs.gov  
 Visit [www.cbp.gov](http://www.cbp.gov)  
 Report Trade Violations at <https://apps.cbp.gov/eallegations/>

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 10, 2011 7:39 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
 (b)(6) (b)(7)(C)  
**Subject:** FW: ROM/Cost Estimates

All,  
 It appears FDA might not be able to identify the Correctional Facilities (name or otherwise). Any ideas? I wonder how they were able to identify the shipments they have identified to date.  
 Thank you,

(b)(6) (b)(7)(C)

Import Safety Division  
 Office of International Trade  
 U.S. Customs and Border Protection  
 Office: 202 (b)(6) (b)(7)(C)

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Thursday, February 10, 2011 7:05 AM

**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) Elder, David K.; Taylor, John M.; Corrigan, Dara  
**Subject:** RE: ROM/Cost Estimates

(b)(6) (b)(7)(C)

(b) (5)

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) @dhs.gov]  
**Sent:** Wednesday, February 09, 2011 10:46 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C) Elder, David K.; Taylor, John M.; Corrigan, Dara  
**Subject:** Re: ROM/Cost Estimates

Domenic,  
Thank you for the information. I will pass it along to everyone. Is there anyway to obtain the names of the Correctional Facilities?

We need to determine if they have an IR# on file so we negate and process the edit with the IR#. An alternative would be to have those that you are aware of identified and established with an IR#. This would require some coordination with the facility.

Thank you,

---

**From:** Veneziano, Domenic J. <Domenic.Veneziano@fda.hhs.gov>  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C) @dhs.gov>; Elder, David K. <David.Elder@fda.hhs.gov>; Taylor, John M. <John.Taylor2@fda.hhs.gov>; Corrigan, Dara <Dara.Corrigan@fda.hhs.gov>; Veneziano, Domenic J. <Domenic.Veneziano@fda.hhs.gov>  
**Sent:** Wed Feb 09 17:57:19 2011  
**Subject:** RE: ROM/Cost Estimates

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)



(b) (5)



Thank you

6/29/2011

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) @dhs.gov]  
**Sent:** Tuesday, February 08, 2011 6:18 PM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** ROM/Cost Estimates

Hello Domenic,  
We are eager to begin costing the options presented by FDA. We will need additional details for Options 4 and 5.

(b) (5)

Please let me know your preference and soon we can start.

Thank you,

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 10, 2011 3:24 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Subject:** FW: ROM/Cost Estimates  
**Importance:** High  
**Attachments:** Tariff Codes Used for Sodium Thiopental Entries.doc; Product Code Combination for Sodium Thiopental.doc

All,  
This is the information FDA has provided as a follow up to our conversation.  
Thank you,

(b)(6) (b)(7)(C)

Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, February 09, 2011 5:57 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C); Elder, David K.; Taylor, John M.; Corrigan, Dara; Veneziano, Domenic J.  
**Subject:** RE: ROM/Cost Estimates

(b)(6) (b)(7)(C)

(b) (5)



(b) (5)



Thank you

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

---

**From:** (b)(6) (b)(7)(C) [redacted]@dhs.gov  
**Sent:** Tuesday, February 08, 2011 6:18 PM

6/29/2011

To: Veneziano, Domenic J.

Cc: (b)(6) (b)(7)(C)

Subject: ROM/Cost Estimates

Hello Domenic,

We are eager to begin costing the options presented by FDA. We will need additional details for Options 4 and 5.

(b) (5)

Please let me know your preference and soon we can start.

Thank you,

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 17, 2011 9:10 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: CALL - CBP - HHS Next Steps  
FDA is able to commit to option one.

(b)(6) (b)(7)(C)  
**Office of International Trade**  
**Import Safety Branch**  
**(202)**(b)(6) (b)(7)(C)

**From:** Park, Todd (HHS/IOS) [mailto:Todd.Park@hhs.gov]  
**Sent:** Thursday, February 17, 2011 9:07 AM  
**To:** (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO); Corrigan, Dara (FDA/ORA); Veneziano, Domenic J. (FDA/ORA); Horowitz, David (HHS/OGC); Smolonsky, Marc (HHS/IOS); (b)(6) (b)(7)(C) @dhs.gov; Petrou, Laura (HHS/OS); Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C) BALDWIN, DAN (AC-OT)  
**Cc:** (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORA)  
**Subject:** RE: CALL - CBP - HHS Next Steps

(b) (5)

Todd

**From:** Park, Todd (HHS/IOS)  
**Sent:** Thursday, February 17, 2011 2:30 AM  
**To:** (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO); Corrigan, Dara (FDA/ORA); Veneziano, Domenic J. (FDA/ORA); Horowitz, David (HHS/OGC); Smolonsky, Marc (HHS/IOS); (b)(6) (b)(7)(C) @dhs.gov; (b)(6) (b)(7)(C) @cbp.dhs.gov; (b)(6) (b)(7)(C) @cbp.dhs.gov; (b)(6) (b)(7)(C) @cbp.dhs.gov; (b)(6) (b)(7)(C) @dhs.gov; Petrou, Laura (HHS/OS); Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C) @cbp.dhs.gov; (b)(6) (b)(7)(C) @dhs.gov; (b)(6) (b)(7)(C) daniel.baldwin@dhs.gov  
**Cc:** (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORA)  
**Subject:** CALL - CBP - HHS Next Steps

(b) (5)

Thanks very much,  
Todd

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, April 18, 2011 10:25 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Comments on Sodium Pentothal Doc  
**Attachments:** 040411 Sodium Pentothal.doc

(b)(6) (b)(7)(C)

Attached is the latest issue paper for Sodium Pentothal. I believe a copy of the issue paper was given to (b)(6) (b)(7)(C) back on the 4<sup>th</sup>.

Thanks  
(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)  
Office of International Trade  
Import Safety Branch  
(202) (b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, April 14, 2011 12:51 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: Comments on Sodiueme Pentothal Doc

(b)(6) (b)(7)(C)

May TOD get a copy of the most updated issue paper on the topic of Sodiueme Pentothal. The most updated version we have is the attached copy where our Director made comments.

Given the news article from today, the issue is likely to come up again soon.

<http://www.nytimes.com/2011/04/14/us/14lethal.html?ref=us#>

Thank you,

(b)(6) (b)(7)(C)

Chief, Import Safety and IPR Operations Branch  
Trade Operations Division (TOD)  
Cargo and Conveyance Security  
CBP- Office of Field Operations  
Telephone: (202) (b)(6) (b)(7)(C) Facsimile: (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) [cbp.dhs.gov](http://cbp.dhs.gov)

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**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 11:03 AM

**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Comments on Sodlume Pentothal Doc

Thanks (b)(6) (b)(7)(C) for participating and attaching your comments. I will distribute the updated document shortly. We will also provide a meeting summary tomorrow.  
Thanks again,

(b)(6) (b)(7)(C)  
Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 10:37 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Comments on Sodlume Pentothal Doc

(b)(6) (b)(7)(C)

See attached. Consistent with my comments on the tele conference call this A.M.

(b)(6) (b)(7)(C)  
Director  
Trade Operations Division  
Field Operations  
U.S. Customs and Border Protection  
PH # (202) (b)(6) (b)(7)(C)  
FAX (202) (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) @dhs.gov



(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 02, 2011 11:40 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: FDA Issue Paper-Sodium Pentothal

**Importance:** High

Review OCC's comments below and provide me comments today.  
Thank you,

(b)(6) (b)(7)(C)

Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

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

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 02, 2011 11:38 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Fw: FDA Issue Paper-Sodium Pentothal

Are we ok with this?

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

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Wed Feb 02 10:31:55 2011  
**Subject:** FW: FDA Issue Paper-Sodium Pentothal

(b)(6) (b)(7)(C)

FYI.

(b)(6) (b)(7)(C)

This document, and any attachment(s), may contain information which is law enforcement sensitive, attorney-client privileged, attorney work-product, or U.S. Government information. It is not for release, review, retransmission, dissemination or use by anyone other than the intended recipient. Please consult with the CBP Office of Chief Counsel before disclosing any information contained in this message or any attachment(s).

---

**From:** ROBLES, ALFONSO  
**Sent:** Wednesday, February 02, 2011 10:26 AM  
**To:** BERSIN, ALAN D.  
**Cc:** BALDWIN, DAN (AC-OT); (b)(6) (b)(7)(C) AGUILAR, DAVID V; (b)(6) (b)(7)(C)  
**Subject:** RE: FDA Issue Paper-Sodium Pentothal

Commissioner,

(b) (5)



(b) (5)



(b) (5)



(b) (5)



Please let us know if you have any further questions on this issue.

--Alfonso

Alfonso Robles

Chief Counsel

U.S. Customs and Border Protection

(202) 344-2940

This communication might contain information that is confidential and/or subject to the attorney-client, attorney work product, and/or the deliberative process privileges. It might also contain U.S. Government information that is sensitive and not for release, review, retransmission, dissemination or use by anyone other than the intended recipient. Please notify the sender if this email has been misdirected and immediately destroy all originals and copies. Any disclosure of this communication must be approved by the Office of Chief Counsel, U.S. Customs and Border Protection.

---

From: BALDWIN, DAN (AC-OT)  
Sent: Tuesday, February 01, 2011 5:28 PM  
To: BERSIN, ALAN D.; (b)(6) (b)(7)(C) AGUILAR, DAVID V  
Cc: ROBLES, ALFONSO  
Subject: FDA Issue Paper-Sodium Pentothal

Sir,

Attached is a briefing paper regarding a brewing issue with FDA regarding imports of Sodium Pentothal. We have a conference call scheduled with FDA tomorrow afternoon to move the ball forward, and I suspect it will also come up during our Border Interagency Executive Council (BIEC) meeting on Thursday. Commissioner Hamburg came on the call personally last time. In addition, we have worked extensively with Alfonso's office and they are submitting a document under separate cover.

Please let me know if you would like to discuss further, perhaps at tomorrow's Intel.

Dan

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 7:38 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: Updated: CALL - CBP - HHS Next Steps  
**Attachments:** 0200711\_options paper (3).doc

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 7:37 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** RE: Updated: CALL - CBP - HHS Next Steps

(b)(6) (b)(7)(C)

I couldn't help myself - I edited the document.

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, February 07, 2011 6:20 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Fw: Updated: CALL - CBP - HHS Next Steps

Fyi

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) Executive Director  
Commercial Targeting and Enforcement  
U.S. Customs and Border Protection  
Office of International Trade  
Washington, DC 20229  
202 (b)(6) (b)(7)(C) (office)  
202 (b)(6) (b)(7)(C) (fax)

**From:** (b)(6) (b)(7)(C)@dhs.gov  
**To:** Park, Todd (HHS/IOS) <Todd.Park@dhs.gov>; Taylor, John M. (FDA/OC) <John.Taylor2@fda.hhs.gov>; Teeter, John (OS/ASA/OCIO) <John.Teeter@HHS.GOV>; Corrigan, Dara (FDA/ORR) <Dara.Corrigan@fda.hhs.gov>; Veneziano, Domenic J. (FDA/ORR) <Domenic.Veneziano@fda.hhs.gov>; Petrou, Laura (HHS/OS) <Laura.Petrou@dhs.gov>; Horowitz, David (HHS/OGC) <David.Horowitz@dhs.gov>; Smolonsky, Marc (HHS/IOS) <Marc.Smolonsky@dhs.gov>; Hughes, Dora (HHS/IOS) <Dora.Hughes@dhs.gov>; (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
dan.baldwin@dhs.gov <dan.baldwin@dhs.gov>; (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)@dhs.gov  
**Sent:** Mon Feb 07 18:14:30 2011  
**Subject:** RE: Updated: CALL - CBP - HHS Next Steps

All,

I have attached a brief summary of options that CBP, Office of International Trade would like considered for discussion during the 02/08/11 teleconference call. Please reply with any concerns, comments or suggestions.

Thank you,

<<0200711\_options paper (3).doc>>

(b)(6) (b)(7)(C)

Director, Import Safety Division

Office of International Trade

U.S. Customs and Border Protection

Office: 202 (b)(6) (b)(7)(C)

-----Original Appointment-----

**From:** Park, Todd (HHS/IOS) [<mailto:Todd.Park@hhs.gov>]

**Sent:** Friday, February 04, 2011 4:42 PM

**To:** Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO); Corrigan, Dara (FDA/ORO); Veneziano, Domenic J. (FDA/ORO); Petrou, Laura (HHS/OS); Horowitz, David (HHS/OGC); Smolonsky, Marc (HHS/IOS); Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) dan.baldwin@dhs.gov; (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) @dhs.gov; Park, Todd (HHS/IOS)

**Cc:** (b)(6) (b)(7)(C)

**Subject:** Updated: CALL - CBP - HHS Next Steps

**When:** Tuesday, February 08, 2011 4:30 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).

**Where:** see dial in below

When: Tuesday, February 08, 2011 4:30 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).

Where: see dial in below

\*~\*~\*~\*~\*~\*~\*~\*~\*~\*

\*\*time changed from 2/7 at 10:30 to 2/8 at 4:30.

1-877-620-9475

Leader/Todd: 7326142

Participant: 8533363

From: Park, Todd (HHS/IOS)

Sent: Thursday, February 03, 2011 9:56 AM

To: (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO);  
Corrigan, Dara (FDA/ORO); Veneziano, Domenic J. (FDA/ORO); Petrou, Laura (HHS/OS); Horowitz, David  
(HHS/OGC); Kendall, Damaris (HHS/OS); Smolonsky, Marc (HHS/IOS); Hughes, Dora (HHS/IOS)

Cc: (b)(6) (b)(7)(C)

Subject: RE: CBP-HHS next steps

Hi team, as a follow-up note, just to reinforce one of the points below, after chatting with HHS leadership folks here, we would most definitely like to concentrate on options (b)(5)

(b)(5) Thank you, .

Todd

---

From: Park, Todd (HHS/IOS)

Sent: Wednesday, February 02, 2011 10:43 PM

To: (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO);  
Corrigan, Dara (FDA/ORO); Veneziano, Domenic J. (FDA/ORO); Petrou, Laura (HHS/OS); Horowitz, David  
(HHS/OGC); Kendall, Damaris (HHS/OS); Smolonsky, Marc (HHS/IOS); Hughes, Dora (HHS/IOS)

Cc: (b)(6) (b)(7)(C)

Subject: CBP-HHS next steps

Importance: High

Hi team, thanks for the great discussion today! As promised, here's the writeup of the (b)(5) options (b)(5)

(b)(5)

(b) (5)




(b) (5)



(b) (5)



HHS would vastly prefer options (b) (5)



As we discussed, if folks could investigate the relative time/cost/feasibility of each of the above (on both the CBP and FDA sides of the equation) over the next couple of days, that would be terrific.

And if anyone comes up with an alternative or modified option, please circulate it to the group as soon as it occurs to you!

Damaris, please arrange a next call of this group for this coming Monday morning – 1 hour. Thanks!

Todd

7/6/2011

(b)(6) (b)(7)(C)

**From:** (b) (5)  
**Sent:** Tuesday, February 08, 2011 5:57 PM  
**To:** (b) (5)  
**Cc:** (b) (5)  
(b) (5)

**Subject:** Re: Sodium Thiopental - Call Details

I agree.

**From:** (b) (5)  
**To:** (b) (5)  
**Cc:** (b) (5)  
(b) (5)  
(b) (5)  
**Sent:** Tue Feb 08 17:52:15 2011  
**Subject:** Re: Sodium Thiopental - Call Details

(b) (5)

Sent from my Blackberry Wireless Device.

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 03:19 PM  
**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Subject:** RE: Sodium Thiopental - Call Details

All,  
Thanks again for speaking with us on such short notice. I have included the call-in details below for this afternoon. Let's plan to have a follow up discussion after the call with FDA/HHS. We can review our position, your concerns and next steps. We can plan to discuss Friday or Monday please let me know if you have a preference.

**From:** Park, Todd (HHS/IOS) [<mailto:Todd.Park@hhs.gov>]  
**Sent:** Friday, February 04, 2011 4:42 PM  
**To:** Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO); Corrigan, Dara (FDA/ORA); Veneziano, Domenic J. (FDA/ORA); Petrou, Laura (HHS/OS); Horowitz, David (HHS/OGC); Smolonsky, Marc (HHS/IOS); Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) 'dan.baldwin@dhs.gov'; (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) dhs.gov'; Park, Todd (HHS/IOS)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Updated: CALL - CBP - HHS Next Steps  
**When:** Tuesday, February 08, 2011 4:30 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).  
**Where:** see dial in below

**When:** Tuesday, February 08, 2011 4:30 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).  
**Where:** see dial in below

\*~\*~\*~\*~\*~\*~\*~\*~\*~\*



\*\*time changed from 2/7 at 10:30 to 2/8 at 4:30.

1-877-620-9475  
Leader/Todd: 7326142  
Participant: 8533363

Thanks for joining us,  
(b)(6) (b)(7)(C)  
Import Safety Division  
Office of International Trade  
U.S. Customs and Border Protection  
Office: 202 (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 2:15 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Subject:** Re: Sodium Thiopental

Good Afternoon Everyone,

Below is the conference line information for the 2:30 call:

Conference Phone Numbers:  
571-468-6338 or 1-877-215-3475

Pin:  
473967

Thank you,  
(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C) @dhs.gov>  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Sent:** Tue Feb 08 14:00:11 2011  
**Subject:** Re: Sodium Thiopental

We are working on getting a conference line and would welcome all those interested in participating.

Thank you,  
(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Tue Feb 08 13:52:41 2011  
**Subject:** RE: Sodium Thiopental

Fascinating.

7/6/2011

May I listen in on the 2:30 call?

Thanks,

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) PhD  
Director, Chemical Security Policy  
Office of Policy  
Dept. of Homeland Security  
Desk: (202) (b)(6) (b)(7)(C)  
BlackBerry: (202) (b)(6) (b)(7)(C)  
Email: (b)(6) (b)(7)(C)@dhs.gov  
HSDN: (b)(6) (b)(7)(C)@dhs.sgov.gov  
JWICS: (b)(6) (b)(7)(C)@dhs.ic.gov

---

**From:** (b)(6) (b)(7)(C)@dhs.gov]  
**Sent:** Tuesday, February 08, 2011 1:37 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Re: Sodium Thiopental

Thanks (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

Are you available at 2:30 for an internal call?

Thanks,

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Sent:** Tue Feb 08 13:31:27 2011  
**Subject:** Re: Sodium Thiopental

Hi, (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) from my team is available. He's on our trade policy distro here.

Thanks,

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)  
Director  
Trade Policy and Economic Analysis  
Office of Policy  
U.S. Department of Homeland Security

7/6/2011

Email: (b)(6) (b)(7)(C)@dhs.gov  
Phone: (202) (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)@dhs.gov]  
**Sent:** Tuesday, February 08, 2011 01:25 PM  
**To:** (b)(6) (b)(7)(C)@dhs.gov>  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: Sodium Thiopental

Hi (b)(6) (b)(7)(C)

I have attached the issue paper for Sodium Pentothal and our options paper. Are you available for an internal call prior to 4:30?

Thanks,

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)  
Office of International Trade  
Import Safety Branch  
(202) (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 1:11 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Fw: Sodium Thiopental

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**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Tue Feb 08 12:59:49 2011  
**Subject:** Re: Sodium Thiopental

Thanks for looping us in (b)(6) (b)(7)(C). If you wouldn't mind one of us joining the call to follow along, please send us the call-in info. We'd also be happy to receive the paper whenever you're ready to share it.

I'm also cc'ing my colleague (b)(6) (b)(7)(C) she is Director for Biological Policy in our office and interacts with FDA/HHS and OHA on a range of issues. For the same reason, I've also copied (b)(6) (b)(7)(C) Director for Chem Policy here.

Thanks,

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)  
Director  
Trade Policy and Economic Analysis  
Office of Policy  
U.S. Department of Homeland Security  
Email: (b)(6) (b)(7)(C)@dhs.gov  
Phone: (202) (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)@dhs.gov]

**Sent:** Tuesday, February 08, 2011 12:16 PM  
**To:** (b)(6) (b)(7)(C) @dhs.gov>  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Sodium Thiopental

(b)(6) (b)(7)(C) (b) (5)  
(b) (5)

There is a conference call at 4:30 today with FDA and HHS to discuss options (I can send you a background paper if you're interested, when we've finalized) if you're interested in participating.

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

Executive Director, Trade Policy and Programs  
Office of International Trade  
Customs and Border Protection  
1400 L St., NW, 12th Fl.  
Washington, DC 20005

Phone: 202 (b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 08, 2011 11:05 AM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** WTOP article...

## Judge who halted CA executions to tour death room

February 8, 2011 - 4:28am



FILE - In this Sept. 21, 2010 file photo, the new lethal injection facility at San Quentin State Prison is seen in San Quentin, Calif. A federal judge who shut down the death chamber at the prison after an inspection five years ago returns there Tuesday, Feb. 8, 2011, to tour the new facility. (AP Photo/Eric Risberg, File)

By PAUL ELIAS  
Associated Press

SAN FRANCISCO (AP) - California hasn't executed anyone in more than five years and its death row population has risen, recently reaching 720 inmates \_ the largest in the country.

U.S. District Court Judge Jeremy Fogel imposed a de facto moratorium on lethal injection executions in California in 2006. His ruling came after he inspected San Quentin Prison's death room and found the converted gas chamber to be so dim, cramped and antiquated that inmates were at risk of suffering cruel and unusual pain.

On Tuesday, the judge returns to the death chamber for the first time since putting the state's executions on hold.

Prison officials, represented by lawyers from the state attorney general's office, want to show the judge the prison's new \$900,000 death chamber and argue that the state is ready to immediately resume. They will also argue at the unusual federal court hearing at the prison that they have adopted new regulations and improved staff training to address the judge's other reasons to shelve California's executions.

Attorneys for two death row inmates who are challenging the legality of California's lethal injections argue that the revised system is just as flawed as the execution process that Fogel ordered fixed five years ago.

Fogel is not expected to rule on Tuesday.

The judge called off the execution of convicted murderer Albert Greenwood Brown days before a scheduled Sept. 30 execution, ruling that he needed more time to determine if the state's new death chamber and lethal injection process protected inmates from cruel and unusual punishment.

The state Attorney General's office dropped its appeal of Fogel's ruling after an adverse California Supreme Court ruling made it impossible to carry out Brown's execution because the state's entire stock of a drug needed for lethal injections expired.

Prison officials have since acquired a new stock of the drug, sodium thiopental, from a London supplier. The sole U.S. manufacturer of the anesthesia announced it would no longer make the drug.

The overseas supplier is not the subject of Tuesday's hearing, but will likely be the target of new legal challenges to capital punishment in California and in the nearly three dozen states that use sodium thiopental in executions.

Attorneys for death row inmates and capital-punishment foes argue that buying sodium thiopental outside the United States is an unreliable process that puts inmates at risk of suffering cruel and unusual pain.

(b)(6) (b)(7)(C)

---

**From:** Park, Todd (HHS/IOS) [Todd.Park@hhs.gov]  
**Sent:** Thursday, February 17, 2011 2:30 AM  
**To:** (b)(6) (b)(7)(C) Taylor, John M. (FDA/OC); Teeter, John (OS/ASA/OCIO);  
Corrigan, Dara (FDA/ORO); Veneziano, Domenic J. (FDA/ORO); Horowitz, David (HHS/OGC);  
Smolonsky, Marc (HHS/IOS); (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C) dhs.gov'; Petrou, Laura (HHS/OS);  
Hughes, Dora (HHS/IOS); (b)(6) (b)(7)(C)  
F; BALDWIN, DAN (AC-OT)  
**Cc:** (b)(6) (b)(7)(C) Corrigan, Dara (FDA/ORO)  
**Subject:** CALL - CBP - HHS Next Steps  
**Attachments:** 021511\_options paper vedits.docx

(b) (5)

Thanks very much,  
Todd

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 17, 2011, 11:01 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Sodium Pentothal Issue Paper  
**Attachments:** Sodium Pentothal Issue Paper v5.doc



Sodium Pentothal  
Issue Paper v... (b)(6) (b)(7)(C)

Attached is the updated draft of the Sodium Pentothal Issue Paper. Could you please review it and forward to (b)(6) (b)(7)(C)

Thank you,

(b)(6) (b)(7)(C)

International Trade Specialist

Interagency Requirements Branch

Office of International Trade

Tel: (202) (b)(6) (b)(7)(C)

Fax: (202) (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C) @dhs.gov

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Thursday, February 17, 2011 10:09 AM  
**To:** Veneziano, Domenic J.  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** RE: Tariff Number

Thanks Domenic,

We will analyze and plan to have a follow discussion with you and your team. Who should we coordinate with?

Thank you,

(b)(6) (b)(7)(C)

Import Safety Division

Office of International Trade

U.S. Customs and Border Protection

Office: 202 (b)(6) (b)(7)(C)

---

**From:** Veneziano, Domenic J. [mailto:Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, February 16, 2011 7:37 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: Tariff Number

(b)(6) (b)(7)(C)

(b) (5)

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(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

Thanks

Domenic

---

**From:** Veneziano, Domenic J.

**Sent:** Thursday, February 10, 2011 1:13 PM

**To:** (b)(6) (b)(7)(C)

**Cc:** (b)(6) (b)(7)(C)

**Subject:** Tariff Number

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

Domenic J. Veneziano

CDR U.S. Public Health Service

Director, Division of Import Operations and Policy

Work: (301) 796-0356

FAX: TBD

Cell: (240) 888-9316

(b)(6) (b)(7)(C)

**From:** Veneziano, Domenic J. [Domenic.Veneziano@fda.hhs.gov]  
**Sent:** Wednesday, February 16, 2011 7:37 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: Tariff Number

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b) (5)

Thanks

Domenic

---

**From:** Veneziano, Domenic J.  
**Sent:** Thursday, February 10, 2011 1:13 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Tariff Number

(b)(6) (b)(7)(C)

(b) (5)

(b) (5)

(b) (5)

(b) (5)

Domenic J. Veneziano  
CDR U.S. Public Health Service  
Director, Division of Import Operations and Policy  
Work: (301) 796-0356  
FAX: TBD  
Cell: (240) 888-9316

(b)(6) (b)(7)(C)

**Subject:** Updated: Sodium Pentothal Options - Premeet  
**Location:** Call - 571-468-6338 #297207

**Start:** Wed 2/16/2011 9:30 AM  
**End:** Wed 2/16/2011 10:30 AM  
**Show Time As:** Tentative

**Recurrence:** (none)

**Meeting Status:** Not yet responded

**Required Attendees:**

(b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Optional Attendees:**

(b)(6) (b)(7)(C)



021511\_options  
paper.doc (53 K...

Added the updated options paper. Changes are tracked in red. Thanks to everyone for contributing.

Added Options Paper as reference for our discussion. Please review.....

Added call-in details 571-468-6338 #297207

All,  
This call will be necessary to establish the CBP recommendations prior to the FDA/HHS call scheduled for 02/16/11 (I will forward the details separately). If you can not make this call please have an alternate participate or provide me your comments and concerns related to the issue.

I will follow up with an updated options/recommendations paper by COB today.

Thank you,

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 9:35 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:**  
**Subject:** Re: Sodium Pentothal Options - Premeet

The issue has been resolved.

Call# 571-468-6338  
Pin#. 297207

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Wed Feb 16 09:32:35 2011  
**Subject:** RE: Sodium Pentothal Options - Premeet

All: I can't get on the conference line....the code below isn't working....

-----Original Appointment-----

**From:** (b)(6) (b)(7)(C)  
**Sent:** Tuesday, February 15, 2011 4:07 PM  
**To:** (b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Subject:** Updated: Sodium Pentothal Options - Premeet  
**When:** Wednesday, February 16, 2011 9:30 AM-10:30 AM (GMT-05:00) Eastern Time (US & Canada).  
**Where:** Call - 571-468-6338 #297207

<< File: 021511\_options paper.doc >>

Added Options Paper as reference for our discussion. Please review.....

Added call-in details 571-468-6338 #297207

All,

This call will be necessary to establish the CBP recommendations prior to the FDA/HHS call scheduled for 02/16/11 (I will forward the details separately). If you can not make this call please have an alternate participate or provide me your comments and concerns related to the issue.

I will follow up with an updated options/recommendations paper by COB today.

Thank you,

(b)(6) (b)(7)(C)

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 9:35 AM  
**To:** (b)(6) (b)(7)(C)  
**Cc:**  
**Subject:** Re: Sodium Pentothal Options - Premeet

Try again

---

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)  
**Cc:** (b)(6) (b)(7)(C)  
**Sent:** Wed Feb 16 09:34:23 2011  
**Subject:** RE: Sodium Pentothal Options - Premeet

If this is a Beauregard number, probably limited number of call ins... I think it is limited to 5...

(b)(6) (b)(7)(C) Cargo Control & Release

ACE Business Office/ Office of International Trade

U.S. Customs & Border Protection

Department of Homeland Security

**NOTICE:** The Contracting Officer is the sole individual that is authorized to make changes to the contract. The contents of this email are not intended to change the existing scope of contract. If the Contractor considers any part of this communication to constitute a change in scope, the Contractor shall notify the Contracting Officer in accordance with FAR Clause 52.243-7, Notifications of Changes.

**Warning:** This document is FOR OFFICIAL USE ONLY (FOUO). It is to be controlled, stored, handled, transmitted, distributed, and disposed of in accordance with DHS policy relating to FOUO information. This information shall not be distributed beyond the original addressees without prior authorization of the originator

---

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 9:33 AM  
**To:** (b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

**Cc:** (b)(6) (b)(7)(C)

**Subject:** RE: Sodium Pentothal Options - Premeet

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**Sent:** Tuesday, February 15, 2011 4:07 PM

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(b)(6) (b)(7)(C)

**Sent:**

Wednesday, February 16, 2011 9:34 AM

**To:**

(b)(6) (b)(7)(C)

**Cc:**

**Subject:**

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(b)(6) (b)(7)(C)

Cargo Control & Release

ACE Business Office/ Office of International Trade

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**Sent:** Tuesday, February 15, 2011 4:07 PM  
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**Subject:** Updated: Sodium Pentothal Options - Premeet  
**When:** Wednesday, February 16, 2011 9:30 AM-10:30 AM (GMT-05:00) Eastern Time (US & Canada).  
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**Sent:** Wednesday, February 16, 2011 9:33 AM  
**To:** (b)(6) (b)(7)(C)  
  
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**Subject:** RE: Sodium Pentothal Options - Premeet

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**Sent:** Tuesday, February 15, 2011 4:07 PM  
**To:** (b)(6) (b)(7)(C)  
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**When:** Wednesday, February 16, 2011 9:30 AM-10:30 AM (GMT-05:00) Eastern Time (US & Canada).  
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Added call-in details 571-468-6338 #297207

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I will follow up with an updated options/recommendations paper by COB today.

Thank you,

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 8:18 AM  
**To:** (b)(6) (b)(7)(C)

**Subject:** Updated: Sodium Pentothal Options - Premeet

We have reserved room 909 for everyone at 14 and L.

(b)(6) (b)(7)(C)

**Subject:** Updated: Sodium Pentothal Options - Premeet  
**Location:** Call - 571-468-6338 #297207

**Start:** Wed 2/16/2011 9:30 AM  
**End:** Wed 2/16/2011 10:30 AM  
**Show Time As:** Tentative

**Recurrence:** (none)

**Meeting Status:** Not yet responded

**Required Attendees:** (b)(6) (b)(7)(C)

**Optional Attendees:**



021511\_options  
paper.doc (53 K...

Added the updated options paper. Changes are tracked in red. Thanks to everyone for contributing.

Added Options Paper as reference for our discussion. Please review.....

Added call-in details 571-468-6338 #297207

All,  
This call will be necessary to establish the CBP recommendations prior to the FDA/HHS call scheduled for 02/16/11 (I will forward the details separately). If you can not make this call please have an alternate participate or provide me your comments and concerns related to the issue.

I will follow up with an updated options/recommendations paper by COB today.

Thank you,

(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, February 16, 2011 9:13 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: Fda?

Certainly, when would you like it ready to go?

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

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Sent:** Wed Feb 16 16:19:35 2011  
**Subject:** FW: Fda?

Can we update our one pager quickly so we can send to the front office?

(b)(6) (b)(7)(C)

Executive Director, Trade Policy and Programs Office of International Trade Customs and Border Protection  
1400 L St., NW, 12th Fl.  
Washington, DC 20005

Phone: 202 (b)(6) (b)(7)(C)

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

**From:** BALDWIN, DAN (AC-OT)  
**Sent:** Wednesday, February 16, 2011 4:19 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** Re: Fda?

Great!!! Please modify the 1-pager on this to reflect latest agreement so we can get this to front office.

Dan

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

**From:** (b)(6) (b)(7)(C)  
**To:** (b)(6) (b)(7)(C)  
**Cc:** BALDWIN, DAN (AC-OT)  
**Sent:** Wed Feb 16 16:15:57 2011  
**Subject:** RE: Fda?

We got our option! Option 1 (the disclaimer flag on the HTS). (b)(5)

(b)(5)

Everyone seemed pleased.

(b)(5)

(b) (5)

(b)(6) (b)(7)(C)

Executive Director, Trade Policy and Programs Office of International Trade Customs and Border Protection 1400 L St., NW, 12th Fl.  
Washington, DC 20005

Phone: 202 (b)(6) (b)(7)(C)

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

From: (b)(6) (b)(7)(C)

Sent: Wednesday, February 16, 2011 4:12 PM

To: (b)(6) (b)(7)(C)

Subject: Fda?

How was the FDA call? I was going to call in for a bit to listen but got tied up on another call until 3:15....

(b)(6) (b)(7)(C) Executive Director  
Commercial Targeting and Enforcement  
U.S. Customs and Border Protection  
Office of International Trade  
Washington, DC 20229  
202 (b)(6) (b)(7)(C) (office)  
202 (b)(6) (b)(7)(C) (fax)

## Handling of Sodium Pentathol (Sodium Thiopental) by CBP

Over the past several years, shipments of Sodium Pentathol (Sodium Thiopental) have been made through couriers who generally file entry notice electronically through CBP-FDA interface. This process alerts CBP that the product is regulated by FDA and requires FDA to notify customs that they have made a decision on the entry. (b) (5)

(b) (5)

(b) (5)

To implement this process, we would need to notify all parties involved in the importation process that (b) (5)

(b) (5)

Once the process is implement and guidance provided to CBP, they [CBP] will be able to process the entry without referral to FDA.

Below are the actions that are needed to implement this process:

1.

(b) (5)

2.

(b) (5)

3.

(b) (5)

4.

(b) (5)

**Option for Importation process of Sodium Pentothal absent notification by FDA to CBP  
Regarding Admissibility on a Shipment-by-Shipment Basis**

**Background:** Over the past several years, shipments of Sodium Pentothal have entered into the commerce of the United States through couriers who generally file entry notice electronically via the automated broker interface (ABI). The automated broker interface (ABI) transmits the entry data electronically to both CBP and FDA via electronic interface. When the importer files information electronically concerning this type of importation, the process automatically alerts CBP that the product is regulated by FDA. In order for CBP to release these shipments, FDA is required to notify CBP that it has made an admissibility determination on the entry.

It has been requested that CBP and FDA develop an option for these entries that would not involve FDA's notification requirement in the system on a shipment-by-shipment basis. After discussion between CBP and FDA counterparts, it was determined that the following three options could minimize FDA's involvement in the shipment-by-shipment review of Sodium Pentothal:

**Option #1:** (b) (5)

(b) (5)

**Pros:**

(b) (5)

**Cons:**

(b) (5)

**Sodium Pentothal Options**

**Background Statistics:**

Total Entry Lines (FY10): 4,156

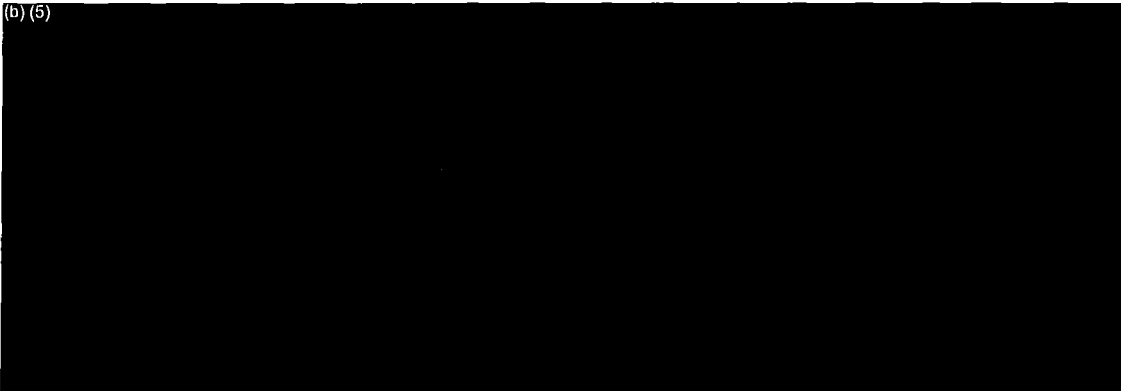
Top 5 Ports by Entry Lines:

- 2095 Fed Ex, Memphis – 1207 (29.04%)
- 4601 Newark – 471 (11.33%)
- 4701 JFK – 382 (9.19%)
- 3901 Chicago – 319 (7.68%)
- 3195 Fed Ex, Anchorage Alaska – 265 (6.38%)

\* Data derived with HTS# 2933.59.9500


**CBP Proposed Short Term Option:**

(b) (5)



**CBP Proposed Long Term Options:**

1. (b) (5)



2. (b) (5)



\* Additional analysis of impact to CBP resources and statutory/regulatory review is necessary.

**FDA Options Requested:**

(b) (5)

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(b) (5)

A black rectangular redaction box covering a portion of the page's content.

(b) (5)

A black rectangular redaction box covering a portion of the page's content.

(b) (5)

A black rectangular redaction box covering a portion of the page's content.



## **Importation process of Sodium Pentothal Option Paper**

**Background:** It has been requested that U.S. Customs and Border Protection (CBP) and the Food and Drug Administration (FDA) develop an option for entries of Sodium Pentothal that would not involve FDA's notification requirement in the system on a shipment-by-shipment basis.

Total Entry Lines (FY10): 4,156

Top 5 Ports by Entry Lines:

- 2095 Fed Ex, Memphis – 1207 (29.04%)
- 4601 Newark – 471 (11.33%)
- 4701 JFK – 382 (9.19%)
- 3901 Chicago – 319 (7.68%)
- 3195 Fed Ex, Anchorage Alaska – 265 (6.38%)

The following two options would minimize FDA's involvement in the shipment-by-shipment review of Sodium Pentothal:

### **Option #1: Change FDA required flag in CBP System**

The current system to system interface between CBP and FDA transmits FDA data that was submitted by the trade through CBP's Automated Broker Interface (ABI) to FDA for review. Data is transmitted to FDA based on the harmonized tariff number (HTS) submitted with the entry. The HTS number for sodium pentothal currently is flagged to require FDA data be provided by the Trade and sent to FDA for an admissibility review. If the flag associated with the HTS number for sodium pentothal was changed to a "*may be required*" the additional FDA data would not be sent to FDA for an admissibility decision. The following steps would need to be completed in order to implement this option:

- FDA would need to provide the written legal analysis as to why FDA can, within its agency discretion, choose not to review these importations on a shipment-by-shipment basis to determine admissibility as set forth in its laws and regulations.
- FDA would need to provide guidance to the Trade that shipments of Sodium Pentothal being used for law enforcement purposes should be disclaimed as requiring an FDA admissibility decision.

### **Advantages:**

- This solution would require very little programming to existing system to system interface. The use of a "*may be required*" flag is currently being utilized for other HTS numbers and would require little change in current procedures.

### **Disadvantages:**

- The HTS number for Sodium Pentothal covers a broad range of products and FDA would need to monitor those shipments being disclaimed to ensure they are Sodium Pentothal for law enforcement use.

**Option #2:** (b) (5)

(b) (5)

- (b) (5)
- (b) (5)
- (b) (5)

**Advantages:**

- ((b) (5))

**Disadvantages:**

- (b) (5)

The below options were submitted by FDA:

**FDA Options Requested:**

(b) (5)

(b) (5)

(b) (5)



**CBP Recommendation of FDA Options:**

CBP would recommend option 1. This option would not require any changes to the current policy. Programming changes would be necessary to add the additional FDA messaging between FDA and the Trade. Cost associated with these programming changes would need to be determined.

## Tariff Codes Used for Sodium Thiopental Entries

Finished dosage forms of Sodium Thiopental would fall under Chapter 30 of the HTS codes. Unfortunately, the HTS codes, under this chapter, group products together in broad categories based on intended action. As a result, finished dosage forms of Sodium Thiopental are grouped together with all other drug products that are considered "anticonvulsants, hypnotics, and sedatives" (HTS 3004.90.9130).

This HTS code is flagged FD2 (FDA notification is required) since all products under this heading are also drugs by FDA definition.

FDA checked the HTS code declared for all of the Sodium Thiopental entries in OASIS since FY2002. There were four different HTS codes used for these entries under the Chapter 3004 (i.e. finished dosage forms). Under the HTS codes, there is no product grouping that includes the term "anesthetic" as FDA defines this product. The most common HTS code used for Sodium Thiopental shipments was 3004.90.90.30, which is shown below.

3004.90.91		Other .....
	03	For veterinary use .....
		Other:
		Anti-infective medicaments:
	05	Sulfonamides .....
	10	Other .....
	15	Antineoplastic and immunosuppressive medicaments .....
	20	Cardiovascular medicaments .....
		Medicaments primarily affecting the central nervous system:
		Analgesics, antipyretics and nonhormonal anti-inflammatory agents:
	22	Tolmetin .....
	24	Tolmetin sodium dihydrate .....
	26	Tolmetin sodium (anhydrous) .....
	28	Other .....
	<b>30</b>	<b>Anticonvulsants, hypnotics and sedatives</b> .....
	35	Antidepressants, tranquilizers, and other psychotherapeutic agents .....
	40	Other .....

CBP has never issued a binding ruling covering the appropriate HTS code. Therefore, there is no clear guidance on the proper classification, resulting in multiple codes being used. The following codes have also been used for Sodium Thiopental.

3004.90.90.35 - Antidepressants, tranquilizers, and sedatives

3004.90.90.40 - other

3004.90.91.90 - other

The other HTS codes basically cover all other products that do not fall in the designated categories. As a result, these other groupings would cover a wide range of products.

The bulk chemical would fall under Chapter 29 since the bulk is not considered a finished or packaged product. Product intended for compounding would fall under Chapter 29.

### Product Code Combination for Sodium Thiopental

60QAA28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Prompt Release Tablets  
60QAB28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Extended Release Tablets  
60QAC28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Delayed Release Tablets  
60QAE28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Prompt Release Hard Gelatin Capsules  
60QAF28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Modified Release Hard Gelatin Capsules  
60QAH28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Soft Gelatin Capsules  
60QAI28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Premix  
60QAJ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;NonSterile Ointment  
60QAK28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Sterile Liquid  
60QAL28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;NonSterile Liquid  
60QAM28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Suppositories  
60QAN28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Large Volume Parenteral  $\geq 100$ ml  
60QAO28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Sterile Ointment  
60QAP28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Small Volume Parenteral  $< 100$ ml  
60QAQ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Aerosol Dispersed Medication  
60QAR28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;NonSterile Powder  
60QAS28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Active Pharm Ingrid/Chems for Further Manuf  
60QAU28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Block  
60QAV28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Compressed Medical Gas  
60QAW28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Bolus  
60QAX28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Block Or Bolus Premix  
60QAY28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;NEC  
60QAZ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Single Ingredient;Sterile Powder  
60QBA28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Prompt Release Tablets  
60QBB28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Extended Release Tablets  
60QBC28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Delayed Release Tablets

60QBE28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Prompt Release Hard Gelatin Capsules  
60QBF28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Modified Release Hard Gelatin Capsules  
60QBH28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Soft Gelatin Capsules  
60QBI28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Premix  
60QBJ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;NonSterile Ointment  
60QBK28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Sterile Liquid  
60QBL28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;NonSterile Liquid  
60QBM28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Suppositories  
60QBN28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Large Volume Parenteral >=100ml  
60QBO28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Sterile Ointment  
60Q28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Small Volume Parenteral <100ml  
60QBQ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Aerosol Dispersed Medication  
60QBR28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;NonSterile Powder  
60QBS28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Active Pharm Ingred/Chems for Further Manuf  
60QBU28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Block  
60QBV28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Compressed Medical Gas  
60QBW28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Bolus  
60QBX28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Block Or Bolus Premix  
60QBY28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;NEC  
60QBZ28 - Thiopental Sodium (Anesthetic);Human - Non/Rx Combination Ingredient;Sterile Powder  
60QCA28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Prompt Release Tablets  
60QCB28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Extended Release Tablets  
60QCC28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Delayed Release Tablets  
60QCE28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Prompt Release Hard Gelatin Capsules  
60QCF28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Modified Release Hard Gelatin Capsules  
60QCH28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Soft Gelatin Capsules  
60QCI28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Premix  
60QCJ28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;NonSterile Ointment

60QCK28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Sterile Liquid  
60QCL28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;NonSterile Liquid  
60QCM28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Suppositories  
60QCN28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Large Volume Parenteral >=100ml  
60QCO28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Sterile Ointment  
60QCP28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Small Volume Parenteral <100ml  
60QCQ28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Aerosol Dispersed Medication  
60QCR28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;NonSterile Powder  
60QCS28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Active Pharm Ingred/Chems for Further Manuf  
60QCU28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Block  
60QCV28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Compressed Medical Gas  
60QCW28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Bolus  
60QCX28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Block Or Bolus Premix  
60QCY28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;NEC  
60QCZ28 - Thiopental Sodium (Anesthetic);Human - Rx/Single Ingredient;Sterile Powder  
60QDA28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Prompt Release Tablets  
60QDB28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Extended Release Tablets  
60QDC28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Delayed Release Tablets  
60QDE28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Prompt Release Hard Gelatin Capsules  
60QDF28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Modified Release Hard Gelatin Capsules  
60QDH28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Soft Gelatin Capsules  
60QDI28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Premix  
60QDJ28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;NonSterile Ointment  
60QDK28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Sterile Liquid  
60QDL28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;NonSterile Liquid  
60QDM28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Suppositories  
60QDN28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Large Volume Parenteral >=100ml  
60QDO28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Sterile Ointment



60QDP28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Small Volume Parenteral <100ml  
60QDQ28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Aerosol Dispersed Medication  
60QDR28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;NonSterile Powder  
60QDS28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Active Pharm Ingred/Chems for Further Manuf  
60QDU28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Block  
60QDV28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Compressed Medical Gas  
60QDW28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Bolus  
60QDX28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Block Or Bolus Premix  
60QDY28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;NEC  
60QDZ28 - Thiopental Sodium (Anesthetic);Human - Rx/Combination Ingredient;Sterile Powder  
60QIA28 - Thiopental Sodium (Anesthetic);Human - Investigational;Prompt Release Tablets  
60QIB28 - Thiopental Sodium (Anesthetic);Human - Investigational;Extended Release Tablets  
60QIC28 - Thiopental Sodium (Anesthetic);Human - Investigational;Delayed Release Tablets  
60QIE28 - Thiopental Sodium (Anesthetic);Human - Investigational;Prompt Release Hard Gelatin Capsules  
60QIF28 - Thiopental Sodium (Anesthetic);Human - Investigational;Modified Release Hard Gelatin Capsules  
60QIH28 - Thiopental Sodium (Anesthetic);Human - Investigational;Soft Gelatin Capsules  
60QII28 - Thiopental Sodium (Anesthetic);Human - Investigational;Premix  
60QIJ28 - Thiopental Sodium (Anesthetic);Human - Investigational;NonSterile Ointment  
60QIK28 - Thiopental Sodium (Anesthetic);Human - Investigational;Sterile Liquid  
60QIL28 - Thiopental Sodium (Anesthetic);Human - Investigational;NonSterile Liquid  
60QIM28 - Thiopental Sodium (Anesthetic);Human - Investigational;Suppositories  
60QIN28 - Thiopental Sodium (Anesthetic);Human - Investigational;Large Volume Parenteral >=100ml  
60QIO28 - Thiopental Sodium (Anesthetic);Human - Investigational;Sterile Ointment  
60QIP28 - Thiopental Sodium (Anesthetic);Human - Investigational;Small Volume Parenteral <100ml  
60QIQ28 - Thiopental Sodium (Anesthetic);Human - Investigational;Aerosol Dispersed Medication  
60QIR28 - Thiopental Sodium (Anesthetic);Human - Investigational;NonSterile Powder  
60QIS28 - Thiopental Sodium (Anesthetic);Human - Investigational;Active Pharm Ingred/Chems for Further Manuf

60QIU28 - Thiopental Sodium (Anesthetic);Human - Investigational;Block  
60QIV28 - Thiopental Sodium (Anesthetic);Human - Investigational;Compressed Medical Gas  
60QIW28 - Thiopental Sodium (Anesthetic);Human - Investigational;Bolus  
60QIX28 - Thiopental Sodium (Anesthetic);Human - Investigational;Block Or Bolus Premix  
60QIY28 - Thiopental Sodium (Anesthetic);Human - Investigational;NEC  
60QIZ28 - Thiopental Sodium (Anesthetic);Human - Investigational;Sterile Powder  
60QJA28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Prompt Release Tablets  
60QJB28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Extended Release Tablets  
60QJC28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Delayed Release Tablets  
60QJE28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Prompt Release Hard Gelatin Capsules  
60QJF28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Modified Release Hard Gelatin Capsules  
60QJH28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Soft Gelatin Capsules  
60QJI28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Premix  
60QJJ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;NonSterile Ointment  
60QJK28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Sterile Liquid  
60QJL28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;NonSterile Liquid  
60QJM28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Suppositories  
60QJN28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Large Volume Parenteral  $\geq 100$ ml  
60QJO28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Sterile Ointment  
60QJP28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Small Volume Parenteral  $< 100$ ml  
60QJQ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Aerosol Dispersed Medication  
60QJR28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;NonSterile Powder  
60QJS28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Active Pharm Ingred/Chems for Further Manuf  
60QJU28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Block  
60QJV28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Compressed Medical Gas

60QJW28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Bolus  
60QJX28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Block Or Bolus Premix  
60QJY28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;NEC  
60QJZ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx/Single Ingredient;Sterile Powder  
60QKA28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Prompt Release Tablets  
60QKB28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Extended Release Tablets  
60QKC28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Delayed Release Tablets  
60QKE28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Prompt Release Hard Gelatin Capsules  
60QKF28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Modified Release Hard Gelatin Capsules  
60QKH28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Soft Gelatin Capsules  
60QKI28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Premix  
60QKJ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;NonSterile Ointment  
60QKK28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Sterile Liquid  
60QKL28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;NonSterile Liquid  
60QKM28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Suppositories  
60QKN28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Large Volume Parenteral >=100ml  
60QKO28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Sterile Ointment  
60QKP28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Small Volume Parenteral <100ml  
60QKQ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Aerosol Dispersed Medication  
60QKR28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;NonSterile Powder  
60QKS28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Active Pharm Ingred/Chems for Further Manuf  
60QKU28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Block  
60QKV28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Compressed Medical Gas  
60QKW28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Bolus  
60QKX28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Block Or Bolus Premix

60QKY28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;NEC  
60QKZ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Non-Rx Comb Ingredient;Sterile Powder  
60QLA28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Prompt Release Tablets  
60QLB28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Extended Release Tablets  
60QLC28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Delayed Release Tablets  
60QLE28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Prompt Release Hard Gelatin Capsules  
60QLF28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Modified Release Hard Gelatin Capsules  
60QLH28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Soft Gelatin Capsules  
60QLI28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Premix  
60QLJ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;NonSterile Ointment  
60QLK28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Sterile Liquid  
60QLL28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;NonSterile Liquid  
60QLM28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Suppositories  
60QLN28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Large Volume Parenteral >=100ml  
60QLO28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Sterile Ointment  
60QLP28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Small Volume Parenteral <100ml  
60QLQ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Aerosol Dispersed Medication  
60QLR28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;NonSterile Powder  
60QLS28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Active Pharm Ingrid/Chems for Further Manuf  
60QLU28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Block  
60QLV28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Compressed Medical Gas  
60QLW28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Bolus  
60QLX28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Block Or Bolus Premix  
60QLY28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;NEC  
60QLZ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Single Ingredient;Sterile Powder  
60QMA28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Prompt Release Tablets  
60QMB28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Extended Release Tablets

60QMC28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Delayed Release Tablets  
60QME28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Prompt Release Hard Gelatin Capsules  
60QMF28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Modified Release Hard Gelatin Capsules  
60QMH28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Soft Gelatin Capsules  
60QMI28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Premix  
60QMJ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;NonSterile Ointment  
60QMK28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Sterile Liquid  
60QML28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;NonSterile Liquid  
60QMM28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Suppositories  
60QMN28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Large Volume Parenteral >=100ml  
60QMO28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Sterile Ointment  
60QMP28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Small Volume Parenteral <100ml  
60QMQ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Aerosol Dispersed Medication  
60QMR28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;NonSterile Powder  
60QMS28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Active Pharm Ingrid/Chems for Further Manuf  
60QMU28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Block  
60QMV28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Compressed Medical Gas  
60QMW28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Bolus  
60QMX28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Block Or Bolus Premix  
60QMY28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;NEC  
60QMZ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Rx/Comb Ingredient;Sterile Powder  
60QNA28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Prompt Release Tablets  
60QNB28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Extended Release Tablets  
60QNC28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Delayed Release Tablets  
60QNE28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Prompt Release Hard Gelatin Capsules  
60QNF28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Modified Release Hard Gelatin Capsules  
60QNH28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Soft Gelatin Capsules

60QNI28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Premix  
60QNJ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;NonSterile Ointment  
60QNK28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Sterile Liquid  
60QNL28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;NonSterile Liquid  
60QNM28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Suppositories  
60QNN28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Large Volume Parenteral >=100ml  
60QNO28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Sterile Ointment  
60QNP28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Small Volume Parenteral <100ml  
60QNQ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Aerosol Dispersed Medication  
60QNR28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;NonSterile Powder  
60QNS28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Active Pharm Ingrid/Chems for Further Manuf  
60QNU28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Block  
60QNV28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Compressed Medical Gas  
60QNW28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Bolus  
60QNX28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Block Or Bolus Premix  
60QNY28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;NEC  
60QNZ28 - Thiopental Sodium (Anesthetic);Animal (Food Producing) - Investigational;Sterile Powder  
60QOA28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Prompt Release Tablets  
60QOB28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Extended Release Tablets  
60QOC28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Delayed Release Tablets  
60QOE28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Prompt Release Hard Gelatin Capsules  
60QOF28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Modified Release Hard Gelatin Capsules  
60QOH28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Soft Gelatin Capsules  
60QOI28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Premix  
60QOJ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;NonSterile Ointment  
60QOK28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Ingrid;Sterile Liquid

60QOL28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;NonSterile Liquid  
60QOM28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Suppositories  
60QON28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Large Volume Parenteral  
>=100ml  
60QOO28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Sterile Ointment  
60QOP28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Small Volume Parenteral <100ml  
60QOQ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Aerosol Dispersed Medication  
60QOR28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;NonSterile Powder  
60QOS28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Active Pharm Inged/Chems for  
Further Manuf  
60QOU28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Block  
60QOV28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Compressed Medical Gas  
60QOW28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Bolus  
60QOX28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Block Or Bolus Premix  
60QOY28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;NEC  
60QOZ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Single Inged;Sterile Powder  
60QPA28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Prompt Release Tablets  
60QPB28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Extended Release Tablets  
60QPC28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Delayed Release Tablets  
60QPE28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Prompt Release Hard Gelatin  
Capsules  
60QPF28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Modified Release Hard Gelatin  
Capsules  
60QPH28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Soft Gelatin Capsules  
60QPI28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Premix  
60QPJ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;NonSterile Ointment  
60QPK28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Sterile Liquid  
60QPL28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;NonSterile Liquid

60QPM28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Suppositories  
60QPN28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Large Volume Parenteral  
>=100ml  
60QPO28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Sterile Ointment  
60QPP28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Small Volume Parenteral <100ml  
60QPQ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Aerosol Dispersed Medication  
60QPR28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;NonSterile Powder  
60QPS28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Active Pharm Inged/Chems for  
Further Manuf  
60QPU28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Block  
60QPV28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Compressed Medical Gas  
60QPW28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Bolus  
60QPX28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Block Or Bolus Premix  
60QPY28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;NEC  
60QPZ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Non Rx/Comb Inged;Sterile Powder  
60QQA28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Prompt Release Tablets  
60QQB28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Extended Release Tablets  
60QQC28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Delayed Release Tablets  
60QQE28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Prompt Release Hard Gelatin  
Capsules  
60QQF28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Modified Release Hard Gelatin  
Capsules  
60QQH28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Soft Gelatin Capsules  
60QQI28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Premix  
60QQJ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;NonSterile Ointment  
60QQK28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Sterile Liquid  
60QQM28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Suppositories  
60QQN28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Large Volume Parenteral >=100ml



60QQO28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Sterile Ointment  
60QQP28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Small Volume Parenteral <100ml  
60QQQ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Aerosol Dispersed Medication  
60QQR28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;NonSterile Powder  
60QQS28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Active Pharm Ingrid/Chems for Further Manuf  
60QQU28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Block  
60QQV28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Compressed Medical Gas  
60QQW28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Bolus  
60QQX28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Block Or Bolus Premix  
60QQY28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;NEC  
60QQZ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Single Ingredient;Sterile Powder  
60QRA28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Prompt Release Tablets  
60QRB28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Extended Release Tablets  
60QRC28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Delayed Release Tablets  
60QRE28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Prompt Release Hard Gelatin Capsules  
60QRF28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Modified Release Hard Gelatin Capsules  
60QRH28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Soft Gelatin Capsules  
60QRI28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Premix  
60QRJ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;NonSterile Ointment  
60QRK28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Sterile Liquid  
60QRL28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;NonSterile Liquid  
60QRM28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Suppositories  
60QRN28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Large Volume Parenteral >=100ml  
60QRO28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Sterile Ointment  
60QRP28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Small Volume Parenteral <100ml

60QRQ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Aerosol Dispersed Medication  
60QRR28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;NonSterile Powder  
60QRS28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Active Pharm IngreD/Chems for Further Manuf  
60QRU28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Block  
60QRV28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Compressed Medical Gas  
60QRW28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Bolus  
60QRX28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Block Or Bolus Premix  
60QRY28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;NEC  
60QRZ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) Rx/Comb Ingredient;Sterile Powder  
60QSA28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Prompt Release Tablets  
60QSB28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Extended Release Tablets  
60QSC28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Delayed Release Tablets  
60QSE28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Prompt Release Hard Gelatin Capsules  
60QSF28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Modified Release Hard Gelatin Capsules  
60QSH28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Soft Gelatin Capsules  
60QSI28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Premix  
60QSJ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;NonSterile Ointment  
60QSK28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Sterile Liquid  
60QSL28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;NonSterile Liquid  
60QSM28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Suppositories  
60QSN28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Large Volume Parenteral >=100ml  
60QSO28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Sterile Ointment  
60QSP28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Small Volume Parenteral <100ml  
60QSQ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Aerosol Dispersed Medication  
60QSR28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;NonSterile Powder  
60QSS28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Active Pharm IngreD/Chems for Further Manuf

60QSU28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Block  
60QSV28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Compressed Medical Gas  
60QSW28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Bolus  
60QSX28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Block Or Bolus Premix  
60QSY28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;NEC  
60QSZ28 - Thiopental Sodium (Anesthetic);Animal (Non-Food Producing) - Investigational;Sterile Powder

## **IMPORTATIONS OF SODIUM PENTOTHAL**

### **Issue:**

Importations of Sodium Thiopental more commonly known as Sodium Pentothal are regulated by the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA). FDA has requested assistance from CBP to allow the release of Sodium Pentothal without providing an admissibility decision.

### **Implementation Plan:**

CBP's Offices of International Trade, Information and Technology, Chief Counsel and Field Operations has been working with FDA and HHS officials to craft a solution that would not

- Impact CBP's workforce or require them to act beyond their expertise
- Result in transferring legal issues from FDA to CBP
- Result in significant fiscal or scheduling impact on CBP's automated systems.

The solution we have developed has been approved by CBP, DHS, FDA and HHS officials. It allows importers to claim, through CBP's automated system, a law enforcement exemption for imports of sodium pentothal used by correctional facilities.

The benefits of this implementation are:

- The solution would require very little programming.
- FDA would be removed from the admissibility review process if a law enforcement exemption is claimed.
- CBP would be removed from the FDA admissibility review process.

Before this solution is implemented, CBP has asked FDA to provide the following:

1. Written legal analysis (on a one-time basis to cover all relevant shipments) as to why FDA can, within its agency discretion, choose not to review these importations on a shipment-by-shipment basis to determine admissibility as set forth in its laws and regulations, resulting in CBP's release of the merchandise on importation.
2. Guidance to the trade community that shipments of Sodium Pentothal being used for law enforcement purposes should be disclaimed as requiring an FDA admissibility decision. Executive level discussions are continuing over this issue as FDA would prefer CBP to issue the guidance.
3. Resources to cover any costs associated with programming changes, which we believe to be minimal.

### **Background:**

CBP has been working with HHS and FDA to address the importation of drugs used for lethal injections.

- In a recent Supreme Court case, the Court overturned a lower court stay of execution which determined that the lethal injection drugs were brought into the country lawfully. The determination resulted from an action taken by FDA in authorizing the importation of the drugs. Because of a U.S. domestic shortage of **Sodium Thiopental**, better known as **Sodium Pentothal** in the last year, some state correctional facilities have been importing the lethal drug from manufacturers in England.
- FDA would like to remain neutral in these importation cases and not be required to make an admissibility determination. (b) (5)  
(b) (5)  
(b) (5)
- FDA has stated that the White House requested CBP and FDA to find a way that would not involve FDA's with these entries on a shipment-by-shipment basis.

Importations of Sodium Pentothal are listed as schedule III controlled substances. Schedule III controlled substances require a declared be made to DEA at the time of entry. The declaration is filed on DEA form 236. At this time DEA has not requested any additional assistance from CBP.

**Issue:** FDA ISSUES WITH IMPORTATIONS OF SODIUM PENTOTHAL

**Background:**

CBP was recently contacted by the FDA concerning a controversy involving the importation of drugs used for lethal injections for an execution in Arizona. The impetus for this action was a recent Supreme Court case where the Court overturned a lower court stay of execution, determining that the lethal injection drugs were brought into the country lawfully. The determination resulted from an action taken by FDA in authorizing the importation of the drugs. Because of a U.S. domestic shortage of **Sodium thiopental**, better known as **Sodium Pentothal** in the last year, some state correctional facilities have been importing the lethal drug from manufacturers in England. It is reported that more importations are pending FDA approval, and in the meantime, the Government of England has asked the United States to end the importation of lethal drugs on moral grounds, as their government does not approve of capital punishment. FDA would like to remain neutral in these importation cases and not be required to make an admissibility determination, <sup>(b) (5)</sup>

(b) (5)

(b) (5)

FDA has stated that the Administration (White House) has requested that CBP and FDA develop an option for these entries that would not involve FDA's notification requirement in the system on a shipment-by-shipment basis.

FDA had engaged CBP in several discussions concerning procedural changes that would allow them to be removed from the admissibility review process for Sodium Pentothal products destined for state correctional facilities. CBP provided FDA with a set of deliverables that would require FDA follow-up prior to agreement on any type of procedural changes. In lieu of follow-up on the deliverables, FDA contacted CBP's Office of Information Technology (OIT) with the intent to arrange for automation changes to CBP's automated commercial system (ACS) which would effectively allow shipments of sodium pentothal to be released absent FDA review. FDA was unsuccessful in its attempt to arrange for the desired automation changes, and has since re-engaged CBP Policy in discussions to resolve the matter. Both CBP and FDA have agreed in principal to an implementation plan pending final review.

**Implementation Plan:**

The current system to system interface between CBP and FDA transmits FDA data that is submitted by the trade through CBP's Automated Broker Interface (ABI) to FDA for review. Data is transmitted to FDA based on the Harmonized Tariff Schedule number (HTS) submitted with the entry. The HTS number for sodium pentothal currently is flagged to require FDA data be provided by the Trade and sent to FDA for an admissibility review. If the flag associated with the HTS number for sodium pentothal was changed to a "*may be required*" the additional FDA data would not be sent to FDA for an admissibility decision. There would be several advantages to implementing this plan which include the following:

- The solution would require very little programming to the existing system-to-system interface.
- The use of a "*may be required*" flag is currently being utilized for other HTS numbers and would require little change in current procedures.
- FDA would be removed from the admissibility review process when the disclaimer data element is submitted.
- CBP would be removed from the FDA admissibility review process.
- Programming can be completed in a short period of time (less than 1 day given the current HTS# provided by FDA).
- Minimal to no cost incurred for programming changes.
- This approach could be replicated for other drugs.\*

\*If FDA required this programming change for additional HTS numbers, the HTS numbers would need to be provided to CBP for cost estimates and impact assessments.

**Next Steps Forward:**

1. FDA would need to provide the written legal analysis (on a one-time basis to cover all relevant shipments) as to why FDA can, within its agency discretion, choose not to review these importations on a shipment-by-shipment basis to determine admissibility as set forth in its laws and regulations, resulting in CBP's release of the merchandise on importation.
2. FDA would need to provide guidance to the Trade that shipments of Sodium Pentothal being used for law enforcement purposes should be disclaimed as requiring an FDA admissibility decision.
3. FDA needs to identify the tariff number(s) for which this option should be implemented.
4. FDA would incur any costs associated with programming changes.
5. CBP would need to provide guidance to its field personnel on how to process future shipments of sodium pentothal destined for state correctional facilities.

Prepared by:

(b)(6) (b)(7)(C)

Director, ISIRD  
Office of International Trade  
(202) (b)(6) (b)(7)(C)

February 1, 2011

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## SODIUM PENTATHOL

### *BACKGROUND*

- On October 27, 2010 the Food and Drug Administration (FDA) released Import Alert #60-B08, regarding a "Shortage of Sodium Pentathol."
- Sodium Pentathol is an anesthetic that renders a prisoner unconscious before his/her final execution. Hospira Ltd (Lake Forest, IL) is the only U.S. manufacturer and they recently reported that a lack of raw-materials has stopped its drug production. As a result, prisoner executions in the U.S. are being postponed because of the drug shortage.

### *ISSUE*

- With no available Sodium Pentathol in the United States, FDA is concerned that correction facilities located in death penalty states could look to (unapproved) foreign suppliers to meet their needs.
- The concern with foreign manufacturers is that FDA does not approve Sodium Pentathol production outside the U.S. If a correctional facility imports the drug and performs an execution, the facility would be violating state (lethal) injection laws and procedures.
- In response, FDA is trying to document Sodium Pentathol imports. An import Alert was created to monitor formal shipments but has only identified 9 shipments since October, 2006.
- The FDA recognized the fact that it cannot identify all "import safety" shipments using its current targeting process.
- With limited results and the inability to target undeclared shipments – FDA's Division of Import Operations requested that the Commercial Targeting and Analysis Center (CTAC) help to identify shipments of Sodium Pentathol.

### *ANALYSIS*

- CTAC quickly identified several Sodium Pentathol shipments that involved the foreign drug manufacturers Archimedes Pharma Ltd and Dream Pharma Ltd both of Great Britain. These shipments were imported by a number of correction facilities located in Georgia, Arizona, Arkansas and South Carolina.
- CTAC targeting for these shipments started with the (b) (7)(E) using the function code (b) (7)(E). This function code displays FDA Form 701 – which is a requirement of entry (cargo release). FDA Form 701 lists a specific FDA product code, product description, shipper name, manufacturer, and related CBP entry number.

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- Using the FDA information from Form 701, CTAC utilized (b) (7)(E) (b) (7)(E) to review entry details. Shipment identification numbers were used in (b) (7)(E) to locate specific import information. In this case, the entry numbers identified specific shipments; which included, carrier name, shipping pattern, entry type, parties of interest (shipper, importer, consignee), and cargo descriptions (tariff number / manufacturer). After review, there was a clear pattern of Sodium Pentathol shipments from a British manufacturer to a variety of U.S. correction facilities. There is a direct correlation between the targeting data, FDA and media reports.

*AVAILABLE TARGETING ACTIONS:*

- Option #1: (b) (5) [Redacted]
  - Pros: (b) (5) [Redacted]
  - Cons: (b) (5) [Redacted]
- Option #2: (b) (5) [Redacted]
  - Pros: (b) (5) [Redacted]
  - Cons: (b) (5) [Redacted]
- Option #3: (b) (5) [Redacted]
  - Pros: (b) (5) [Redacted]

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- Cons: (b) (5) [REDACTED]

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(b)(6) (b)(7)(C)

**From:** (b)(6) (b)(7)(C)  
**Sent:** Monday, August 29, 2011 4:02 PM  
**To:** (b)(6) (b)(7)(C)  
**Subject:** FW: Shortage of Sodium Pentathol aka Sodium Thiopental  
**Importance:** High  
**Attachments:** Import Bulletin 60-B08.doc

FYSA

(b)(6) (b)(7)(C)

Director, Cargo Control  
Office of Field Operations  
U.S. Customs and Border Protection  
(b)(6) (b)(7)(C) OFC  
BBRY

**From:** (b)(6) (b)(7)(C)  
**Sent:** Wednesday, November 03, 2010 4:37 PM  
**To:** (b)(6) (b)(7)(C)  
(b)(6) (b)(7)(C)

**Cc:** (b)(6) (b)(7)(C)  
**Subject:** FW: As we discussed  
**Importance:** High

All,

See attached Food and Drug Administration (FDA) Import Bulletin "IA#60-B08", regarding "Shortage of Sodium Pentathol aka Sodium Thiopental". The FDA believes that this unapproved drug may be imported by government entities such as state correctional facilities through International Mail Facilities (IMFs) and/or Express Consignment Facilities (ECFs) under the informal entry process (thus falling under the radar of FDA's automated screening procedures - OASIS). Per the bulletin, the drug is currently unavailable in the U.S. until the first quarter of 2011. The FDA has requested that CBP refer any possible shipments of this lethal injection drug to them immediately. The FDA bulletin directs their districts receiving shipments of the subject drug to contact their Director of Import Operations and Policy for further instructions.

At the present time, we have not received any information from the FDA such as possible country(s) of origin, manufacturer/shipper, etc., to assist in targeting for these shipments. Any information that becomes available from the FDA will be disseminated immediately. Shipments of the subject drug encountered at the IMFs and/or ECFs should immediately be referred to local FDA.

**NOTE: THIS INFORMATION IS NOT FOR PUBLIC RELEASE OUTSIDE OF CBP.**

Please pass this information to all IMFs and/or ECFs under your purview.

(b)(6) (b)(7)(C)

Program Manager  
U.S. Customs & Border Protection  
1300 Pennsylvania Avenue N.W.  
Room (b)(6) (b)(7)(C)

8/29/2011

Washington, D.C. 20229

(b)(6) (b)(7)(C) - Phone  
- Fax  
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**Issue: FDA ISSUES WITH IMPORTATIONS OF SODIUM PENTOTHAL**

**Background:** CBP was recently contacted by the FDA concerning a controversy involving the importation of drugs used for lethal injections for an execution in Arizona. The impetus for this action was a recent Supreme Court case where the Court overturned a lower court stay of execution, determining that the lethal injection drugs were brought into the country lawfully. The determination resulted from an action taken by FDA in authorizing the importation of the drugs. Because of a U.S. domestic shortage of **Sodium thiopental**, better known as **Sodium Pentothal** in the last year, some state correctional facilities have been importing the lethal drug from manufacturers in England. It is reported that more importations are pending FDA approval, and in the meantime, the Government of England has asked the United States to end the importation of lethal drugs on moral grounds, as their government does not approve of capital punishment. FDA would like to remain neutral in these importation cases and not be required to make an admissibility determination, (b) (5)

(b) (5)  
(b) (5) FDA has stated that the Administration (White House) has requested that CBP and FDA develop an option for these entries that would not involve FDA's notification requirement in the system on a shipment-by-shipment basis.

**Recap of Previous Meeting:** On December 21, 2010, CBP (OT & Chief Counsel) participated in a teleconference with FDA. The FDA Commissioner, Dr. Margaret Hamburg, and FDA Chief Counsel were also participants on the conference call. CBP initiated the discussion by providing a brief explanation of the import process. The Interagency Requirements Branch explained that the CBP-FDA automated interface is set up to trigger an automated response that requires FDA review of entries filed with certain harmonized tariff schedule (HTS) numbers. The premise of this being that the products are regulated by FDA, and in order for CBP to release the shipment, an FDA notification of admissibility is required to CBP.

(b) (5)

(b) (5)

**Recommendation:** CBP provided FDA with the following deliverables in order to successfully implement (b) (5)

1. (b) (5) [Redacted]
2. (b) (5) [Redacted]
3. (b) (5) [Redacted]
4. (b) (5) [Redacted]
5. (b) (5) [Redacted]

During the discussion that took place, FDA agreed in principal with all of the listed deliverables with the exception of recommendations two and three. FDA advised CBP that (b) (5) [Redacted] (b) (5) [Redacted] FDA will reconvene with CBP on this matter in a follow up discussion. The follow up meeting will also include discussion on FDA's long-term goal of implementing a system change that would allow for blanket deferral on these shipments.

Prepared by: (b)(6) (b)(7)(C) [Redacted]  
Director, ISIRD  
Office of International Trade  
(b)(6) (b)(7)(C) [Redacted]  
December 21, 2010

Office of Field Operations  
Cargo and Conveyance Security  
December 21, 2010

Action Required: Information Only

**Issue:** Regulation of Import of Lethal Injection Drugs

**Background:**

Currently, Thiopental sodium, a lethal injection drug, is not available in the United States. Manufacture in the U.S. has been hampered by unavailability of necessary ingredients to produce the drug. It is anticipated that this situation will continue at least into 2011. Several states have imported the drug. FDA's role with respect to these importations has been limited to verifying appropriate documentation from State correctional or similar state authorities of their intended law enforcement use of the drug. These drugs have not been tested or evaluated by FDA. (b) (5)

(b) (5)

(b) (5)

Further, FDA's involvement in determining admissibility of these drugs is open to misinterpretation regarding the regulatory use of the drug. Therefore, FDA is proposing a new procedure that will not require them to review these drugs being imported into the U.S. when that drug is imported for the law enforcement purpose of carrying out a state court authorized capital sentence (execution). FDA is proposing to provide CBP with a letter setting forth the FDA's legal authority to exercise enforcement discretion and that FDA declines to review, or recommend detention or refusal for, any shipment of thiopental sodium, when that drug is being imported by state correctional authorities. It is further proposed that such shipments would be handled by CBP without referrals to FDA.

**Recommendation:**

(b) (5)

Submitted by:

(b)(6) (b)(7)(C)

Program Manager, CCS