



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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

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

January 7, 2011

**UNITED PARCEL SERVICE**  
**Delivery Signature Requested**

(b) (7)(C)

(b) (4)

RE: Entry Number 112-9938358-2

Dear (b) (7)(C):

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

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

Sincerely,

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

**From:** Boulmay, Christopher  
**Sent:** Tuesday, November 30, 2010 4:00 PM  
**To:** (b) (7)(C)  
**Cc:** (b) (7)(C); Halpenny, Susan M; Dixon, Ruth P  
**Subject:** RE: FDA entry item # 112-99-38358-2  
(b) (7)(C)

This entry is currently under review by our DIOP branch. Due to the intended use (b) (7)(E) if you need additional information you can call Supervisor Susan Halpenny at 901-333-3521 or Supervisor Ruth Dixon at 901-333-3522. I am not authorized to make an admissibility decision on the entry.

Thank you,

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

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**From:** (b) (7)(C)  
**Sent:** Tuesday, November 30, 2010 3:37 PM  
**To:** Boulmay, Christopher  
**Cc:** (b) (7)(C)  
**Subject:** FDA entry item # 112-99-38358-2

Mr. Boulmay

I am inquiring into the shipment (# 112-99-38358-2) that is currently awaiting FDA approval. The shipment is to be sent to (b) (4). X. (b) (7)(C) is the (b) (4) contact person. I also called your phone number (b) (4) and left a message. If you could please return my call I would like to know the timeline for release. Thank you in advance.

(b) (7)(C)  
(b) (4)

# United States Food and Drug Administration

New Orleans District Office

## Notice of FDA Action

Entry Number: 112-9938358-2

Notice Number: 2  
January 6, 2011

Importer:

(b) (4)

>

Port of Entry: (b) (4) Memphis, TN

Carrier: (b) (4)

Date Received: November 24, 2010

Arrival Date: November 19, 2010

Filer of Record: (b) (4)

Consignee: (b) (4)

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### COMMERCIAL ENTRY CLOSED

#### Summary of Current Status of Individual Lines

Line ACS/FDA	Product Description	Quantity	Current Status
* 001/001	688760418962 THIOPENTAL	(b) (4)	Released 01-06-2011

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

@ = Consignee ID

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

### CORRESPONDENCE

Line ACS/FDA	Product Description
001/001	688760418962 THIOPENTAL

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

Randy N. Boling, Compliance Officer (Region/District) (901) 333-3537  
U.S. Food and Drug Administration (901) 333-3579 (FAX)  
959 Ridgeway Loop Road, Suite 100 RANDY.BOLING@FDA.HHS.GOV  
Memphis, TN 38120-4042

Notice of FDA Action  
Entry Number: 112-9938358-2

Notice Number: 2  
Page: 2

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**LINES RELEASED**

<u>Line ACS/FDA</u>	<u>Product Description</u>
001/001	688760418962 THIOPENTAL
	Randy N. Boling, Compliance Officer (Region/District) (901) 333-3537 U.S. Food and Drug Administration (901) 333-3579 (FAX) 959 Ridgeway Loop Road, Suite 100 RANDY.BOLING@FDA.HHS.GOV Memphis, TN 38120-4042

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

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

TABS:

DEPARTMENT OF THE TREASURY  
UNITED STATES CUSTOMS SERVICE

Form Approved  
OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

TEL: (b) (4) (b) (4) (b) (4)

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE 111910	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME (b) (4)	4. ENTRY NUMBER 112-9938358-2
5. PORT 2095	6. SINGLE TRANS. BOND	7. BROKER/IMPORTER FILE NUMBER (b) (4)	
	8. CONSIGNEE NUMBER (b) (4)	9. IMPORTER NUMBER (b) (4)	
10. ULTIMATE CONSIGNEE NAME (b) (4)		11. IMPORTER OF RECORD NAME (b) (4)	
12. CARRIER CODE (b) (4)	13. VOYAGE/FLIGHT/TRIP (b) (4)	14. LOCATION OF GOODS-CODE(S)/NAME(S) (b) (4)	
15. VESSEL CODE/NAME			
15. U.S. PORT OF UNLADING 2095	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE (b) (4)

20. DESCRIPTION OF MERCHANDISE

PHARMACEUTICALS NOT RESTRICTED

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER ID.
	TOTAL	(b) (4)	(b) (4)	GB	GBDREPHA176LON
M	02358560751				
H	688760418962				

27. CERTIFICATION

28. CUSTOMS USE ONLY

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

OTHER AGENCY ACTION REQUIRED, NAMELY:

SIGNATURE OF APPLICANT

(b) (7)(C)

PHONE NO.

(b) (4)

DATE

11/24/10

CUSTOMS EXAMINATION REQUIRED.

ENTRY REJECTED, BECAUSE:

29. BROKER OR OTHER GOVT. AGENCY USE

DELIVERY AUTHORIZED:

SIGNATURE

DATE

Paperwork Reduction Act Notice: This information is needed to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary.

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

Customs Form 3481 (010189)

FDA000033

**Dream Pharma Ltd.**

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

**Invoice Details**

Number: 2727INV

Date: 19-11-2010

Address:

(b) (4)

Delivery Address:

(b) (4)

Tel: (b) (4)

(b) (4)

VAT no:  
Purchase Order:

Currency: USD - US Dollar  
Heading: PHARMACEUTICALS NOT RESTRICTED

**Order Details**

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

**Statement Details**

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

**Shipping Details**

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

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

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

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

(b)(4) Manifest report

SHP DT 19-NOV-2010

SNDR: (b)(4)

METER

THERMAL  RECEIPT

Routing code

(b) (4)

(b) (4)

MPS shipment

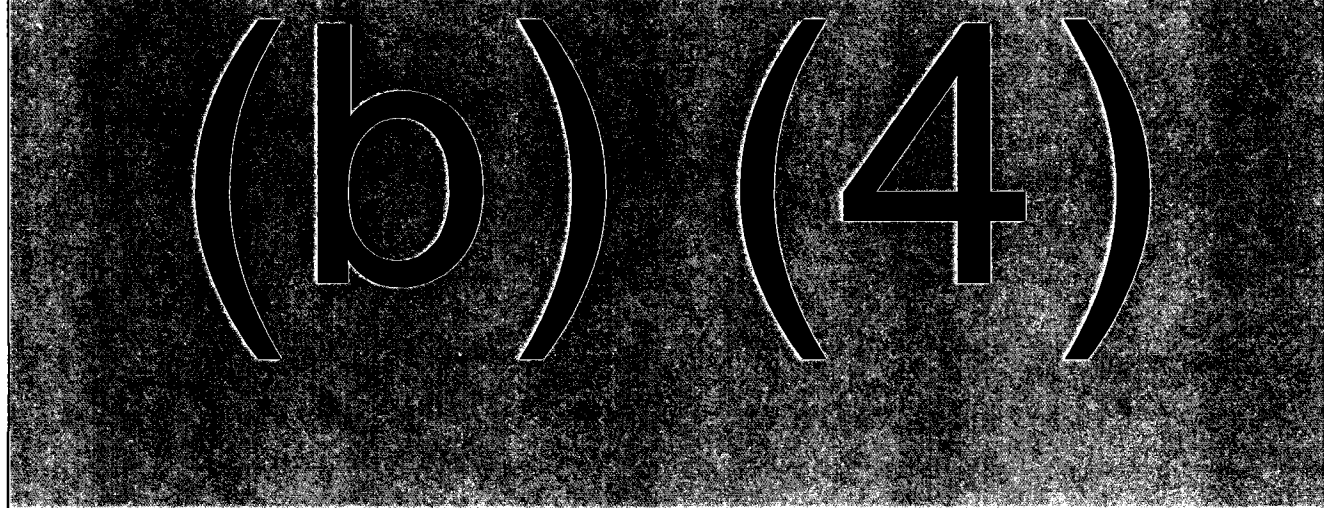
Package #	Package Weight
(b) (4)	(b) (4)

(b) (4)

LOCATION MEM

NEW INTERNATIONAL AIRBILL ENTRY

ENT# 112-9938358-2







01/22/2010 12:00pm

From (b) (4)

(b) (4)

T-859 P.001/001 F-698

(b) (4)

Approved through 12/1/95. OMB NO. 1545-0047 See back of form for Paperwork Reduction Act Notice.

DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE

IMPORTER ID INPUT RECORD

FILL 2A OR 2B

19 CFR 24.5

1. TYPE OF ACTION (mark all applicable)

- Notification of importer's number
- Change of name\*
- Change of address
- Check here if you also want your address updated in the Fines, Penalties, and Forfeitures Office

\*NOTE--if a continuous bond is on file, a bond rider must accompany this change document

2. IMPORTER NUMBER (Fill in one format) (b) (4)

2A. IR S Number (b) (4)

2B. Social Security Number

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

2D. Customs Assigned Number

RETURN TO :

AWB REF #:

3. Importer Name (b) (4) (b) (4)

4. DIV AKA DBA 5. DIV AKA/DBA Name

6. Type

Corporation Partnership Sole Proprietorship Individual U.S. Government Other

7. Importer Mailing Address (232 character lines maximum)

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

11. Country ISO Code (Non-U.S. Only) (b) (4)

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

(b) (4) ACCOUNT (b) (4) 14. State Code (b) (4) 15. ZIP (b) (4)

16. Country ISO Code (Non-U.S. Only) (b) (4)

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

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

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

18. Print or Typed Name and Title (b) (7)(C)

19. Telephone No. including Area Code PH (b) (4) FAX (b) (4) 21. Date 11-22-2010

22. Broker Use Only

CUSTOMS FORM 5106 (012293)