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 112-673446-4

Dear (b)(7)(C)

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

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

Sincerely,

Patricia K. Schafer
Acting District Director
New Orleans District Office

Enclosure: FDA Notice of Action

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number: 112-9673446-4

Notice Number: 2
January 6, 2011

Consignee:
(b) (4)

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Port of Entry: (b) (4) Memphis, TN
Carrier: (b) (4)
Date Received: November 5, 2010
Arrival Date: November 5, 2010

Filer of Record: (b) (4)
Importer of Record: (b) (4)

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	688760418804/THIOPENTAL SODIUM	(b) (4)	Released 01-06-2011

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

@ = Consignee ID

This is the final notice concerning entry 112-9673446-4. Any status changes are reflected in the Line summary and line detail sections.

CORRESPONDENCE

Line ACS/FDA	Product Description
001/001	688760418804/THIOPENTAL SODIUM

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

Denise D. Duncan, Compliance Officer
(Region/District)
(901) 333-3520
(901) 333-3579 (FAX)
DENISE.DUNCAN@FDA.HHS.GOV

U.S. Food and Drug Administration
959 Ridgeway Loop Road, Suite 100
Memphis, TN 38120-4042

LINES RELEASED

Line ACS/FDA	Product Description
001/001	688760418804/THIOPENTAL SODIUM

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

(901) 333-3520
(901) 333-3579 (FAX)
DENISE.DUNCAN@FDA.HHS.GOV

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

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

TABS:

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form Approved
OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

01-06-11

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

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
110510		(b)(4)	112-9673446-4
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
2095		(b)(4)	
	8. CONSIGNEE NUMBER		**9. IMPORTER NUMBER**
	NAME/ADDRESS		(b)(4)
10. ULTIMATE CONSIGNEE NAME		**11. IMPORTER OF RECORD NAME**	
(b)(4)		(b)(4)	
12. CARRIER CODE	**13. VOYAGE/FLIGHT/TRIP**	**14. LOCATION OF GOODS-CODE(S)/NAME(S)**	
(b)(4)	(b)(4)	(b)(4)	
15. VESSEL CODE/NAME			
16. U.S. PORT OF UNLADING	**17. MANIFEST NUMBER**	**18. G.O. NUMBER**	**19. TOTAL VALUE**
2095			(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	02358543833				
H	688760418804				

27. CERTIFICATION

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

SIGNATURE OF APPLICANT: (b)(7)(C)

PHONE NO.: (b)(4)

DATE: 11/05/10

29. BROKER OR OTHER GOVT. AGENCY USE

28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CUSTOMS EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED:	SIGNATURE	DATE

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

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

Customs Form 3461 (010189)

FDA000041

Dream Pharma Ltd.

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

Invoice Details

Number: 2716INV

Date: 05-11-2010

Address:

(b) (4)

Tel: (b) (4)

Delivery Address:

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

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

ENTRY NUMBER: 112 9673446 4 PAGE: 1
AWB/BL NBR : (b)(4) INVOICE # 11/05/2010
LINE CONSOL. WORKSHEET 08:19 PM

ITEMS MARKED 1 C/O- GB LINE VALUE- USD
TARIFF # 3004.90.9135
QTY 1: KG
(b)(4)

** **
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(b)(4)

*** END OF REPORT ***

ENTRY NUMBER: 112 9673446 4 PAGE: 1
AWB/BL NBR : (b)(4) INVOICE # 11/05/2010
SHIPPER : DREAM PHARMA LTD 08:19 PM

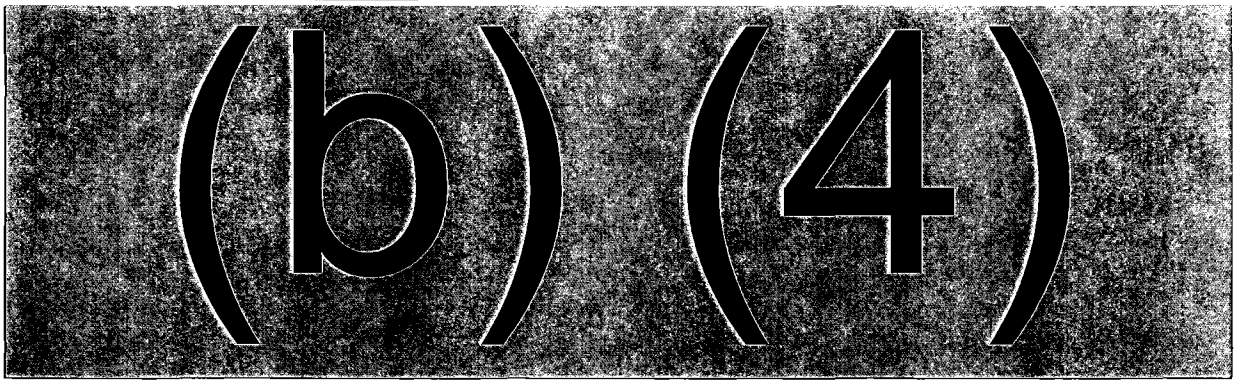
ITEM MARKED REFERENCE

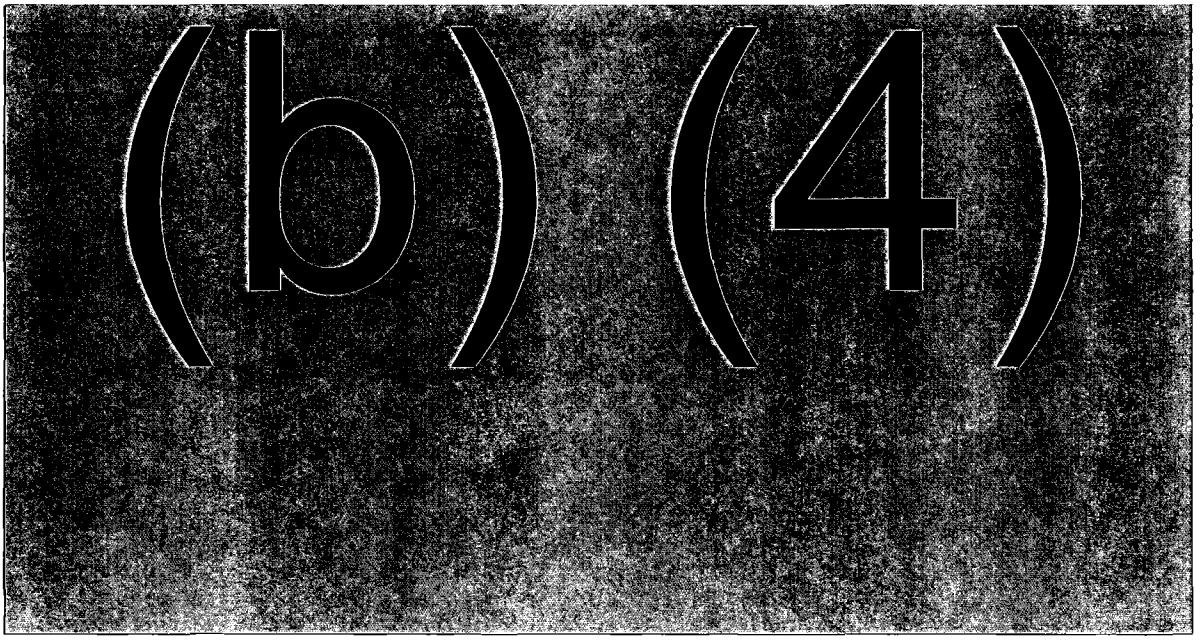
INVOICE LINE#	ITEM MARK	TARIFF NUMBER	COUNTRY OF ORIG.	RATE OF DUTY	VALUE-USD
1	1	(b)(4)	GB	Q:	(b)(4)

*** END OF REPORT ***

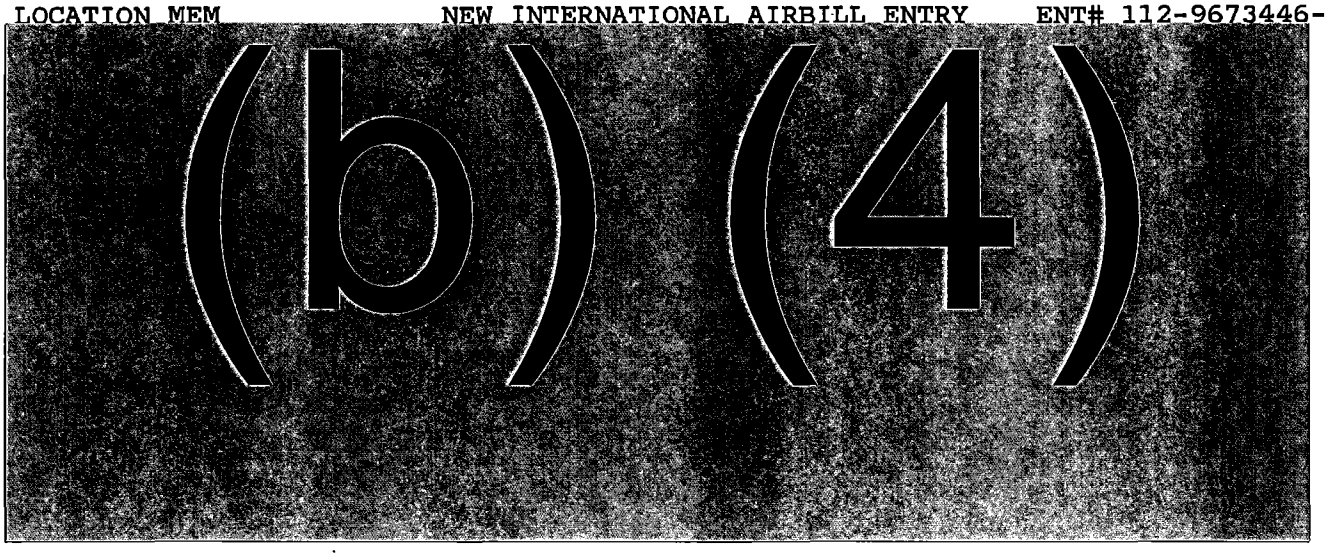
(b) (4) Manifest report

SHP DT 05-NOV-2010 SHIP (b) (4) METER [illegible] Routing code





LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY ENT# 112-9673446-4



United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number: 112-9673446-4

Notice Number: 1
November 8, 2010

Consignee:
(b)(4)

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Port of Entry: (b)(4) Memphis, TN
Carrier: (b)(4) ;
Date Received: November 5, 2010
Arrival Date: November 5, 2010

Filer of Record: (b)(4)
Importer of Record: (b)(4)

HOLD DESIGNATED

Summary of Current Status of Individual Lines

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

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

@ = Consignee ID

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

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

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