United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number: 112-7818637-8

Notice Number: 3
August 13, 2010

Importer:
(b) (4)

>

Port of Entry: (b) (4) Memphis, TN
Carrier: (b) (4)
Date Received: June 28, 2010
Arrival Date: June 28, 2010

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

<

COMMERCIAL ENTRY CLOSED

Summary of Current Status of Individual Lines

	Line ACS/FDA	Product Description	Quantity	Current Status
*	001/001	688760417429/THIOPENTAL 500MG	(b) (4)	Released after Detention 08-12-2010

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

@ = Consignee ID

This is the final notice concerning entry 112-7818637-8. Any status changes are reflected in the Line summary and line detail sections.

LINES RELEASED AFTER DETENTION

Line ACS/FDA	Product Description
001/001	688760417429/THIOPENTAL 500MG

Rebecca A. Asente, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

(504) 219-8818 ext. 104
(504) 219-8813 (FAX)
REBECCA.ASENTE@FDA.HHS.GOV

These products are released. This notice does not constitute assurance that the product released complies with all

112-7818637-8

provisions of the Food, Drug, and Cosmetic Act, or other related Acts, and does not preclude action should the product later be found violative.

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

United States Food and Drug Administration

New Orleans District Office

Notice of FDA Action

Entry Number: 112-7818637-8

Notice Number: 2
July 16, 2010

Consignee:
(b) (4)

>

Port of Entry: (b) (4) Memphis, TN
Carrier: (b) (4)
Date Received: June 28, 2010
Arrival Date: June 28, 2010

<

Filer of Record: (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	688760417429/THIOPENTAL 500MG	(b) (4)	Detained 07-15-2010

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

@ = Consignee ID

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

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

DETENTION

The following products are subject to refusal pursuant to the Federal Food Drug and Cosmetic Act (FD&CA), Public Health Service Act (PHSA),or other related acts in that they appear to be adulterated, misbranded or otherwise in violation as indicated below:

Line ACS/FDA	Product Description	Respond By
001/001	688760417429/THIOPENTAL	August 4, 2010

500MG

FD&CA Section 502(o), 801(a)(3); MISBRANDING
It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k). Mfr not Listed or Registered with FDA.

Please direct your response to:

Rebecca A. Asente, Compliance Officer
(Region/District)
U.S. Food and Drug Administration
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

(504) 219-8818 ext. 104
(504) 219-8813 (FAX)
REBECCA.ASENTE@FDA.HHS.GOV

You have the right to provide oral or written testimony, to the Food & Drug Administration, regarding the admissibility of the article(s) or the manner in which the article(s) can be brought into compliance. This testimony must be provided to FDA on or before the dates shown above.

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

Spikes, Michael

From: Asente, Rebecca
Sent: Wednesday, June 30, 2010 3:23 PM
To: Spikes, Michael
Cc: Schafer, Patricia
Subject: Import Entries Update 2nd for Today

Hi Michael,

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

LEX completed 7-1-2010

Released:
[redacted]

Created an LEX for:
112 7818637-8

I will put in interoffice mail the paperwork corresponding with the released entries.

Now, I will start working on the DTRs you just sent me today. I will send future updates to "reply all" from the emails you send w/the DTR hyperlinks.

Good to talk with you, R

Rebecca A. Asente, M.S., R.D., Compliance Officer
U.S. FDA, New Orleans District, Metairie Resident Post, Metairie Center, Suite 410, 2424 Edenborn Avenue, Metairie, LA 70001
(504) 219-8818 ext. 104; fax (504) 219-8813

Detained
RAA
7-15-2010

TABS:

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form Approved
OMB No. 1515-0059

ENTRY/IMMEDIATE DELIVERY

ABI CERTIFIED

AIR EXPRESS

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

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE/NAME	4. ENTRY NUMBER
062810		(b)(4)	112-7818637-8
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	02358388481				
H	688760417429				

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: 06/28/10

28. CUSTOMS USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY: FDES

☐ CUSTOMS EXAMINATION REQUIRED. FDRLS

☐ ENTRY REJECTED, BECAUSE:

DELIVERY AUTHORIZED: | SIGNATURE | DATE

29. BROKER OR OTHER GOVT. AGENCY USE

→ Compounding

ZEX - for pharm Compding only?

→ NO Det 7/15

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

06/28/10 19:45:47 (b)(4) Released 8/12/10

Customs Form 3461 (010189)

FDA000006

Dream Pharma Ltd.

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

Invoice Details

Number: 2583INV.

Date: 24-06-2010

Address:
(b) (4)

Delivery Address:
(b) (4)

VAT no:
Purchase Order:

Currency: GBP - Pounds sterling
Heading: PHARMACEUTICALS

Order Details

Name/Description	Quantity	Price	Total
Thiopental Injection , powder for reconstitution, thiopental sodium, 500-mg vial packs of 25's Batch No: AS3393 EXP: 02/14	(b) (4)	(b) (4)	
Admin fee for orders below £250	(b) (4)	(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) GBP - Pounds sterling
	Payment Method: Prepayment Thank You

Shipping Details

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

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

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

ENTRY NUMBER: 112 7818637 8 PAGE: 1
AWB/BL NBR : (b)(4) INVOICE # 06/28/2010
LINE CONSOL. WORKSHEET 07:49 PM

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

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

*** END OF REPORT ***

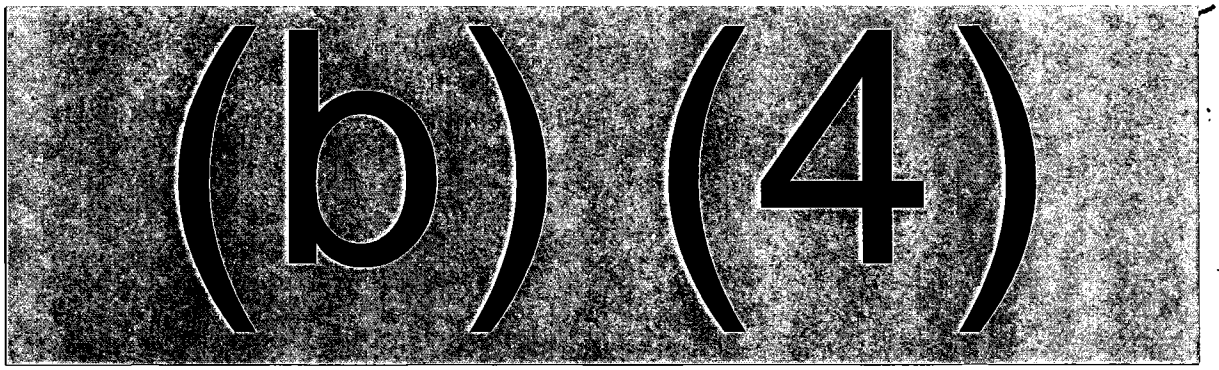
ENTRY NUMBER: 112 7818637 8 PAGE: 1
AWB/BL NBR : (b)(4) INVOICE # 06/28/2010
SHIPPER : DREAM PHARMA LTD 07:49 PM
ITEM MARKED REFERENCE

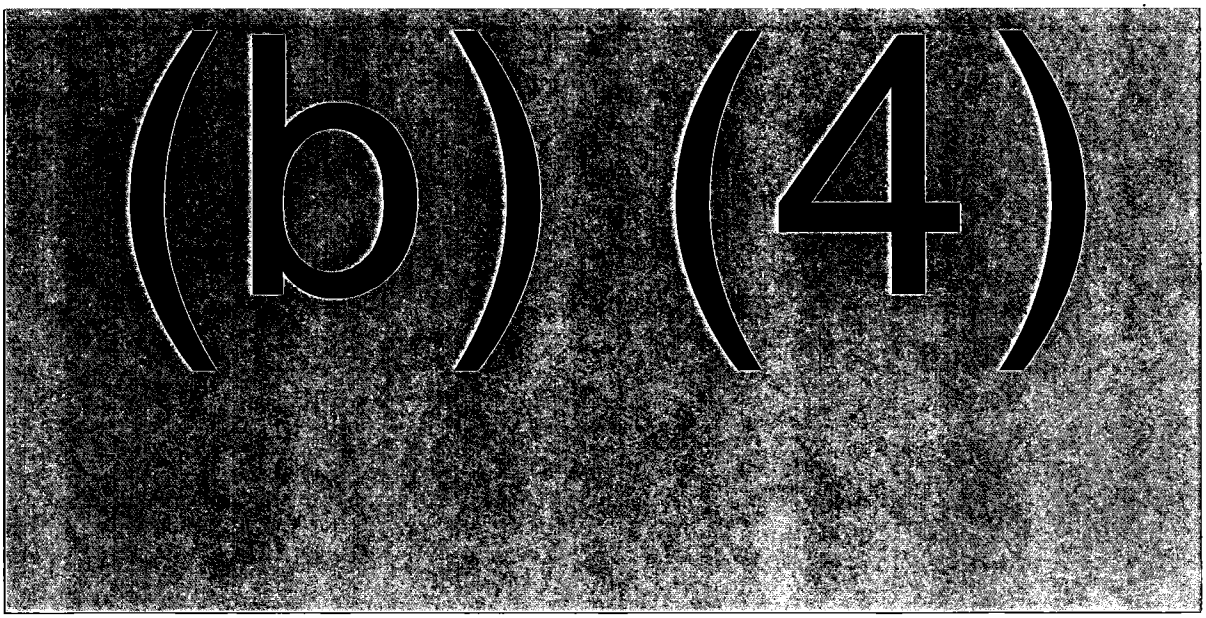
INVOICE LINE#	ITEM MARK	TARIFF NUMBER	COUNTRY OF ORIG.	RATE OF DUTY	VALUE-GBP
1	1	(b)(4)	GB	Q:	(b)(4)

*** END OF REPORT ***

(b) (4) Manifest report

SHP DT 28-JUN-2010 SNDR: (b) (4) METER THERMAL ☒ RECIPI 260722620 Routing code





page: 1

LOCATION MEM NEW INTERNATIONAL AIRBILL ENTRY ENT# 112-7818637-8