



Wholesaler Notification Letter
URGENT: Voluntary Product Recall
Contrave®

October 5, 2018

Dear Wholesaler,

Orexigen Therapeutics, Inc. is conducting a voluntary recall of Contrave® 8 mg/90 mg (naltrexone HCl/bupropion HCl) bottles, NDC 51267-890-99, from wholesalers / distributors and their direct customers. Product is being recalled at the retailer level due to rare occurrences of punctures in the bottle.

This recall is being conducted with the knowledge of FDA.

Our records show that you may have received the impacted lot between July 30, 2018 and August 7, 2018. This recall is only being conducted for Contrave® product with the lot number listed below.

| NDC # | Package Size | Lot # | Expiration Date |
|--------------|---------------------------|-------|-----------------|
| 51267-890-99 | Bottle, 120 count tablets | ZYCY | 11 APR 2021 |

Required Actions:

1. Identify affected Contrave® 8 mg/90 mg (naltrexone HCl/bupropion HCl)
 - Contrave® NDC 51267-890-99
 - Bottles, 120 count

Refer to Figures 1 and 2 for photos of the Contrave® Product Label

2. Return of business reply form and product
 - Contact each of your customers who received impacted Contrave® product directly to notify them of the recall using the attached Wholesaler Customer (Pharmacy) Notification Letter. Please have your customers provide you with quantities of impacted product they have in stock for inclusion on your Business Response Form and request they send their returns back to you.
 - Within five (5) business days, please return to Stericycle, our recall administrator, the completed business reply form; this form should be returned whether or not you have any product from the affected lot. Please include the quantities of impacted product your direct customers have in stock. Email or fax to:

Email: Orexigen5933@stericycle.com
Fax: 877-552-7142

- Within ten (10) business days, return the recalled Contrave[®], including product returned from your direct customers, using the prepaid return label at the following address:

Orexigen Therapeutics, Inc. c/o
Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241

Please do not include non-recalled lots or competitor products with this shipment.

3. Replacement product will be issued to your account upon receipt of the returned Contrave[®] product
4. Provide replacement product to any customer who returns product from the impacted lot. Orexigen will, in turn, provide replacement product to you upon receipt of the returned product.
 - If you need additional prepaid return labels please contact Stericycle at 877-551-7147.

We appreciate your collaboration in this matter. Please accept our apologies for any inconvenience caused. Please feel free to contact Stericycle at 877-551-7147 (between 8am and 5pm (EDT), Monday-Friday) should you have any questions or concerns.

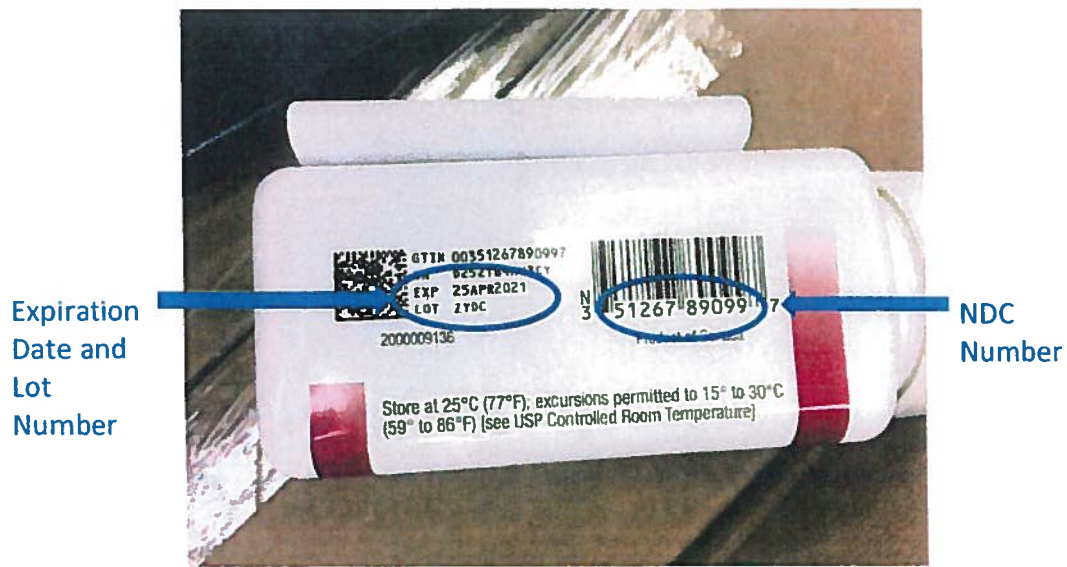
Best regards,

Orexigen Therapeutics, Inc.

Figure 1: Photo of Contrave[®] Product Label – Front



Figure 2: Photo of Contrave[®] Product Label – Side





Wholesaler Customer (Pharmacy) Notification Letter

URGENT: Voluntary Product Recall
Contrave®

October 5, 2018

Dear Wholesaler Customer (Pharmacy),

Orexigen Therapeutics, Inc. is conducting a voluntary recall of Contrave® 8 mg/90 mg (naltrexone HCl/bupropion HCl) bottles, NDC 51267-890-99. Product is being recalled at the retailer level due to rare occurrences of punctures in the bottle.

This recall is being conducted with the knowledge of FDA.

The recall is being conducted only for the Contrave® product with the lot number listed below.

| NDC # | Package Size | Lot # | Expiration Date |
|--------------|---------------------------|-------|-----------------|
| 51267-890-99 | Bottle, 120 count tablets | ZYCY | 11 APR 2021 |

Required Actions:

1. Identify affected Contrave® 8 mg/90 mg (naltrexone HCl/bupropion HCl)
 - Contrave® NDC 51267-890-99
 - Bottles, 120 count

Refer to Figures 1 and 2 for photos of the Contrave® Product Label

2. Return of product
Within five (5) business days, please
3. Notify the wholesaler from which you purchased your product of the quantities of bottles of the affected lot you have in inventory.
4. Return any Contrave® product you have with the lot number above to the Wholesaler you purchased your product from.

Please do not include non-recalled lots or competitor products with this shipment.

5. Replacement product will be shipped to you by your Wholesaler upon receipt of the returned Contrave® product.

We appreciate your collaboration in this matter. Please accept our apologies for any inconvenience caused. Please contact your Wholesaler with any questions.

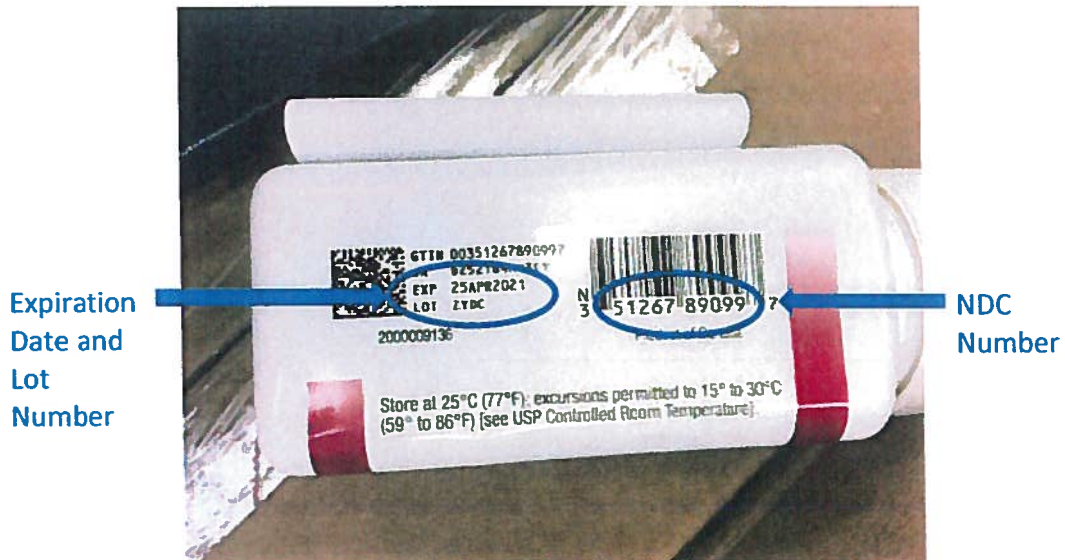
Best regards,

Orexigen Therapeutics, Inc

Figure 1: Photo of Contrave[®] Product Label – Front



Figure 2: Photo of Contrave[®] Product Label – Side



PLEASE COMPLETE THIS FORM AND RETURN IT VIA EMAIL (Orexigen5933@Stericycle.com), OR FAX IT TO 1-877-552-7142.

PLEASE COMPLETE THIS FORM EVEN IF YOU DO NOT HAVE ANY OF THE RECALLED PRODUCT. INCLUDE QUANTITY OF PRODUCT REPORTED BY YOUR DIRECT CUSTOMERS.

PLEASE MAKE A COPY OF THIS FORM TO INCLUDE WITH YOUR PRODUCT RETURN.

Check one box

- We do not have any Contrave® product listed in this recall notification in stock
- We are returning the number of bottles specified below:

Contrave® 8 mg/90 mg (naltrexone HCl/bupropion HCl)

| NDC # | Package Size | Lot # | Expiration Date | Organization | # Bottles to return |
|--------------|---------------------------|-------|-----------------|----------------------------|---------------------|
| 51267-890-99 | Bottle, 120 count tablets | ZYCY | 11 APR 2021 | Wholesaler | |
| 51267-890-99 | Bottle, 120 count tablets | ZYCY | 11 APR 2021 | Retailers/Direct Customers | |

Your timely response to this recall notification is requested. **Please complete and email or fax this reply form within five (5) business days**, even if you do not have any of the recalled product. Thank you.

Signature: _____

Title: _____

Name: _____

Company: _____

Phone: _____

If a Pharmacy is responding, please list wholesaler/location you purchased product from, if applicable:

Wholesaler Name: _____

Wholesaler Location (City, State): _____