

# Teva Pharmaceuticals USA Inc.

URGENT MARKET WITHDRAWAL – RETAIL LEVEL – INITIATED 10/03/2012

**Budeprion XL™ (Bupropion HCl ER Tablets) 300 mg**

**NDC# 0093-5351-56, 30 count bottles**

MANUFACTURED BY:  
IMPAX Laboratories, Inc.  
Hayward, CA 94544 USA

DISTRIBUTED BY:  
Teva Pharmaceuticals USA  
Sellersville, PA 18960

**All lots within expiry**

Dear Customer:

Impax Laboratories, Inc. has notified Teva Pharmaceuticals USA, Inc. of their intent to market withdraw all lots of **Budeprion XL™ (Bupropion HCl Extended-release Tablets) 300 mg** within expiry distributed under the Teva label. This market withdrawal is being carried out to the RETAIL LEVEL due to the therapeutic equivalence rating in the Orange Book change from AB to BX.

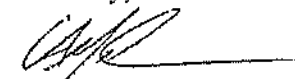
Wholesalers / Distributors / Retailers - Please perform the following activities:

- Please examine your inventory immediately for the specified lots of **Budeprion XL™ (Bupropion HCl Extended-release Tablets) 300 mg**. Our records indicate we shipped this product between January 26, 2011 and September 27, 2012.
- Immediately discontinue distribution of the product lots being market withdrawn.
- **Please perform a SUB-MARKET WITHDRAWAL to your RETAIL accounts using this Market Withdrawal Notification and Stock Response Form.**
- Promptly complete the attached market withdrawal stock response and reply via fax number 817-868-5343 or mail, even if you have no product to return.

Completed Market withdrawal Stock Response forms can be mailed, emailed, or sent via fax to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: [rarequest@inmar.com](mailto:rarequest@inmar.com). Inmar fax: 817-868-5343. Inmar will send a Return Goods Authorization label and shipping label. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All market withdrawn product returned without a Return Goods Authorization label may delay the issuance of your credit.

This market withdrawal is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Services at 800-545-8800. Medical related questions, please contact Teva Medical Affairs at 888-838-2872. If you need a stock response form, contact Inmar at 800-967-5952.

Sincerely,



Christopher A. Murdock, PhD  
Sr. Director, Regulatory Compliance  
Teva Pharmaceuticals USA, Inc.

**Teva Pharmaceuticals USA Inc.**

**URGENT MARKET WITHDRAWAL – RETAIL LEVEL – INITIATED 10/03/2012**

**STOCK RESPONSE FORM**

**Budeprion XL™ (Bupropion HCl ER Tablets) 300 mg**

**NDC# 0093-5351-56, 30 count bottles**

**All lots within expiry**

**Please fill out completely:**

Customer/Store Name: \_\_\_\_\_ DEA #: \_\_\_\_\_

*\*DEA # is required; if not provided, the processing of your form will be delayed.*

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Contact Name (please print): \_\_\_\_\_ Telephone #: \_\_\_\_\_

| Lot # | QTY to return<br>(Count partial as 1) |
|-------|---------------------------------------|
|       |                                       |
|       |                                       |
|       |                                       |
|       |                                       |
|       |                                       |
|       |                                       |

**Customers who did not purchase the product directly from the Manufacturer must complete the following.**

Purchased From: Name \_\_\_\_\_ DEA #: \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

**I have checked my stock and:** \_\_\_\_\_ I do not have any stock of the market withdrawn items, **OR**

I have quarantined and listed in the stock response form the quantity of units of **Budeprion XL™ (Bupropion HCl Extended-release Tablets) 300 mg** and will be returning to Inmar. Upon receipt of this Response Form, Inmar, will issue a recall return authorization and shipping label(s) \_\_\_\_\_ (please indicate the # of box labels needed)

**Inquiries regarding this market withdrawal are to be directed to the following:**

Market Withdrawal Stock Response Forms or product return information only - contact Inmar at 1-800-967-5952

Customer service related questions - contact Teva Customer Services at 1-800-545-8800

Medical related questions - contact Teva Medical Affairs at 1-888-838-2872

Please fax this Stock Response Form to: 1-817-868-5343 or E-mail at: [rarequest@inmar.com](mailto:rarequest@inmar.com)

|                         |        |       |     |     |
|-------------------------|--------|-------|-----|-----|
| Inmar/MedTurn Use Only: |        |       |     |     |
| Scan                    | Labels | Store | Kit | D.B |

**Budeprion (Bupropion) Lots within Expiry**

| <b>NDC#</b>  | <b>LOT#</b> | <b>EXP DATE</b> | <b>Strength</b> | <b>Size</b>     |
|--------------|-------------|-----------------|-----------------|-----------------|
| 0093-5351-56 | H0110541    | Oct-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | H0110551    | Oct-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | H0110561    | Oct-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 1000119     | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 1000120     | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000334    | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000402    | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000408    | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000409    | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000651    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000652    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000653    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000726    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000727    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000728    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000729    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000730    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000731    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000779    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000780    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10000996    | Jan-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10001026    | Nov-12          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10001351    | Feb-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10001713    | Mar-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10001714    | Mar-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10001715    | Mar-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002427    | Jun-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002428    | Jun-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002493    | Jun-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002705    | Aug-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002767    | Aug-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002771    | Aug-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10002775    | Jun-13          | 300mg           | 30 count bottle |
| 0093-5351-56 | 10005132    | Jun-14          | 300mg           | 30 count bottle |