APOTEX
ADVANCING GENERICS

April 12, 2013

URGENT DRUG RECALL

Apotex is updating all direct account **Wholesalers, Distributors, and Retailers** that have received the impacted lots below. In addition to our recall letters issued on April 03, 2013 and April 09, 2013, Apotex is initiating a recall of **all lots distributed to date on a precautionary basis**. This product is manufactured by Laboratorios Leon Farma, S.A. and distributed by Apotex. This voluntary TYPE I and II recall is being conducted to the **Patient Level**, and in collaboration with Health Canada. **Only the lots identified in this recall letter are impacted.**

Product Name	DIN	Strength	PKG Format	UPC Code	LOT Numbers	EXP. Date
ALYSENA™ 28 (Levonorgestrel and Ethinyl Estradiol Tablets USP)	02387883	100 µg / 20µg	28 x 1 BLS in a carton	771313219914	**LF01901A LF01900A LF01898A LF01894B**	**10/2014**
					LF01980A LF01982A LF01981A LF01979A LF02037A LF02036A LF02026A	**11/2014**

REASON FOR MARKET ACTION

Apotex is recalling these additional lots of ALYSENA™ 28 as a precautionary measure, while it investigates why the original lot of ALYSENA™ 28, LF01899A, contained blisters with extra placebo tablets (white) in place of active tablets (pink). Blisters of ALYSENA™ 28 should have three rows of active tablets (pink) and only one row of placebo tablets (white).

HEALTH ASSESSMENT

Ingestion of only 14 tablets of active instead of intended 21 of oral contraceptive would result in reduced efficacy for contraception and therefore possibility of unplanned pregnancy cannot be ruled out.

ACTIONS TO BE TAKEN

1. **Stop distributing and quarantine** above mentioned lots of ALYSENA™ 28 Tablets.
2. **Individuals** who have received impacted lots of ALYSENA™ 28 Tablets or have questions regarding this recall please contact your pharmacy. **Individuals should not interrupt their therapy, use a non-hormonal method of birth control,** contact their health care provider for medical advice and should return unopened packages to their pharmacist.

   As an alternative to ALYSENA™ 28 tablets, individuals may continue their therapy with ALYSENA™ 21 tablets until the supply of ALYSENA™ 28 tablets resumes with new lots *not* impacted by this recall. The only difference between ALYSENA™ 28 and ALYSENA™ 21 is that ALYSENA™ 28 includes a row of seven placebo tablets (white), which are not a critical part of the therapy. Alternatively, if ALYSENA™ 21 tablets are not available and individuals urgently require tablets for immediate therapy, **pharmacists** may consider inspecting the blisters of ALYSENA™ 28 that are currently available to determine whether they contain all three rows of seven active tablets (pink), for a total of 21 tablets, in which case such blisters of ALYSENA™ 28 tablets may be used for an individual's current menstrual cycle only.

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3. **Retail and hospital pharmacies** that track lot numbers dispensed to individuals please contact individuals who have received the impacted lots of ALYSENA™ 28 Tablets identified above, advise them of the recall, and recover any units of the impacted lots for return.

   For retail and hospital pharmacies that are unable to confirm the lot number of ALYSENA™ 28 Tablets dispensed to individuals, please contact individuals who have received ALYSENA™ 28 Tablets between November 19th, 2012 and receipt of this notification, advise them of the recall, and recover any units of the impacted lots identified above for return.

4. **Wholesalers/ Distributors are to conduct a sub-recall** to retail customers to whom you have shipped the affected lots, by informing them of the recall, requesting that they remove the affected lots from sale and return the stock to the wholesaler from whom it was purchased. Your customers **should not** return stock directly back to Apotex or Stericycle.

5. **Customers who purchased the affected product DIRECTLY from Apotex**, you are requested to conduct a physical count of affected inventory on hand. **Note:** Wholesaler/Distributors must also include in their count, inventory that was returned by their retail customers.

   Record total inventory on hand on the Business Reply Form (BRF) included in this letter and fax to Stericycle to the Toll-Free fax number below. **Note:** If you have NO inventory on hand, you are still required to complete the BRF and fax it back to Stericycle documenting that no affected inventory is on hand.

6. **If this letter has been forwarded to a retail pharmacy or institution that has purchased affected inventory through a wholesaler/distributor:**

   The below mentioned return process **DOES NOT** apply to you. Retail customers, who purchased through a wholesaler/distributor, must return the affected inventory back to the establishment from where the inventory was purchased. For these retailers, please contact your Wholesaler for specific return and credit instructions**. DO NOT** return your affected inventory back to Apotex or Stericycle.

7. **Returning affected inventory to Stericycle. For customers who purchased affected product DIRECTLY from Apotex**, place all affected product in a shipping carton, enclose a hard copy of the completed BRF, identify the product as "Recall Product" on the outside of the shipper and apply the prepaid shipping label provided. Contact Stericycle for additional return labels if required.

   Return address:

   Event #: 8415
   Stericycle Inc. 25 Ironside Crescent,
   Toronto, Ontario M1X 1G5
   Toll-free FAX: 1-866-324-3734

ADDITIONAL INFORMATION

For customers who purchased affected product DIRECTLY from Apotex, a credit will be issued for affected stock upon receipt of inventory at Stericycle.

Please complete and return by fax the enclosed Business Reply Form to receive prompt credit to your account. Also, please identify the returned merchandise as "RECALL PRODUCT" on the outside of the shipper.

If further assistance is required for returns please contact Stericycle at: **1-866-367-4537.**

Sincerely,

Apotex