

William C. Kennally III  
President



100 Route 206 North  
Peapack, NJ 07977

Board of  
JAN 06 2009  
Pharmacy

GREENSTONE  
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**URGENT: DRUG RECALL**

December 29, 2008

**Azithromycin 500 mg Tablets**

NDC	Lot	Expiration	Strength	Configuration/Count
59762-3070-2	6HP033A	May 2009	500 mg tablet	30 count bottles

Dear Customer:

Greenstone LLC is voluntarily recalling the above referenced lot of **Azithromycin 500 mg tablets**. Greenstone LLC voluntarily initiated this recall when it was determined that the above mentioned lot may not meet dissolution specifications on stability. Please note that when using this product as directed, the probability of serious adverse health consequences is remote.

Please note that the NDC number stated on the bottle is 59762-3070-2. The NDC number currently listed with the FDA is 59762-3070-1. Greenstone has decided with FDA to revise and list the NDC number 59762-3070-2 as stated on the bottle. **This recall only involves lot 6HP033A in the package configuration of 30 count bottles; it does not affect the blister pack configuration.**

**FEDERAL REGULATIONS REQUIRE THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD AND RETURN IT TO US WITHIN FIVE (5) BUSINESS DAYS.**

The recall of **Azithromycin tablets** is being conducted to the **retail level**.

Our records indicate that you may have received shipment of the affected lot between **August 2006** and **August 2007**. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution and promptly return to **Stericycle Inc.; 2670 Executive Drive Suite A; Indianapolis, IN 46241; Attn: Greenstone LLC – Azithromycin tablets** using the enclosed pre-paid UPS label. If you require additional shipping labels or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093.

If you have further distributed this lot to wholesale or retail level accounts, please conduct a sub-recall and communicate this recall information to those accounts immediately. Please request that they immediately cease distribution of the affected lot and promptly return the product directly to the above address (your accounts do not need to fill out a business reply card; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product return). Further authorization is not required for product return. Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Greenstone Customer Service Representative at 1-800-447-3360.

This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience you may have been caused by this action. If you have any questions regarding the product, please contact Pfizer (Greenstone) Medical Information at 1-800-438-1985.

Sincerely,

**BUSINESS REPLY CARD**

**Azithromycin 500 mg tablets**

NDC #	SIZE	PRODUCT DESCRIPTION	LOT #	EXP. DATE	BOTTLES ON HAND
59762-3070-2	30 Count Bottles	Azithromycin 500 mg tablets	6HP033A	May 2009	

Your timely response to this recall notification is requested. Please fill out, tear off, and mail this reply card within five (5) business days, even if you do not have the recalled product. Thank you.

- We have read and understand the recall instructions.
- We have/will further notify our wholesale and/or retail accounts who received the product.
- We do not have any affected product on hand.

Signature \_\_\_\_\_ Title \_\_\_\_\_  
 Name \_\_\_\_\_ Phone \_\_\_\_\_



Azithromycin 500 mg tablets  
 December 29, 2008

EVENT 1943  
 ID 25565673  
 FLORIDA DEPT OF HEALTH

**Azithromycin 500 mg tablets**

NDC #	SIZE	PRODUCT DESCRIPTION	LOT #	EXP. DATE	BOTTLES ENCLOSED
59762-3070-2	30 Count Bottles	Azithromycin 500 mg tablets	6HP033A	May 2009	

The following information is required to assure proper crediting:

Wholesaler Debit Memo: \_\_\_\_\_

**PACKING SLIP**



Azithromycin 500 mg tablets  
 December 29, 2008

EVENT 1943  
 ID 25565673  
 FLORIDA DEPT OF HEALTH

Ship To: **RS**  
 STERICYCLE RECALL COORDINATOR  
 2670 EXECUTIVE DRIVE SUITE A  
 INDIANAPOLIS IN 46241  
 ID: 25565673  
 Event: 1943  
 Seq: 20420

**IN 462 9-01**

**UPS GROUND**  
 TRACKING #: 1ZE380100696792214

**PACKING INSTRUCTIONS:**

- Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.
- Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)
- Keep this for your records. All followup will be based on this shipping information.

**TRACKING #: 1ZE380100696792214**

ID 25565673 EVENT 1943  
 FLORIDA DEPT OF HEALTH