

PATRIOT
PHARMACEUTICALS

RECEIVED BY CALIF.
2007 APR 12 PM 3:15
PHARMACY

URGENT: DRUG RECALL

April 2, 2007

Patriot Pharmaceuticals, LLC is issuing a drug recall to the U.S. direct wholesale and retail chain account level of the referenced lots of the brand listed below. No other Patriot Pharmaceuticals product is impacted.

<i>Product</i>	<i>NDC Number</i>	<i>Lot Numbers</i>
Griseofulvin Oral Suspension (microsize) 125 mg/5 mL	10147-0810-4	See Attached (Page 2)

DISTRIBUTOR: Patriot Pharmaceuticals, LLC
Plymouth Meeting, PA 19462

MANUFACTURER: Ortho-McNeil Pharmaceutical, Inc.
1000 Route 202 South
Raritan, NJ 08869

REASON FOR MARKET ACTION

Griseofulvin oral suspension is packaged in amber glass bottles that are enclosed in a plastic film full body over-wrap that extends from the top of the cap to the base of the bottle. In certain instances, the over-wrap could potentially mask structural damage to the bottle that may have occurred from an impact during shipping and handling. This structural damage can enable glass fragments to be introduced into the suspension product. Although we have received no complaints of adverse events, the possibility exists to have a patient impact.

Only bottles enclosed in this transparent plastic film full body over-wrap are affected. The replacement product will be packaged with a plastic neckband.

HEALTH ASSESSMENT

In the unlikely event that a damaged bottle is dispensed, a potential exists for serious medical events due to accidental ingestion of broken glass fragments.

ACTION TO BE TAKEN BY THE DIRECT WHOLESALE AND RETAIL CHAIN ACCOUNTS

- Check your inventory for Patriot Pharmaceuticals Griseofulvin Oral Suspension (microsize) 125 mg/5 mL.
- Quarantine any lots listed with this recall letter.
- **We request that you perform a SUB-RECALL to the RETAIL/DISPENSING level.**
- Conduct a physical count of the packages to be returned and record this data on the enclosed Business Reply Card and Packing Slip.
- **Immediately return the Business Reply Card even if you do not have any remaining inventory of the listed products.**
- Return the subject packages using the Packing Slip and prepaid UPS Authorized Return Service™ Shipping Label to:

Stericycle, Inc.
2670 Executive Dr.
Suite A
Indianapolis, IN. 46241

ADDITIONAL INFORMATION

Credit for returned product will be issued to the direct wholesale and retail chain accounts at the current purchase price. For assistance with product return, contact Stericycle, Inc. at 1-800-668-4391. All other questions should be directed to The Consumer Information Center at 1-800-510-0383.



**Griseofulvin Oral Suspension (microsize) 125 mg/5 mL
NDC Number 10147-0810-4**

Lot No.	Expiry Date	Lot No.	Expiry Date	Lot No.	Expiry Date
5LA410	03/31/2007	6BA565	03/31/2008	6KA031	10/31/2008
5LA411	03/31/2007	6BA566	03/31/2008	6KA032	10/31/2008
5LA412	03/31/2007	6CA593	03/31/2008	6KA033	10/31/2008
5LA413	03/31/2007	6CA594	03/31/2008	6KA034	10/31/2008
5LA414	03/31/2007	6CA595	04/30/2008	6KA035	10/31/2008
5LA415	03/31/2007	6CA596	04/30/2008	6KA036	10/31/2008
5LA416	03/31/2007	6CA597	04/30/2008	6KA990	09/30/2008
5LA417	03/31/2007	6DA622	04/30/2008	6KA991	09/30/2008
5LA418	03/31/2007	6DA623	05/31/2008	6LA109	10/31/2008
5NA469	03/31/2007	6DA624	05/31/2008	6LA110	10/31/2008
5NA470	03/31/2007	6DA625	05/31/2008	6LA111	10/31/2008
5NA471	03/31/2007	6DA626	06/30/2008	6LA112	11/30/2008
6AA494	01/31/2008	6GA725	07/31/2008	6LA113	11/30/2008
6AA495	01/31/2008	6GA726	07/31/2008	6LA114	11/30/2008
6AA496	01/31/2008	6GA727	07/31/2008	6LA128	11/30/2008
6AA497	01/31/2008	6GA728	07/31/2008	6LA130	11/30/2008
6AA505	01/31/2008	6GA729	07/31/2008	6MA173	11/30/2008
6AA506	01/31/2008	6HA839	07/31/2008	6MA174	11/30/2008
6AA507	01/31/2008	6HA840	07/31/2008	6MA175	11/30/2008
6AA508	01/31/2008	6HA841	08/31/2008	6MA176	11/30/2008
6AA509	01/31/2008	6HA842	08/31/2008	6MA194	11/30/2008
6AA516	01/31/2008	6HA843	08/31/2008	6MA231	11/30/2008
6AA517	01/31/2008	6HA844	08/31/2008	6MA232	11/30/2008
6AA518	02/29/2008	6HA845	08/31/2008	6MA233	12/31/2008
6AA519	02/29/2008	6HA847	08/31/2008	6MA234	12/31/2008
6AA520	02/29/2008	6HA848	08/31/2008	6MA235	12/31/2008
6AA521	02/29/2008	6HA849	08/31/2008	6MA236	12/31/2008
6AA532	02/29/2008	6HA850	08/31/2008	6MA238	12/31/2008
6AA533	02/29/2008	6HA867	09/30/2008	6MA239	12/31/2008
6AA534	02/29/2008	6HA870	09/30/2008	6MA240	12/31/2008
6AA535	02/29/2008	6HA871	09/30/2008	6MA241	12/31/2008
6AA536	02/29/2008	6HA872	09/30/2008	6MA242	01/31/2009
6BA561	03/31/2008	6HA875	09/30/2008	6MA246	01/31/2009
6BA562	03/31/2008	6KA028	09/30/2008	6MA247	01/31/2009
6BA563	02/29/2008	6KA029	10/31/2008		
6BA564	03/31/2008	6KA030	10/31/2008		

Griseofulvin Oral Suspension (microsize) 125 mg/5 mL

NDC #	PRODUCT DESCRIPTION	LOT #	EXP. DATE	BOTTLES ON HAND
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			

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.

Signature _____ Title _____

Name _____ Phone _____

BUSINESS REPLY CARD



Griseofulvin Oral Suspension (microsize) 125 mg/5 mL

April 2, 2007

Event 1740
ID: 18006699
CALIFORNIA STATE BOARD OF PHA



Griseofulvin Oral Suspension (microsize) 125 mg/5 mL

NDC #	PRODUCT DESCRIPTION	LOT #	EXP. DATE	BOTTLES ENCLOSED
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			
10147-0810-4	Griseofulvin Oral Suspension (microsize) 125 mg/5 mL			

The following information is required to assure proper crediting:

Wholesaler Debit Memo: _____

PACKING SLIP



Griseofulvin Oral Suspension (microsize) 125 mg/5 mL

April 2, 2007

Event 1740
ID: 18006699
CALIFORNIA STATE BOARD OF PHA



Ship To: STERICYCLE RETURNS COORDINATOR
2670 EXECUTIVE DR STE A
INDIANAPOLIS IN 46241

ARS
Event: 1740
18006699

IN 462 9-01

UPS GROUND

Tracking #: 1Z E38 010 06 8767 9819

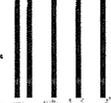
PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.
2. Affix prepaid UPS ARS shipping label to shipping container. 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.)
3. Keep this for your records. All followup will be based on this shipping information.

Tracking #: 1ZE380100687679819

ID #: 18006699
Event # 1740
CALIFORNIA STATE BOARD OF PHAR

CALIFORNIA STATE BOARD OF PHAR
400 R ST
SUITE 4070
SACRAMENTO, CA 95814



RECEIVED BY CALIF.
BOARD OF PHARMACY

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO 2702 INDIANAPOLIS IN

2007 APR 12 PM 3:15

POSTAGE WILL BE PAID BY ADDRESSEE

STERICYCLE INC
2670 EXECUTIVE DR STE A
INDIANAPOLIS IN 46209-4138



STERICYCLE / NNC GROUP
2670 EXECUTIVE DRIVE STE A
INDIANAPOLIS IN 46241



N18006699D1740-58340

CALIFORNIA STATE BOARD OF PHAR
ATTN: PHARMACIST
400 R ST
SUITE 4070
SACRAMENTO, CA 95814