



ORTHO
DERMATOLOGICAL

URGENT: DRUG RECALL

April 2, 2007

Ortho Dermatological, A Division of Ortho-McNeil Pharmaceutical, Inc. 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 Ortho Dermatological product is impacted.

| <i>Product</i> | <i>NDC Number</i> | <i>Lot Numbers</i> |
|--|-------------------|-----------------------|
| Grifulvin V [®] (griseofulvin oral suspension) microsize 125 mg/5 mL | 0062-0206-04 | See Attached (Page 2) |

DISTRIBUTOR: Ortho Dermatological
Division of Ortho-McNeil Pharmaceutical, Inc.
Skillman, NJ 08558

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

REASON FOR MARKET ACTION

Grifulvin V[®] 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.

This recall is limited to the suspension form and does not include any other dosage form.

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 Grifulvin V[®] (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 trade 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 trade 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 list 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 1-800-426-7762.



GRIFULVIN V® (griseofulvin oral suspension) microsize 125 mg/5 mL

NDC Number 0062-0206-04

| Lot No. | Expiry Date |
|----------------|--------------------|
| 5CA136 | 03/31/2007 |
| 5CA138 | 03/31/2007 |
| 5CA139 | 03/31/2007 |
| 5CA143 | 03/31/2007 |
| 5CA144 | 03/31/2007 |
| 5CA145 | 03/31/2007 |
| 5CA146 | 03/31/2007 |
| 5CA147 | 03/31/2007 |
| 5CA148 | 03/31/2007 |
| 5CA149 | 03/31/2007 |
| 5CA150 | 03/31/2007 |
| 5CA151 | 03/31/2007 |
| 5CA164 | 03/31/2007 |
| 5CA165 | 04/30/2007 |
| 6CA616 | 03/31/2008 |
| 6DA636 | 04/30/2008 |
| 6DA637 | 04/30/2008 |
| 6DA638 | 04/30/2008 |
| 6DA640 | 04/30/2008 |
| 6DA646 | 04/30/2008 |
| 6DA647 | 04/30/2008 |
| 6DA648 | 04/30/2008 |
| 6DA649 | 04/30/2008 |
| 6DA657 | 04/30/2008 |
| 6EA670 | 05/31/2008 |
| 6GA731 | 07/31/2008 |
| 6HA846 | 07/31/2008 |
| 6HA851 | 08/31/2008 |
| 6HA868 | 07/31/2008 |
| 6HA873 | 09/30/2008 |
| 6HA874 | 08/31/2008 |
| 6JA936 | 09/30/2008 |
| 6JA937 | 09/30/2008 |
| 6KA987 | 09/30/2008 |
| 6KA988 | 09/30/2008 |
| 6KA989 | 09/30/2008 |
| 6MA193 | 11/30/2008 |

Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL

| NDC # | PRODUCT DESCRIPTION | LOT # | EXP. DATE | BOTTLES ON HAND |
|--------------|---|-------|-----------|-----------------|
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |

BUSINESS REPLY CARD



ORTHO
DERMATOLOGICAL

Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL

April 2, 2007

Event 1739

ID 17910200

CALIFORNIA STATE BOARD OF PH



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 _____

Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL

| NDC # | PRODUCT DESCRIPTION | LOT # | EXP. DATE | BOTTLES ENCLOSED |
|--------------|---|-------|-----------|------------------|
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |
| 0062-0206-04 | Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL | | | |

PACKING SLIP



ORTHO
DERMATOLOGICAL

Grifulvin V® (griseofulvin oral suspension) microsize 125 mg/5 mL

April 2, 2007

Event 1739

ID 17910200

CALIFORNIA STATE BOARD OF PH



The following information is required to assure proper crediting:

Wholesaler Debit Memo: _____

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

ARS
Event# 1739
17910200

IN 462 9-01

UPS GROUND
TRACKING #: 1Z E38 010 06 8753 1290

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 #: 1Z E38 010 06 8753 1290

ID# 17910200 Event# 1739

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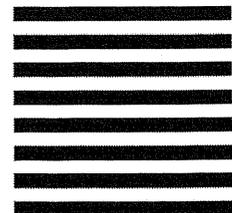
CALIFORNIA STATE BOARD OF PHAR
400 R ST SUITE 4070
SACRAMENTO, CA 95814



NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

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

POSTAGE WILL BE PAID BY ADDRESSEE



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



STERICYCLE / NNC GROUP
2670 EXECUTIVE DR STE A
INDIANAPOLIS, IN 46241



N17910200D1739-60608

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