Patient Safety Alert

Veterans Health Administration Warning System
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March 19, 2004

Item: Potential bacterial contamination of Twice-A-Day Nasal Spray manufactured by Propharma Inc., with Lot No. K4496.

Specific Incident: Propharma Inc. has informed its distributors, Harvard Drug Group and Major Pharmaceutical that it is recalling Twice-A-Day Nasal Spray, 15 mL and 30 mL because of possible bacterial contamination. The product's generic name is Oxymetazoline HCl 0.05% with the following additional identifiers: NDC# 0904-5217-35 and 0904-5217-30, Lot number K4496, expiration date 10/06. The attached RETAIL LEVEL recall letter is the first notification of this issue.

Actions: Immediately remove and quarantine the affected nasal spray bottles from inventory.

Addl. Information: The Food and Drug Administration is reviewing this matter for further potential action. Additional information will be provided as it becomes available from either or both the FDA and the product manufacturer.

Source: Product manufacturer and distributor(s).

Contact: Tom Borysek, Pharmacy Benefits Management Program at (708)-786-7876

Or

Bryanne Patail or Mary Burkhardt, National Center for Patient Safety at (734)-930-5890

The
HARVARD DRUG GROUP
CORPORATE OFFICE
P.O. Box 51640, 31778 Enterprise Drive, Livonia, Michigan 48150
Local 734-525-8700, Wats 800-875-0123, Fax 734-525-8393

March 15, 2004

URGENT DRUG RECALL
****READ CAREFULLY!!****

Recall 1. TWICE-A-DAY NASAL SPRAY, 15mL and 30mL
LOT # (s) K4496 (ONLY)
NDC # (s) 0904-5217-35 and 0904-5217-30

Manufactured By: Propharma Inc. (Identified as supplier code 'M-68' as found on product label only. See attachment 1 for label identification located on the back of the Response Letter.)
7760 NW 56 Street Miami, FL 33166

Dear Customer:

We have been informed by PROPHARMA INC. that they are recalling at the RETAIL LEVEL Twice-A-Day Nasal Spray, 15 mL and 30 mL with the above listed Lot Number Only. The reason for this recall is because of "possible bacterial contamination."

IMPORTANT: If you find any product with these lot numbers in stock, please stop distribution.

Harvard Drug Customers: Please call **customer service** (at the location where you normally call to place your orders), for authorization for your return of recalled product(s). **All** merchandise should be sent with a completed copy of the return merchandise form located on the back of this letter. Please do not ship product C.O.D., all shipments must be preauthorized. This is not your authorization to return product. This is notification of a recall. ****Reminder!** Harvard customers must call Customer Service and obtain authorization prior to returning merchandise!!**

Major Pharmaceutical Customers: This is your return authorization. Please indicate outside the carton "**Recall Products**" and return them with a completed copy of the return merchandise form located on the back of this letter. Please do not ship product C.O.D.; all shipments must be prepaid. (If you are a wholesaler or a distributor, this recall notice concerns only those customers of yours who your records indicate purchased the recalled products from you. We will not reimburse for cost of notification to all of your customers).

To ensure proper credit, please return recalled merchandise before **June 15, 2004**. Any other product sent in addition to or in lieu of the recalled product will be destroyed, without issuance of credit to your account.

Also, please fill out the enclosed response form and return it to us immediately, the FDA requires this even if you do not have any of the recalled product on hand. The response form lets us know that you have received this notice.

We apologize for any inconvenience caused by this recall and we thank you for your cooperation.

Sincerely,

Katherine Zesses
Regulatory Compliance Manager

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