3M Pharmaceuticals

3M Center, Building 275-3W-01
St. Paul, MN, USA 55144-1000

May 7, 2002

TO: ALL 3M PHARMACEUTICALS DISTRIBUTORS

SUBJECT: **URGENT – DRUG RECALL**

Regarding our recall notice dated May 6, 2002 for the following product, enclosed is a copy of the communication that is being sent this week to all Pharmacists via **Pharm/Alert** (it was inadvertently omitted from the fax broadcast).

Product Description	MAXAIR™ **Inhaler** (pirbuterol acetate inhalation aerosol), press and breathe metered dose inhaler, 300 inhalations NDC: **0089-0790-21**
Contact Information	If you have questions regarding this recall correspondence, please contact your 3M Pharmaceuticals Trade Relations National Account Manager: • Gary R. Borsos @ 440-871-0298 • Richard E. Evers @ 972-596-2905 • John H. Hidy @ 770-740-8100 • Marsha Lindquist or Jill Swenson @ 800-328-6523 (option #4) • Helga Rodriguez (3M Puerto Rico) @ 787-620-4594 • Customer Service @ 800-447-4537

Regards,

Tom Doyle

Thomas R. Doyle
National Mgr., Channel Mgmt.
3M PHARMACEUTICALS

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May 6, 2002

TO: ALL 3M PHARMACEUTICALS DISTRIBUTORS

SUBJECT: **URGENT – DRUG RECALL**

3M Pharmaceuticals considers this matter merits immediate attention. This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Product Description	**MAXAIR™ Inhaler** (pirbuterol acetate inhalation aerosol), press and breathe metered dose inhaler, 300 inhalations NDC: **0089-0790-21**
Lot Numbers, Expiration Dates, and Dates Shipped	**Lot Numbers** / **Expiration Date** / **Ship Dates** 000644 / August '03 / 09/20/00 thru 10/26/00 000756 / August '03 / 10/16/00 thru 11/09/00 000947 / October '03 / 11/19/00 thru 12/12/00 001009 / Nov. '03 / 12/27/00 thru 01/24/01 001110 / Dec. '03 / 01/24/01 thru 03/21/01 001111 / Dec. '03 / 02/19/01 thru 04/03/01 010025 / Jan. '04 / 03/13/01 thru 04/27/01 010195 / March '04 / 04/19/01 thru 06/29/01 010413 / April '04 / 06-22-01 thru 09-11-01 010283 / March '04 / 08-08-01 thru 09-25-01 010482 / May '04 / 09-17-01 thru 10-18-01 010580 / June '04 / 10-17-01 thru 11-28-01 010708 / July '04 / 11-28-01 thru 12-20-01 010709 / July '04 / 11-29-01 thru 03-39-02 010414 / May '04 / 01-31-02 thru 03-29-02 011210 / Dec. '04 / 03-15-02 thru 04-17-02
Recall Communications	In addition to this letter, a communication via a **Pharm/Alert** mailing is being sent to pharmacies (copy enclosed) and prescribing physicians. A press release is being issued to inform patients.
IMPORTANT INFORMATION	This recall **does not** affect Maxair™ Autohaler™ (pirbuterol acetate inhalation aerosol), a breath-actuated metered dose inhaler.

Summary	3M Pharmaceuticals is voluntarily issuing this recall as a precaution to address the remote possibility that a Maxair press and breathe aerosol inhaler may stick intermittently and patients may not receive the expected puff of medication. 3M Pharmaceuticals desires to maintain a high level of quality on our products. This action is taken to insure the safety of patients using this product. This is a recall to the wholesaler and pharmacy level. Patients will be alerted to this recall through a press release; therefore, **a call from the pharmacy to the patient is not required**. Patients are being advised that they should return their Maxair press and breathe inhaler to their pharmacy. Currently, there are no replacement units available. 3M Pharmaceuticals is offering patients the following: • Pharmacist can substitute free-of-charge the same medication in a **breath-actuated** inhaler, Maxair™ Autohaler™ (pirbuterol acetate inhalation aerosol, 200 mcg of pirbuterol/inhalation) in exchange for their Maxair press and breathe inhaler (200 mcg of pirbuterol/inhalation) unit. Patients will be informed that a physician prescription will be required. • 3M Pharmaceuticals will provide reimbursement as described below (see specific instructions below).
Patient Recall Assistance Toll-Free Number	3M Pharmaceuticals has provided a dedicated toll-free number to respond to patients regarding this recall. This toll-free number is: **1-800-390-1132**. This line is available seven (7) days a week from 8:30AM to 5:00PM EDT.
Instructions for Recall at Distributor Level	• Check every Distribution Center's inventory for product that is affected by this recall (see lot numbers above) and have it removed immediately and shipped back to 3M Pharmaceuticals' Return Goods Processor, USI (follow steps below for return). • If you have the capability, please run a query that will show all retail customers who may have received this product within the last 24 months and send the notification only to those customers. If you are unable to provide this query, then send a notification to all your retail customers. • Notify any other wholesalers to whom you have sold product. • Send notification to your retail and wholesaler customers to have all product affected by this recall removed from their shelves and sent back to you. Credit will be issued through the wholesaler (see section labeled "Distributor Allowance For Product Recall" below). • **DO NOT** mix this product with other outdated return goods.
Return Authorization Required	• Once product is ready to ship back to USI, call 3M Pharmaceuticals' Customer Service at 1-800-447-4537 (select option #1) to request a Return Authorization (RA) Number. **Product must be shipped back to USI, our authorized return goods processor.** • A Return Authorization label can be mailed to you or we can fax documentation to you with the RA #. • Once you receive this RA#, it is imperative that you: (1) Enclose a copy of your debit memo in the first box, (2) Indicate the RA# on ALL boxes, and (3) Number each box (i.e.: box 1 of 3, box 2 of 3, box 3 of 3).

Distributor Allowance For Product Recall	In accordance with the HDMA guidelines for Product Recalls, reimbursement of the following will be allowed and credited to the wholesaler: • For items retrieved from the distributor's inventory, credit for the merchandise will be at the current WAC, plus $1.41/unit OR a minimum of $50.00. • The actual shipping cost of returning recalled product to USI will also be reimbursed. • For items retrieved from customer's inventory and handled by the distributor, credit for the merchandise will be issued at current WAC, plus $2.82/unit OR a minimum of $50.00. • Costs incurred for recall notification to your customers will be reimbursed as follows: Number of retail customers notified x $1.36.
Instructions For Recall At the Pharmacy Level	For product at the retail pharmacy level: • Pharmacies should check their inventory and remove all affected product from their shelves. • All recall product is to be shipped back to their wholesaler. • Credit for recall product will be issued through the wholesaler. For Patient returns: • A pharmacist or patient will have to contact the physician to obtain a new prescription for either the Maxair Autohaler (NDC # 0089-0815-21) or another inhaler. • If the physician prescribes Maxair Autohaler, the pharmacist is instructed to provide this unit free-of-charge to the patient (3M Pharmaceuticals will replace this unit). • Pharmacist is to call the 3M Pharmaceuticals Pharmacy Exchange Program at 1-800-447-4537 (option #2) for instructions to return the patient's recall product and to obtain replacement (a prepaid mailer to return the unit will be provided). • If the replacement prescription was filled with a Maxair Autohaler unit, 3M will replace the unit free-of-charge.
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