

May 7, 2002



TO: ALL CONTRACT HOLDERS OF
MAXAIR™ Inhaler (pirbuterol acetate inhalation aerosol), press and breathe inhaler

SUBJECT: **URGENT-DRUG RECALL**

3M Pharmaceuticals considers this matter merits immediate attention. This voluntary recall is being conducted to the wholesaler and retail level with the knowledge of the U.S. Food and Drug Administration. You are being notified on this recall as our records indicate we have a contract in place with your organization for this particular product.

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	<u>Lot Numbers</u>	<u>Expiration Date</u>	<u>Ship Dates</u>
	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 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.		
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.		

<p>Summary</p>	<p>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.</p> <p>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.</p> <p>This is a recall to the wholesaler and pharmacy level. Patients will be alerted to this recall through a press release; therefore, <u>a call from the pharmacy to the patient is not required</u>. Patients are being advised that they should return their Maxair press and breathe inhaler to their pharmacy. Currently, there are no replacement units available.</p> <p>3M Pharmaceuticals is offering patients the following:</p> <ul style="list-style-type: none"> • 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).
<p>Instructions For Recall At the HMO Pharmacy Level</p>	<p><u>For inventoried product at the pharmacy level or mail order pharmacy:</u></p> <ul style="list-style-type: none"> • Pharmacies should check their inventory and remove all affected product from their shelves (see lot numbers above) and have it removed immediately and shipped back to 3M Pharmaceuticals' Return Goods Processor, USI (follow steps below for return). • 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. <u>Product must be shipped back to USI, our authorized return goods processor.</u> • 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 xxx, box 2 of xxx). • Credit for recall product will be issued at contract price plus the actual cost to ship product back to USI. <p><u>For Patient returns:</u></p> <ul style="list-style-type: none"> • 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.

Thank you for your kind assistance,

Tom Doyle
 Thomas R. Doyle

National Mgr., Channel Mgmt.
 3M PHARMACEUTICALS