

May 7, 2002



Dear Pharmacist:

**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.

<b>Product Description</b>	<b>MAXAIR™ Inhaler</b> (pirbuterol acetate inhalation aerosol), press and breathe metered dose inhaler, 300 inhalations NDC: <b>0089-0790-21</b>		
<b>Lot Numbers, Expiration Dates, and Dates Shipped</b>	<b><u>Lot Numbers</u></b>	<b><u>Expiration Date</u></b>	<b><u>Ship Dates</u></b>
	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
<b>Recall Communications</b>	In addition to this communication, a letter is being sent via <u>Pharm/Alert</u> mailing to prescribing physicians and a press release is being issued to inform patients.		
<b>IMPORTANT INFORMATION</b>	This recall <b>does not</b> affect Maxair™ Autohaler™ (pirbuterol acetate inhalation aerosol), a breath-actuated metered dose inhaler.		

<p><b>Summary</b></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"> <li>• Pharmacist can substitute free-of-charge the same medication in a <b>breath-actuated inhaler, Maxair™ Autohaler™</b> (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.</li> <li>• 3M Pharmaceuticals will provide reimbursement as described below (see specific instructions below).</li> </ul>
<p><b>Patient Recall Assistance Toll-Free Number</b></p>	<p>3M Pharmaceuticals has provided a dedicated toll-free number to respond to patients regarding this recall. This toll-free number is: <b>1-800-390-1132</b>. This line is available seven (7) days a week from 8:30AM to 5:00PM EDT.</p>
<p><b>Instructions For Recall At the Pharmacy Level</b></p>	<p><u>For product at the retail pharmacy level:</u></p> <ul style="list-style-type: none"> <li>• Pharmacies should check their inventory and remove all affected product from their shelves (see lot numbers above).</li> <li>• <u>All recall product is to be shipped back to your wholesaler.</u></li> <li>• Credit for recall product will be issued through the wholesaler.</li> </ul> <p><u>For Patient returns:</u></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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).</li> <li>• <b>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).</b></li> <li>• If the replacement prescription was filled with a Maxair Autohaler unit, 3M will replace the unit free-of-charge.</li> </ul>

Thank you for your kind assistance,

*Tom Doyle*

Thomas R. Doyle  
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3M PHARMACEUTICALS