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DIVISION OF QUALITY ASSURANCE
ADMINISTRATIVE MEMORANDUM NO. 05-01

TO: DDSO Directors
Voluntary Agency Executive Directors

FROM: Jan Abelseth 
Deputy Commissioner
Division of Quality Assurance

DATE: April 15, 2005

SUBJECT: Seizure of Vail Beds

This memorandum is an advisory to inform you that the U.S. Food and Drug Administration (FDA) and the U.S. Department of Justice has initiated a seizure of all Vail Model 500, 1000 and 2000 enclosed bed systems made by Vail Products, Inc. of Toledo, Ohio as of March 22, 2005. It has been determined that consumers may become entrapped and suffocate in these beds.

The FDA has taken this action at the manufacturing plant. The FDA expects the firm to take action to address safety concerns with same models which may already be in use in hospitals, health care facilities or private homes.

As you may be aware, OMRDD issued a ban on the use of Vail beds in a memo issued in 2001. A copy of this memo is attached.

This memorandum continues that ban. The use of Vail beds is prohibited in any facility operated or certified by OMRDD. Additionally we recommend that you share this information with any individuals and families to whom you provide services.

If you have any questions concerning this memorandum, please contact Kathleen Keating, RN, MSN, CPNP, OMRDD Director of Health Services at (518) 473-9697 or Fred Wetzel, Ph.D., Director of Clinical Review, Division of Quality Assurance at (212) 229-3350.

I N T E R O F F I C E M E M O R A N D U M

Date: 23-Mar-2005 01:31pm EST
From: MEDWATCH - The FDA Safety Information
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Dept:
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TO: MEDWATCH

(MEDWATCH@LIST.NIH.GOV)

Subject: FW: FDA MedWatch: Vail Enclosed Bed Systems Safety Alert due to risk o

MedWatch - The FDA Safety Information and Adverse Event Reporting Program

FDA and the Department of Justice initiated seizures of all finished Vail 500, 1000, and 2000 Enclosed Bed Systems made by Vail Products, Inc., in a response to ongoing concerns about manufacturing quality and labeling. Use of these systems poses a public health risk because patients can become entrapped and suffocate, resulting in severe neurological damage or death. FDA is aware of approximately 30 entrapments resulting from use of the Vail Enclosed Bed Systems, of which at least 7 resulted in death.

FDA advises consumers to stop using Vail 500, 1000 and 2000 Enclosed Bed Systems until they receive additional instructions from Vail Products.

Find the complete MedWatch 2005 Safety Summary, including a link to the FDA Talk Paper, at:

www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Vail

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