State of California-Health and Human Services Agency

California Department of Health Services

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Director

Department of Health Services

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Index: Benefits

TO: ALL CALIFORNIA CHILDREN'S SERVICES (CCS) ADMINISTRATORS, MEDICAL CONSULTANTS, CHIEF AND SUPERVISING THERAPISTS, AND STATE CHILDREN'S MEDICAL SERVICES (CMS) BRANCH AND REGIONAL OFFICE STAFF

SUBJECT: NATIONWIDE RECALL OF VAIL ENCLOSED BED SYSTEMS

The Federal Drug Administration (FDA) has just released the enclosed news bulletin notifying consumers that Vail Products, Inc., Toledo, Ohio, is recalling approximately 5000 "enclosed" bed systems due to associated hazards, injury, and death caused by patient entrapment. Vail Products is permanently ceasing the manufacture, sale and distribution of all "enclosed" bed systems and will no longer be available to provide accessories, replacement parts, or retrofit kits.

Although the FDA has instructed Vail Products, Inc. to notify consumers of this recall, we are uncertain what actions, if any, the company has taken. For these reasons, it is necessary for counties to immediately take the following steps to assure the safety of those children for whom CCS has authorized a Vail "enclosed" bed system:

- Identify all children in your county for whom a Vail "enclosed" bed system was authorized.
- Contact the child's family and determine if the child is still using the bed.
- Issue a copy of the enclosed FDA news bulletin and a copy of FDA's Preliminary Public Health Notification (available at http://www.fda.gov/cdrh/safety/032505-vail.html) to each child's family.

- Ask child's family to have the prescribing physician reevaluate medical necessity for an "enclosed" bed system and consider other alternative interventions that address the child's underlying medical issues.

CCS programs are asked to facilitate this effort by ensuring that authorizations to applicable primary care or specialty providers for these children are in place. A list of known CCS clients who have been authorized for a Vail "enclosed" bed system through EPSDT SS is available through CCS Regional Offices. This is not an all-inclusive authorization list. Other Vail "enclosed" bed systems may have been authorized through straight CCS venues. Please contact your Regional Office Nurse Consultant for information relating to this list.

It is important to document in the CMS Net narrative any family contact regarding this issue and request that families advise CCS if and when Vail Products, Inc. has contacted them. You will be advised at a later date whether or not an alternative "enclosed" bed system will be available for authorization as a replacement for the Vail "enclosed" bed.

If you have any questions, please contact your Regional Nurse Consultant.

Original Signed by Marian Dalsey, M.D., M.P.H.

Marian Dalsey, M.D., M.P.H., Acting Chief
Children's Medical Services Branch

Enclosure

FDA News

FOR IMMEDIATE RELEASE

P05-34

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Media Inquiries:

Brad Stone, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Notifies Public That Vail Products, Inc. Issues Nationwide Recall of Enclosed Bed Systems

FDA today is notifying consumers that Vail Products, Inc., Toledo, Ohio, is initiating a nationwide recall of approximately 5,000 "enclosed" bed systems. The Vail Products enclosed bed systems have been found to cause patient entrapments, resulting in severe neurological damage or death due to asphyxiation.

Under the terms of the recall, the company has sent new instruction manuals and warning labels to every customer informing them of FDA's advice to **stop using the bed system, move patients to alternative beds systems if possible and consult with their physician**. If, after consulting with their physician, it is determined that no alternative bed systems are available for a particular patient, users are advised to follow the safety precautions contained in the new instruction manuals and warning labels to help minimize risk of injury (also available on FDA's website, see below.)

Vail enclosed bed systems are canopy-like padded beds covered with nylon netting that is zipped into place to enclose the patient. They are used for at-risk patients with cognitive impairment, unpredictable behavior, spasms, seizures and other disorders. The beds are an alternative to physical or drug restraint to reduce falls or other injury to patients.

The bed systems pose a hazard in that patients can become entrapped between the side-rail and the mattress or between the canopy and mattress. Due to the presence of the canopy, if their head is entrapped, the patient may experience asphyxiation, which can result in permanent neurological injury or death. FDA is aware of approximately 30 entrapments, of which at least 8 resulted in death.

"FDA is making every effort to make sure that patients and healthcare providers are aware of this problem and are given the information needed to help minimize risk," said Dr. Daniel Schultz, Director of FDA's Center for Devices and Radiological Health.

FDA first issued a Public Health Notification on March 25, 2005 about the potential risk posed by these bed systems. FDA has today further updated its Public Health Notification (available at http://www.fda.gov/cdrh/safety/032505-vail.html) to reflect the latest information on this problem.

On June 23 and 24, 2005, Vail Products mailed corrected instruction manuals and labeling, including warning labels to all users of its Vail 500, Vail 1000, and Vail 2000 enclosed bed systems.

Vail Products publicly stated on June 16, 2005, that it is permanently ceasing the manufacture, sale and distribution of all Vail enclosed bed systems. Vail Products will no longer be available to provide accessories, replacement parts, or retrofit kits. Users who have not received a copy of the corrected instruction manual may attempt to contact Vail Products at 1-800-235-8245.

FDA encourages individual users to report any adverse events related to Vail enclosed bed systems to MedWatch, the FDA's voluntary reporting program at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at http://www.fda.gov/medwatch/report.htm. Consumers can also report directly to MedWatch.