FDA Asks U.S. Marshals to Seize Adulterated and Misbranded Hospital Bed Systems

FDA
March 22, 2005

In a response to ongoing concerns about manufacturing quality and labeling, the Food and Drug Administration (FDA) and the Department of Justice today initiated seizures of all finished Vail 500, 1000, and 2000 Enclosed Bed Systems made by Vail Products, Inc., located in Toledo, OH. Use of these systems poses a public health risk because patients can become entrapped and suffocate, resulting in severe neurological damage or death.

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

FDA is aware of approximately 30 entrapments resulting from use of the Vail Enclosed Bed Systems, of which at least 7 resulted in death.

The U.S. Marshal's Office also seized welded in-process components and all labeling and promotional materials for the Vail 500, 1000, and 2000 products.

FDA believes the Vail products seized today do not meet with the Quality System regulations of the Federal Food, Drug and Cosmetic Act and pose significant health risk for consumers.

The Enclosed Bed Systems are misbranded because they are dangerous to health when used in the manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling. They are further misbranded because they lack adequate directions for use and adequate warnings, thereby placing patients at an increased risk of entrapment and asphyxiation.

Additionally, Vail Products failed or refused to furnish material or information to the FDA as required by Medical Device Reporting regulation and the Reports of Corrections and Removals regulation.

FDA inspections of Vail Products, Inc., revealed that the firm has continually failed to follow the requirements of the Quality System regulation when manufacturing enclosed bed systems. Vail Products has previously received two FDA Warning Letters outlining unacceptable practices. The firm was given an opportunity to correct the violations, but failed to take appropriate actions.

FDA has initiated this action as part of its responsibility for promoting and protecting the public health by enforcing the Federal Food, Drug, and Cosmetic Act. FDA's mission includes ensuring the safety or safety and effectiveness of a broad spectrum of regulated products, including food, human and animal drugs, vaccines, blood products, medical devices, devices that emit radiation, and cosmetics.

FDA Preliminary Public Health Notification