This is an official CDC HEALTH ADVISORY

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Nosocomial Burkholderia cepacia pneumonia associated with contaminated alcohol-free mouthwash

The Centers for Disease Control and Prevention (CDC) has been notified by several states of clusters of pneumonia and other infections caused by Burkholderia cepacia. These cases had exposure to alcohol-free mouthwash manufactured by Carrington Labs (Irving, TX) for Medline Industries (Mundelein, IL). Cultures performed by a hospital laboratory where the first cases were detected indicate that multiple lots of Medline alcohol-free mouthwash are intrinsically contaminated with B. cepacia. In August 2005, the Texas Department of State Health Services was notified of a cluster of nosocomial pneumonia involving three patients hospitalized at a Texas health-care facility.

All three patients were intubated and in the intensive care unit for their underlying illnesses when they developed signs of pneumonia and respiratory cultures grew B. cepacia. All three patients had received oral care using 4 oz. bottles of Medline alcohol-free mouthwash prior to illness onset. One patient has recovered and has been discharged. The second and third remain hospitalized, one with a poor prognosis. Molecular typing is pending. An additional two clusters (2 cases and 5 cases), both associated with prior use of Medline alcohol-free mouthwash, are currently being investigated in two Florida health-care facilities.

CDC is working with state health departments and the Food and Drug Administration to determine the magnitude of this outbreak. Carrington Labs analysis of in-house retain samples has confirmed contamination in multiple lots of the product in both 4 oz. and 2 oz. bottles leading to a recall of all alcohol-free mouthwash manufactured by Carrington Labs for Medline.

The suspect product bears a 7 or 8 digit lot number on the bottom of the bottle; suspect lot numbers include numbers 0503*** through 0508*** and 0503**** through 0508**** (asterisks represent any digit). The product is available in 2 oz. bottles as well as 4 oz. bottles and was distributed only to hospitals and long term care facilities. The product is not distributed for direct retail sale to the consumer. However, the 2 oz. bottles are packaged with other items, such as toothbrushes, toothpaste, etc. by Medline into a 'personal hygiene hospital admission kit' so some mouthwash may be in the possession of the consumer within a residential setting. Medline alcohol-free mouthwash with the above lot numbers should not be used. Individuals who are aware of cases of B. cepacia colonization or infection occurring during or shortly after exposure to these products should contact their health department and CDC at 1-800-893-0485.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES