EPA Begins Testing Hospital Disinfectants as Sterilant Testing Program Nears Completion

The US Environmental Protection Agency (EPA) announced civil penalties totalling $3.1 million against the manufacturers (registrants) and distributors of several sterilant and hospital disinfectant products. Sterilant and disinfectant products play a critical role in infection control, and healthcare providers, consumers, and others rely on the labeling (registration) of these products as evidence that they work as claimed on the label. EPA has been conducting a testing program to determine the effectiveness of all antimicrobial products registered for use as sterilants, tuberculocides, and hospital disinfectants. The testing has been divided into two phases: sterilant testing, and hospital and tuberculocidal disinfectant testing. In an effort to protect the public health, EPA has taken enforcement action to remove certain products from the market that have failed to perform effectively when used in accordance with the label directions. The enforcement actions have been levied against the manufacturers of eight ineffective sterilants that failed the EPA testing program, one registrant of two disinfectants that failed testing, and a number of distributors for selling unregistered sterilants and disinfectants. The Table summarizes the status of chemical sterilant products in the EPA efficacy testing program.

These actions will bring the enforcement component of the sterilant testing program nearly to completion, with emphasis shifting to validation tests of hospital disinfectants. EPA issued civil complaints, and a stop sale, use, or removal order, against the hospital disinfectant products Broadspec 128 and Broadspec 256 (Bridin and Co) for failing the agency’s tuberculocidal and hospital disinfectant testing program. In addition, EPA has issued civil administrative complaints and proposed civil penalties against 10 distributors of seven unregistered Wipeout (disinfectant) products produced by Celltech Media, Inc (formerly Health Care Products, Inc) and one registered ineffective product (Wipeout Cold Sterilizing and Disinfecting Solution). The EPA recommends that holders discontinue use of existing stocks of any products that failed the testing program.

The EPA testing program was started in 1991 with sterilants. Testing began in 1992 on the 1,200 registered hospital disinfectants and 130 registered tuberculocides, and will be ongoing. The recent action against registrants of Broadspec 128 and Broadspec-256 is the first against a failed disinfectant or disinfectant with a tuberculocidal claim.

For additional information regarding the sterilant, hospital disinfectant, and tuberculocide testing programs, call EPA’s toll-free hotline, the National Pesticide Telecommunications Network, at (800) 447-6349, from 7 AM to 6 PM (CST).

FROM: (1.) EPA Press Release: Sterilant and Disinfectant Enforcement Action; February 19, 1995. (2.) EPA Questions and answers: enforcement actions against registrants and distributors of ineffective and unregistered sterilants and disinfectants; February 15, 1995. (Table)

Tuberculosis-Related Hospitalizations Double in 3 Years and Cost Up to $8 Billion-HIV Infection Adds to Price Tag

The results of the first study to use a nationally representative sample of hospitals, combined with cost data, to estimate hospitalizations and their costs for HIV and tuberculosis (TB) care was reported by Dr. Lisa Rosenblum and colleagues at the Centers for Disease Control and Prevention (CDC).

Data were obtained from a survey of discharges from US nonfederal short-stay hospitals and from statewide billing information. Patients included in the survey were 15 to 44 years of age with a listed diagnosis of HIV infection (N = 418,200) or active TB (N = 77,700) during 1985 to 1990.

During 1985 to 1990, hospitalizations related to HIV infection increased six-fold, from 18 to 102 per 100,000 persons. During 1988 to 1990, hospitalizations related to TB increased twofold, from 8 to 16 per 100,000 persons. The prevalence of TB among HIV-infected patients increased from 2.4% from 1985 to 1988 to 5.1% from 1989 to 1990. The prevalence of HIV infection among patients with TB increased from 11% from 1985 to 1988 to 28% in 1989 to 39% in 1990.

From 1985 to 1990, inpatient care costs increased 7.7-fold for HIV and 3.2-fold for TB hospitalizations. During this period, HIV and TB hospitalizations resulted in 5.7 and 1.1 million days of care, respectively, with an estimated direct cost of $5.7 to $7.4 billion and $0.89 to $1.07 billion, respectively. Estimated national costs of inpatient care for HIV infection or TB or both totaled $6.4 to $8.1 billion, 5% of which was used for patients with both HIV infection and TB.

These findings suggest that the convergence of the HIV and TB epidemics has had an increasing effect on morbidity and the cost of care among young adults in the United States. The authors conclude that the increasing prevalence of comorbidity of HIV infection and tuberculosis in inpatients underscores the need for strict infection control of tuberculosis on the part of hospitals, increased attention to prevention, and early identification and treatment of HIV and tuberculosis to reduce morbidity, hospitalizations, and the cost of care.

FROM: Rosenblum LS, Castro KG, Dooley S, and Mor-