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FDA WARNS ABOUT POSSIBLE *ENTEROBACTER SAKAZAKII* INFECTIONS IN HOSPITALIZED NEWBORNS FED POWDERED INFANT FORMULAS

Warning Does Not Apply to Liquid Forms of Infant Formula

FDA today alerted health care professionals about the risk of *Enterobacter sakazakii* (*E. sakazakii*) infections in hospitalized newborn infants, particularly premature infants or other immuno-compromised infants fed powdered infant formulas. This alert issued by FDA is targeted to concerns for immuno-compromised infants in hospital settings. The FDA is not aware of *E. sakazakii* infections among healthy full term infants in home settings. In addition, this alert does not involve the use of liquid infant formulas.

E. sakazakii is an emerging foodborne pathogen that can cause sepsis, meningitis, or necrotizing enterocolitis in newborn infants, particularly premature infants or other infants with weakened immune systems. Over the last several years, investigations of several outbreaks of *E. sakazakii* infection occurring in neonatal intensive care units worldwide have shown the outbreak to be associated with milk-based powdered infant formulas.

Recently, the U. S. Centers for Disease Control and Prevention (CDC) investigated a fatal *E. sakazakii* meningitis case in a neonatal intensive care unit in the United States. According to the CDC, the use of milk-based powdered formula was a likely factor in the infection of this child. The details

of CDC's investigation will be outlined in an upcoming edition of the Morbidity and Mortality Weekly Report (MMWR).

The FDA letter to health professionals, which is available at <http://www.cfsan.fda.gov/~dms/inf-ltr3.html>, provides recommendations for minimizing the risk in those circumstances when a powdered formula must be used for premature or immuno-compromised infants.

FDA urges health care providers to report adverse events associated with the use of infant formulas as soon as possible to FDA's MedWatch program by calling their toll-free number (1-800-332-1088) or through the Internet (<http://www.fda.gov/medwatch>). Healthcare providers should report invasive disease in infants due to

E. sakazakii, particularly bloodstream infection or meningitis with onset in the healthcare setting, to CDC's Division of Healthcare Quality Promotion (1-800-893-0485).

FDA and CDC will continue their efforts to prevent *E. sakazakii* infections associated with powdered infant formula.

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This is a mirror of the page at

<http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01146.html>

E. sakazakii Infections Associated with use of Powdered Infant Formulas - Tennessee, 2001 (Morbidity and Mortality Weekly Report; April 12, 2002) (available in [PDF](#))

[Health Professionals Letter on Enterobacter sakazakii Infections Associated With Use of Powdered \(Dry\) Infant Formulas in Neonatal Intensive Care Units](#) April 11, 2002

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