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January 3, 2012

**RE: FDA and CDC Update Regarding an Investigation of *Cronobacter* Illness in Infants**

Dear Clinicians:

I am writing to share with you an important update issued by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) regarding *Cronobacter* illness in infants. Many of you may have heard about this situation through the press and media. I wanted to be sure you have accurate and timely information to address questions that may arise from your patients. It is important to note that *Cronobacter* can cause a severe infection in young infants that may lead to bacterial sepsis or meningitis. While no cases have been reported to the Virginia Department of Health, four recent cases of *Cronobacter* infection have occurred in infants in other states that resulted in two deaths.

If you diagnose a *Cronobacter* case in an infant by laboratory culture, please notify your local health department. As always, your local health department staff will work with you to collect additional information about the case and potential exposures. If you have any questions about *Cronobacter*, please contact Dr. Laurie Forlano, Acting State Epidemiologist, at 804-864-7554.

Thank you for your continued efforts and support in keeping our most vulnerable Virginians healthy.

Sincerely,

Karen Remley, MD, MBA, FAAP
State Health Commissioner

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**FDA and CDC Update Regarding an Investigation of *Cronobacter* Illness in Infants**
RELEASED: December 30, 2011

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and state health departments continue to investigate four recent cases of *Cronobacter* infection in infants in four states: Florida, Illinois, Missouri, and Oklahoma. There is currently no evidence that indicates the *Cronobacter* infections in these infants are related.

Based on test results to date, there is no need for a recall of infant formula, and parents may continue to use powdered infant formula following the manufacturer's directions on the printed label.

The ongoing investigation includes laboratory testing of various types and brands of powdered infant formula, nursery water, and, when available, clinical samples from the infants. The investigation also includes the inspection of manufacturing facilities for infant formula and nursery water.

The following results have been confirmed from completed laboratory tests, although additional lab results are pending release:

- CDC's laboratory conducted DNA fingerprinting of the bacteria from two recent cases of *Cronobacter* infection in infants (Missouri and Illinois). The results show that the *Cronobacter* bacteria differ genetically suggesting they are not related. (Bacteria from cases in Oklahoma and Florida are not available for analysis.)

- CDC laboratory tests of samples provided by the Missouri Department of Health and Senior Services found *Cronobacter* bacteria in an opened container of infant formula, an opened bottle of nursery water, and prepared infant formula. It is unclear how the contamination occurred.

- The FDA tested factory-sealed containers of powdered infant formula and nursery water with the same lot numbers as the opened containers collected from Missouri, and no *Cronobacter* bacteria were found.

The FDA has inspected the facilities that manufactured the infant formula and the nursery water that tested positive for *Cronobacter* bacteria. Those manufacturers have programs that test their products before they are distributed. The lots in question were tested and found negative for *Cronobacter*. There is currently no evidence to conclude that the infant formula or nursery water was contaminated during manufacturing or shipping.

The FDA, CDC, and state agencies continue to investigate the cause of the infections using epidemiological and laboratory methods. Currently, CDC and FDA laboratories are testing infant formula, water, and other environmental samples related to the ill infants from Illinois and Oklahoma; the results are pending. Additional steps include: completion of inspections of manufacturers, additional laboratory testing of samples, and additional DNA fingerprinting investigation.

Last week following single reports of *Cronobacter* illness in infants in Missouri and Illinois, CDC asked public health officials around the country to look for other cases of *Cronobacter* infection among infants. This generated reports to CDC of two additional cases, one in Oklahoma and the fourth recent case in Florida. The illnesses in these infants occurred in late November and early December. The infants in Missouri and Florida, tragically, died as a result of their infection while the infants in Illinois and Oklahoma have survived.
*Cronobacter* is a very rare cause of a severe infection in young infants, and usually occurs in the first days or weeks of life. Typically CDC is informed of about 4-6 cases of *Cronobacter* a year. With recent increased awareness, CDC has been informed of a total of 12 cases in 2011.

*Cronobacter* causes severe bacterial sepsis or meningitis in infants, which often starts with fever, and usually includes poor feeding, crying, or listlessness. *Cronobacter* illness is diagnosed by a laboratory culture.

Any young infant with these symptoms should be in the care of a physician. There is no need to test a child that is not sick. If a *Cronobacter* infection is diagnosed by a laboratory culture, CDC encourages clinicians and laboratories to inform their local or state health departments.

*Cronobacter* bacteria is found in the environment and in hospitals and homes. It also can multiply in powdered infant formula after the powder is mixed with water.

CDC recommends breastfeeding whenever possible. When using powdered infant formula, CDC and FDA advises that caregivers make up fresh formula each time they feed the baby and discard any leftovers. In addition, recommendations for how to prepare and use powdered infant formula more safely include:

- Wash your hands with soap and water before preparing the formula.
- Clean all feeding equipment in hot soapy water.
- Prepare only enough formula for one feeding at a time and give it to the baby right away.
- Follow the manufacturer's directions on the printed label.

For more information from FDA on infant formula safety, please see:

- Once Baby Arrives (http://www.fda.gov/Food/ResourcesForYou/HealthEducators/ucm089629.htm)
- DA 101: Infant Formula (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048694.htm)