FDA Takes Final Step on Infant Formula Protections

The Food and Drug Administration (FDA) oversees manufacturers of infant formulas and helps ensure that these products are safe and support healthy growth in infants who consume them.

In keeping with that mission, FDA announced on June 9, 2014 that it is finalizing a rule—first published as an interim final rule on February 10, 2014—that sets standards for manufacturers of infant formula. In light of comments received after the interim rule published, the final rule provides some modifications and clarifications, and sets a date of September 8, 2014 for manufacturer compliance.

Under the final rule, standards include:

- Current good manufacturing practices specifically designed for infant formula, including required testing for the harmful pathogens (disease-causing bacteria) *Salmonella* and *Cronobacter.*
- A requirement that manufacturers demonstrate that the formulas they produce support normal physical growth.

- A requirement that infant formulas be tested for nutrient content in the final product stage, before entering the market, and at the end of the products' shelf life.

"FDA sets high quality standards for the safety and nutritional quality of infant formulas during this critical time of development," says Stephen Ostroff, M.D., FDA's acting chief scientist.

The final rule applies only to infant formulas intended for use by healthy infants without unusual medical or dietary problems. The agency notes that many companies now manufacturing infant formula for the U.S. market have been producing safe products and have voluntarily applied many of the current good manufacturing practices and quality control procedures included in the final rule. But this rule will set in place federally enforceable requirements for the safety and quality of infant formula.

FDA does not approve infant formulas before they can be marketed. However, all formulas marketed in the United States must meet federal nutrient requirements, which are not changed by the new rule. Infant formula manufacturers are required to register with FDA and provide the agency with a notification prior to marketing a new formula.

FDA conducts yearly inspections of all facilities that manufacture infant formula and collects and analyzes product samples. FDA also inspects new facilities. If FDA determines that an infant formula presents a risk to human health, the manufacturer of the formula must conduct a recall.

Products on the Market

While breastfeeding is strongly recommended and many mothers hope to breastfeed their infants, most infants in the U.S. rely on infant formula for some portion of their nutrition. An estimated 1 million infants in the United States are fed formula from birth, and by the time they are three months old, about 2.7 million rely on formula for at least part of their nutrition.

Infant formula comes in three forms:

- Powder—the least expensive of the infant formulas. It must be mixed with water before feeding.
- Liquid concentrate—must be mixed with an equal amount of water.
- Ready-to-feed—the most expensive form of formula that requires no mixing.

The protein source varies among different types of infant formula.

FDA's nutrient specifications for infant formulas are set at levels to meet the nutritional needs of infants. In addition, formula manufacturers set nutrient levels that are generally above the FDA minimum requirements. Thus, babies fed infant formulas do not need additional nutrients unless they are fed a low-iron formula.

The infant formulas currently available in the United States are either "iron-fortified"—with approximately 12 milligrams of iron per liter—or "low iron"—with approximately 2 milligrams of iron per liter. The American Academy of Pediatrics (AAP) recommends that formula-fed infants receive an iron-fortified formula as a way of reducing the prevalence of iron-deficiency anemia.

Safety Issues

- Formula preparation. In most cases, it's safe to mix formula using ordinary cold tap water that's boiled for one minute and cooled. Remember that formula made with hot water needs to be cooled quickly to body temperature—about 98 degrees Fahrenheit—if it is to be fed to the baby immediately. If the formula is not being fed immediately, refrigerate it right away and keep refrigerated until feeding.
- Bottles and nipples. The Mayo Clinic says you may want to consider sterilizing bottles and nipples before first use. After that, you can clean them in the dishwasher or wash them by hand with soapy water.
- Water. Use the exact amount of water recommended on the label.
- Formula warming. This isn't necessary for proper nutrition. The best way to warm a bottle of formula is by placing the bottle in a pot of water and heating it on the stove until warm (at body temperature). Never use microwave ovens for heating infant formulas. Microwaving may cause the bottle to remain cool while hot spots develop in the formula. Overheated formula can cause serious burns to the baby.
- "Use by" date. This is the date after which a package or container of infant formula should not be fed to infants. It indicates that the manufacturer guarantees the nutrient content and the general acceptability of the quality of the formula up to that date. FDA regulations require this date to be specified on each container of infant formula.
- Storage. Manufacturers must include instructions on infant formula packaging for its handling before and after the container is opened. They must also include information on the storage and disposal of prepared formula.
- Freezing formula. This is not recommended, as it may cause a separation of the product's components.

If you have concerns about infant formula, contact your health care provider and FDA at 1-888-INFO-FDA (1-888-463-6332): or by the Internet at MedWatch (*www.fda.gov/Safety/MedWatch/default.htm*).

Find this and other Consumer Updates at *www.fda.gov/ForConsumers/ConsumerUpdates*

Sign up for free e-mail subscriptions at *www.fda.gov/consumer/consumerenews.html*