What to Know About the New Requirement for Manufacturers of Critical Food (Including Infant Formula) to Develop a Redundancy Risk Management Plan

U.S. FOOD & DRUG ADMINISTRATION

The Food and Drug Omnibus Reform Act of 2022 (FDORA) added section 424 to the Federal Food, Drug, and Cosmetic Act (FD&C Act) and included a requirement for manufacturers of critical food to "develop, maintain, and implement, as appropriate, a redundancy risk management plan." This requirement was established following a months-long infant formula shortage sparked by insanitary conditions at one of the nation's largest infant formula facilities, which led to a significant voluntary recall and multiple-month production shutdown. The shortage of a food that is the sole-source of nutrition for infants elevated the need for firms to have plans in place to deal with supply chain and manufacturing disruptions that could significantly impact the amount of infant formula (or other critical foods) available to consumers.

What does FDORA say about developing a redundancy risk management plan?

The statutory language in section 424 of the FD&C Act as added by FDORA says:

"(b) RISK MANAGEMENT PLANS.—Each manufacturer of a critical food shall develop, maintain, and implement, as appropriate, a redundancy risk management plan that identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured. A risk management plan under this subsection—

(1) may identify and evaluate risks to the supply of more than one critical food, or critical food category, manufactured at the same establishment;

(2) may identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means; and

(3) shall be subject to inspection and copying by the Secretary pursuant to an inspection under section 704."

What is a redundancy risk management plan?

Under section 424(b) of the FD&C Act, a redundancy risk management plan identifies and evaluates risks to the supply of the food, as applicable, for each establishment in which such food is manufactured. A risk management plan (1) may identify and evaluate risks to the supply of one or more critical food, or critical food category, manufactured in the same establishment, and (2) may identify mechanisms by which the manufacturer would mitigate the impacts of a supply disruption through alternative production sites, alternative suppliers, stockpiling of inventory, or other means.

Who is required to develop a redundancy risk management plan?

Each manufacturer of a critical food shall develop, maintain, and implement, as appropriate, a redundancy risk management plan.

What is a critical food?

Critical food is defined as any infant formula or medical food, as defined in section 5(b)(3) of the Orphan Drug Act.[1]

Do I need to develop a separate redundancy risk management plan for each individual product?

No. Under section 424(b)(1) of the FD&C Act, a redundancy risk management plan may address more than one critical food, or critical food category, that is manufactured at the same establishment.

When did this requirement go into effect?

This requirement became effective immediately with the enactment of FDORA on December 29, 2022.

1. As defined in section 5(b)(3) of the Orphan Drug Act, the term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.