Following one death, FDA warns hospitals about giving probiotics to preemies

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Federal regulators are cautioning doctors not to give probiotics to

preterm infants.

An infant given probiotics at an undisclosed hospital has died, U.S. Food and Drug Administration officials said in a recent warning letter.

Preterm infants given probiotics are at risk of potentially fatal infection because of the bacteria and fungi that may be contained in those supplements, according to the FDA.

The infant who died weighed less than 2.2 pounds and was given the probiotic Evivo with MCT Oil as part of in-hospital care. The baby developed sepsis caused by a type of bacteria that turned out to be a genetic match to the bacteria contained in the probiotic, the FDA said.

Microorganisms found in probiotics have previously been reported to cause illness in very preterm or very low birthweight babies.

The American Academy of Pediatrics has also issued guidelines on the issue, saying that, "given the lack of FDA-regulated pharmaceutical grade products in the United States, conflicting data on safety and efficacy, and potential for harm in a highly vulnerable population, current evidence does not support the routine, universal administration of probiotics to preterm infants, particularly those with a birth weight of less than 1,000 grams [2.2 pounds]."

The FDA noted that it hasn't approved any probiotic product for use in infants.

However, some products are marketed, without approval, as being good for preventing the risk of a condition called necrotizing enterocolitis in preterm infants.

The National Institutes of Health describes this condition as an

inflammation of the intestine leading to bacterial invasion that causes cell death in the colon and intestine.

The probiotic involved in the investigation was made by California-based Infinant Health. The company said in a statement that it is "cooperating with FDA's ongoing investigation" and has agreed to stop shipping its Evivo with MCT Oil product, CBS News reported.

Health care providers and consumers should report adverse events involving probiotics both to the manufacturer using contact information on the product label and to the FDA at 1- 800-FDA-1088 or online.

More information: The National Institutes of Health has more on necrotizing enterocolitis.