# FDA: New Warnings Required on Use of Gadolinium-Based Contrast Agents

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SILVER SPRING, Md., Sept. 9 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration is requiring that gadolinium-based contrast agents (GBCAs) carry new warnings on their labels about the risk of a rare and potentially fatal condition known as nephrogenic systemic fibrosis (NSF), if the drug is administered to certain patients with kidney disease.

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Three of the GBCAs – Magnevist, Omniscan, and Optimark – will be described as inappropriate for use among patients with acute kidney injury or chronic severe kidney disease. All GBCA labels will emphasize the need to screen patients to detect these types of kidney dysfunction before administration.

GBCAs are intravenous drugs approved by the FDA for use with magnetic resonance imaging or magnetic resonance angiography to help detect abnormalities of body organs, blood vessels, and other tissues.

NSF is a condition involving the formation of excess fibrous connective tissue in the skin, joints, eyes, and internal organs. Symptoms of NSF can include scaling, hardening and tightening of the skin, red or dark patches on the skin, and stiffness. NSF may lead to death, especially if it involves body organs.

The FDA's review of the safety of the most widely used GBCAs determined that Magnevist, Omniscan, and Optimark are associated with a greater risk than other GBCAs for NSF in certain patients with kidney disease. Data suggest that NSF may follow the administration of any GBCA and the FDA continues to assess the safety of each GBCA to better estimate its NSF risks.

"The FDA is requiring these labeling changes to enhance the safe use of gadolinium-based contrast agents, including avoidance of ce
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