《New safety issues identified for 1 in 3 FDA-approved drugs:》

WASHINGTON, May 9 (Xinhua) -- Nearly a third of drugs approved by the U.S. Food and Drug Administration (FDA) have a new safety issue detected in the years after approval, a U.S. study said Tuesday.

While most of the safety concerns are not serious enough to require withdrawal of a drug from the market, the finding highlights the need for continuous monitoring of the safety of new drugs in the post-market period, according to the study published by the Journal of the American Medical Association (JAMA).

Currently, the majority of premarket trials that form the basis for FDA approval for new drugs enroll fewer than 1,000 patients with follow-up of six months or less, which the study said may make it challenging to identify uncommon or long-term serious safety risks.

In the new study, Joseph Ross, associate professor of medicine and public health at the Yale University School of Medicine, and colleagues analyzed data on the 222 new drugs approved between 2001 and 2010, with follow up through 2017.

It turned out that 32 percent of new drugs were flagged for a safety issue after approval.

"That is very rarely a drug withdrawal, but more commonly a black box warning, or drug safety communication issued by the FDA to let physicians and patients know that new safety information has been determined," said Ross.

Characteristics of drugs that were more likely to be associated with a safety concern, according to the researchers, include biologic therapies, psychiatric drugs, those receiving accelerated approval, and those with near-regulatory deadline approval.

However, the study was also quick to point out that the FDA's current process is working. "The fact that the FDA is issuing safety communications means it is doing a good job of following newly approved drugs and evaluating their safety up in the post-market period," Ross noted.