FDA approves warfarin labeling change

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The U.S. Food and Drug Administration has approved a labeling change for the widely used blood-thinning drug Coumadin (warfarin).

The Bristol-Myers Squibb Co. of Princeton, N.J., the manufacturer of Coumadin -- as well as manufacturers of warfarin, the generic version of the drug -- will add information to labels explaining a person's genetic makeup might influence how they respond to the drug. Research has shown a person's response to warfarin depends on variants of the genes CYP2C9 and VKORC1.

The FDA said the labeling change highlights the opportunity for healthcare providers to use genetic tests to improve their initial estimate of what is a reasonable warfarin dose for individual patients.

It's estimated about 2 million people start taking warfarin in the United States every year to prevent blood clots, heart attacks and stroke. Warfarin is a difficult drug to use because people taking a dose larger than they can tolerate are at risk of life-threatening bleeding. Those who receive too low a dose are at risk of equally dangerous blood clots.

Warfarin is the second most common drug -- after insulin --implicated in U.S. emergency room visits for adverse drug events.