FDA won't accept Merck's application for new drug

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FILE - In this May 22, 2008 file photo, the company logo is seen on the doors of a building at Merck & Co. headquarters in Whitehouse Station, N.J. U.S. regulators won't accept drugmaker Merck's application Monday, Nov. 2, 2009, for a new combination cholesterol pill that includes rival Pfizer's Lipitor, the world's top-selling drug. (AP Photo/Mel Evans, file)

(AP) -- U.S. regulators have refused to accept drugmaker Merck & Co.'s application for a new, combination cholesterol pill that includes rival Pfizer's Lipitor, the world's top-selling drug.

Merck disclosed the rare move by the Food and Drug Administration in a regulatory filing Monday.

The company 2 1/2 years ago said it planned to make a dual cholesterol pill that at the time looked sure to be a blockbuster: a combination of

Pfizer Inc.'s Lipitor - which generates nearly $13 billion in annual sales - and Zetia, a cholesterol pill Merck sells with Schering-Plough Corp. The two drugmakers have been partners on cholesterol medicines since 2000 and are about to merge.

Merck, of Whitehouse Station, N.J., applied to the FDA in September for approval of the combo pill. But Merck said the FDA refused to file the application and instead is requiring more data on the manufacturing and stability of the drug.

"For a company this size, this is not the norm," said analyst Steve Brozak, president of WBB Securities.

Normally, when companies seek approval of an experimental drug, the FDA accepts the application and spends months reviewing it. Most contain thousands of pages of data on testing of the drug in people and animals, details about the manufacturing process and information about how long the drug remains stable and effective.

After a thorough review by FDA staff, if the data is deemed inadequate or otherwise problematic, they usually require further information and sometimes additional patient studies.

In this case, the FDA would not file the application.

Merck's filing with the Securities and Exchange Commission states the FDA "has identified additional manufacturing and stability data that are needed."

"We do intend to refile" with additional data, said Merck spokesman Ron Rogers.

Brozak said the agency, which has become increasingly cautious and

unpredictable in its decisions, might only have minor questions on the details.

"Or, it could mean that they've found something they don't like," he said.

One possibility, he added, is that Merck and Schering-Plough took a common shortcut on stability testing by heating the combo pills to a high temperature, rather than monitoring them at room temperature for the standard two or three years of shelf life.

Because Pfizer holds patents on Lipitor, Merck and Schering-Plough would not be able to sell their combo pill - assuming it does get approved - until those patents expire. That happens as early as next year in some countries. In the U.S., generic competition is expected starting on Nov. 30, 2011.

FDA spokespeople could not immediately say how often applications are rejected upfront.

Merck is about to acquire Schering-Plough for $41.1 billion in a deal expected to close shortly. U.S. and other antitrust regulators have recently approved it.

The two New Jersey companies already sell a cholesterol combo pill, Vytorin. It contains Zetia, which limits the cholesterol absorbed from food, and Merck's older cholesterol drug Zocor, which reduces how much cholesterol the body produces due to family history.

Lipitor works the same way as Zocor, but research shows it's more effective at preventing heart attacks, strokes and death. That could make a Lipitor-Zetia pill very popular.

Still, any sales likely will be less than what Merck and Schering-Plough

once envisioned, Brozak said, with health care reform imminent and cheap generic Zocor grabbing a growing share of the cholesterol market.

Merck shares rose 33 cents, or 1.1 percent, to close at $31.26 Monday. Schering-Plough gained 20 cents to end at $28.40, while Pfizer shares shed 8 cents to $16.95.