Pfizer gets EU approval for kids' cholesterol drug

6 July 2010, By LINDA A. JOHNSON , AP Business Writer

(AP) -- The European Union has approved a new chewable form of cholesterol blockbuster Lipitor for children 10 and up with high levels of bad cholesterol and triglycerides, a type of blood fat, Pfizer said Tuesday.

The approval includes children whose high blood fats are due to an inherited disease that causes extremely high cholesterol levels, familial hypercholesterolemia.

New York-based Pfizer Inc. won U.S. approval for Lipitor use in children 10 to 17 with that condition in 2002.

Lipitor is the world's top-selling drug, with 2009 sales of about $13 billion, but its U.S. patent expires at the end of November 2011. Pfizer, the world's biggest drugmaker, will quickly lose most Lipitor revenue once generic competition hits, so the company has been trying to boost sales where possible before then.

Pfizer said last fall that it plans to apply for a six-month extension of its patent in European countries, after doing studies of Lipitor in youngsters.

As in the United States, the European Union allows drug makers to seek an additional six months of patent protection for medications if they test them in children, who generally are excluded from the drug studies performed to win approval for a new medication.

Pfizer already won such an extension for its crucial U.S. patent on Lipitor.

For blockbuster drugs, those extensions can easily bring hundreds of millions of dollars in additional revenue. Normally, they are for drugs that are widely used by different age groups.

Until recently, cholesterol drugs have been primarily taken by adults with heart disease, but their use has expanded to younger patients as more obese, sedentary teenagers and adolescents develop heart disease and diabetes.

Lipitor is approved to lower risk of heart attack and stroke, but can cause dangerous muscle pain or weakness, and it cannot be taken by patients with liver problems or by nursing or pregnant women.