

FDA: Arthritis drugs pose cancer risk to children

August 4 2009, By MATTHEW PERRONE, AP Business Writer

(AP) -- Federal regulators on Tuesday added stronger warnings to a group of best-selling drugs used to treat arthritis and other inflammatory diseases, saying they can increase the risk of cancer in children and adolescents.

After more than a year of review, <u>Food and Drug Administration</u> scientists said the drugs appear to increase the risk of <u>cancer</u> after they are used beyond 2 1/2 years. The agency studied several dozen reports of cancer in children taking the drugs. Half of the patients had lymphomas, a cancer that attacks the immune system.

The drugs are known as tumor necrosis factor blockers and work by neutralizing a protein that causes <u>inflammation</u> and damage to bones, cartilage and other tissue. The drugs are prescribed to children with rheumatoid <u>arthritis</u>, inflammatory bowel disorder and Crohn's disease.

The agency will bolster the "black box" warning on the five drugs on the U.S. market, including Abbott Laboratories' Humira, Johnson & Johnson's Remicade and Simponi, and Enbrel which is co-marketed by Amgen Inc. and Wyeth. All of the products are multibillion-dollar sellers.

The action also affects Belgian drugmaker UCB's Cimizia, which launched in May.

The FDA said it is working with the manufacturers to further define the



scope of the cancer risk.

Calls placed to the companies Tuesday afternoon were not immediately returned.

Along with updating the drugs' labels, the FDA is requiring companies to add information about cancer risks to the medication guides given to patients.

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