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FDA approves second near-copy of Remicade for immune disorders

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Federal regulators on Friday approved another alternative version of Remicade, an expensive injected drug widely used for rheumatoid arthritis and other immune system disorders.

The U.S. Food and Drug Administration approved Renflexis, developed by Samsung Bioepis Co. of South Korea. Its U.S. partner, Merck & Co. of Kenilworth, New Jersey, will market Renflexis.

Merck said Renflexis should be available in six months. The delay is required under U.S. regulations for a relatively new category called biosimilars. That's the industry term for generic but not quite identical versions of biotech drugs.

Without insurance, Remicade generally costs more than $30,000 annually for adults; dosage varies by weight. The first biosimilar for Remicade, Inflectra from New York-based Pfizer Inc., went on sale in November at a 15 percent discount. The companies refused to disclose the list price of Renflexis.

Many U.S. insurers are requiring patients to switch to lower-priced biosimilars, and the new competition will help insurers negotiate bigger discounts from manufacturers.

Remicade is health care giant Johnson & Johnson's top seller, with 2016 sales totaling $7 billion. It's approved to treat eight different immune disorders, including two in children. Renflexis is approved for seven of

those: Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis, plus Crohn's in children.

Remicade and Renflexis both carry serious risks. More-common side effects include respiratory infections, headache, rash and stomach pain. Because the drugs suppress the immune system, their use can also result in serious infections, including tuberculosis, and unusual cancer types.