



News Articles

FDA committed to affordable generic drugs for children

by from the Food and Drug Administration Office of Generic Drugs, Office of Pediatric Therapeutics, and Division of Pediatrics and Maternal Health

The Food and Drug Administration (FDA) recognizes that generic drugs decrease costs and improve access to needed medications. Therefore, the agency recently announced efforts to lift barriers to generic drug competition (<http://bit.ly/2xer6lp>).

The FDA published a list of medications for which there are no approved generics and no blocking patents or exclusivities that otherwise would preclude or prevent generic drug approval (<http://bit.ly/2wwUdXI>). For example, there are no generic versions of glucagon and calcium chloride, which are used in pediatric patients.

By highlighting the therapeutic areas where generic drugs are lacking, the FDA aims to promote drug development. It also is committed to expedite review for generic drug applications submitted for these products.

The entry of generic drugs to the market drives down prices, such that when at least three generic drugs are marketed, the price is approximately 40%-50% less than the brand name drug. Therefore, the FDA has taken steps to prioritize generic drug application review until there are three approved generic drug products. On May 30, for example, it approved four generic versions of Strattera (atomoxetine), which is used to treat attention-deficit/hyperactivity disorder.

The FDA is committed to making high-quality, affordable generic drugs available to the public as soon as possible.

Resources

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