The Veeda Newsletter

June 2017

FDA

FDA Cites Florida Drugmaker for Serious Quality Violations

An FDA investigation into serous quality problems at a Florida pharmaceutical company revealed a litany of unsound practices in the manufacture of experimental drugs.

Read More:http://www.fdanews.com/articles/181855-fda-cites-florida-drugmaker-for-serious-quality-violations

FDA Approves First Strattera Generic for ADHD, Plus Five Other First-Time Generics

The FDA approved the first generic versions of Strattera (atomoxetine) to treat attention-deficit hyperactivity disorder in pediatric and adult patients, including multiple strengths manufactured by Apotex, Teva, AurobindoPharma and Glenmark Pharmaceuticals.

Read More:http://www.fdanews.com/articles/182031-fda-approves-first-strattera-generic-for-adhd-plus-five-other-first-time-generics

483 Roundup: FDA Hits Three Firms for Product Changes, Complaints

The FDA cited three device manufacturers for a range of violations including unreported product changes and failure to properly investigate complaints.

The agency issued a Form 483 to the Oakworks facility in New Freedom, Pennsylvania, following a March 2017 inspection. According to inspectors, the firm made alterations to devices without reporting the changes in writing to the FDA, and took several months to update owner manuals to reflect the changes.

Read More:http://www.fdanews.com/articles/182026-roundup-fda-hits-three-firms-for-product-changes-complaints

MHRA Outlines Regulatory Goals in Preparation for Leaving the EU

The U.K.'s Medicines and Healthcare products Regulatory Agency laid out its top 10 priorities for 2017 and 2018 — including developing a model for the agency's future, post-Brexit.

One of its top priorities is to devise a five-year plan encompassing national and international strategies for collaboration; delivering the agency's new Patient Safety and Vigilance Strategy, securing global

Read More:http://www.fdanews.com/articles/181780-mhra-outlines-regulatory-goals-in-preparation-for-leaving-the-eu