

The October 6, 2017 posting will serve as the final “Postmarket Drug and Biologic Safety Evaluations” posting (posted in accordance with the previous requirement in section 505(r) as added by section 915 of FDAAA).

On July 21, 2017, FDA published its [Drug and Biologics Safety Surveillance Best Practice Statement](#) announcing its plan to implement certain provisions of the 21<sup>st</sup> Century Cures Act (Cures Act), which was enacted on December 13, 2016. One of the provisions of the Cures Act includes a revision to a previous statutory requirement that generally required FDA to undertake routine safety analyses of drugs 18 months following approval or after 10,000 individuals have used the drug, whichever occurs later. The Cures Act replaced this requirement for an 18-month/10,000 patient analysis with a new requirement that FDA make publicly available on the internet its best practices for drug safety surveillance activities for drugs approved under section 505 of the Food, Drug & Cosmetic Act or licensed as biological products under section 351 of the Public Health Service Act.