

exemption from the FDA trials process (assuming certain conditions are met) is a big deal.

TITLE I: PHARMACY COMPOUNDING AND 503B

The Drug Quality and Security Act created a new section, 503B. In this section, a compounding pharmacy can elect to become an outsourcing facility. As stated before, an outsourcing facility can now qualify for exemptions from the FDA new drug approval requirements and labeling requirements. Outsourcing facilities are now subject to the cGMP requirements, whereas before they were more than likely considered pharmacies and considered exempt from them. They will now be inspected by the FDA according to a risk-based schedule in addition to the aforementioned reporting of adverse events.

This new law continues to exempt compounded drugs from new drug requirements, labeling requirements, and the forthcoming track and trace requirements under certain conditions. These new conditions are as follows: the drug/medication must be compounded by or under direct supervision of a licensed pharmacist, the drug/medication must be compounded in a registered outsourcing facility, and the drug/medication must meet other applicable requirements.⁸ It also must be noted that the Drug Quality and Security Act mandates that outsourcing compounding pharmacies must be in compliance with the FDA's cGMP.

Outsourcing Facility Registration and Reporting

The Drug Quality and Security Act establishes an annual registration requirement for any outsourcing facility. Under the new law, compounding pharmacies that compound sterile drugs are now allowed to register with the FDA as an outsourcing facility. Once registered (and of course the fees are paid), an outsourcing facility must then meet certain conditions, as stated earlier, in order to be exempt from the Food, Drug, and Cosmetic Act's approval requirements and the requirement to label products with adequate directions for use. In addition to the aforementioned conditions, the outsourcing facility must also report specific information about the products that it compounds, including a list of all of the products it