

drugs to the Food and Drug Administration (FDA) and state boards of pharmacy. Let's take a look at what they did pass with the new law.

DRUG QUALITY AND SECURITY ACT*

There are two sections or titles in the H.R. 3204 Drug Quality and Security Act:

- Title I: Compounding Quality Act
- Title II: Drug Supply Chain Security Act

In this chapter, we focus on Title I: Compounding Quality Act, and the act that the Drug Quality and Security Act amended.

FOOD AND DRUG MODERNIZATION ACT OF 1997 AND 503A REVISITED

As we discussed in Chapter 1, the Drug Quality and Security Act amended the Federal Food, Drug, and Cosmetic Act (FFDCA) with respect to the regulation of compounding drugs. Section 127 of the FDA Modernization Act of 1997 (FDAMA) added Section 503A to the FFDCA, exempting compounded drugs from new drug laws as long as the compounded drug met several conditions/restrictions. Included in the exemptions were the myriad and lengthy new drug requirements (FDA trials, etc.), labeling requirements (the information/labeling on and with the manufacturer's bottle that a pharmacy normally gets and that the consumers would get if they got the prepackaged manufactured drug, e.g., a nasal spray in the manufacturer's box or a birth control packet), and the requirement that the compounded drugs had to be produced using cGMP. These exemptions were well intentioned, but left a lot of gaps and unanswered questions for compounding pharmacies.

* The following is summarized from multiple sources, with the two primary sources being www.congress.gov and www.fda.gov. Please take special note that the provisions of this act are continuously changing and being updated. If any of my readers have specific questions that are compliance related, please contact the FDA or your state board of pharmacy.