removed the uncertainty regarding the validity of Section 503A, which will be applicable to compounders nationwide.[13]

Last but not least, this act requires the comptroller general (Government Accountability Office (GAO)) to report on pharmacy compounding and the adequacy of state and federal efforts to ensure the safety of compounded drugs.[14]

TRADITIONAL COMPOUNDING

So what happened to pharmacies that do traditional compounding? Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A to qualify for the exemptions specified in that section. Even if the conditions of Section 503A are met, the compounded drugs are only exempt from those provisions of the FFDCA listed above. All other applicable provisions of the FFDCA remain in effect for compounded drugs, even if the conditions in Section 503A are met. For example, a compounded drug cannot be contaminated or made under unsanitary conditions, as was the case with the New England Compounding Center. And if a compounded drug does not qualify for the exemptions under either Section 503A or 503B (see below) of the FFDCA, the compounded drug would be subject to all of the requirements of the FFDCA that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements. The FDA assumes that compounding pharmacies that only perform traditional compounding will fall under the oversight of state boards of pharmacy.[15]

Under the new section, 503B, 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 this requirement. They will now be inspected by the FDA according to a risk-based schedule in addition to the aforementioned reporting of adverse events and information on the drugs they are compounding.[16]