
AND WE HAVE LIFTOFF—MAYBE

If nothing changes by the time readers read this chapter, compounding pharmacies can elect to become outsourcing facilities under 503B, register with the FDA as an outsourcing facility, and market/advertise their compounded medications to hospitals, medical facilities, and health care providers. The doctors and patients can purchase these compounded drugs, knowing that they were compounded in outsourcing facilities subject to cGMP requirements and federal oversight by licensed pharmacists under state oversight.

Compounding pharmacies that do not elect to become outsourcing facilities or register with the FDA will still be subject to FFDC requirements. They may be considered manufacturers and subject to FDA new drug approval requirements and labeling requirements. These compounding pharmacies are also anticipated to be under the oversight of the state boards of pharmacy.¹⁷

ISSUES TO BE RESOLVED

The Title I regulations are still being drafted. Progress has been made to address the regulatory gaps in the compounding of drugs. However, there are numerous issues that still need to be resolved. In my opinion, there needs to be a uniform standard to define which drugs fall under pharmacy compounding and which drugs are considered in the manufacturing or compounding for office use category. We will discuss the issue of inspections of facilities, which keeps coming up in both the Drug Quality and Security Act and the states' responses. Compounding pharmacies and manufacturers need to know who will be doing the inspections, how often these inspections will take place, and what organization will do the accreditation of the inspectors. (We discuss inspections in Chapter 3.) In addition, the question on everyone's mind is, who will pay for these inspections? Another issue is transparency. Two compounding pharmacy owners I spoke with had opposite opinions on this issue. One said he wanted the inspections to remain private. This way, if there are issues uncovered, his team has a chance to fix them without the issues becoming