Escalating Enforcement Actions
Compounding Pharmacies / Outsourcing Facilities

Compounding pharmacies have been the subject of enhanced FDA scrutiny on the GMP front since the incidents of fungal meningitis associated with the New England Compounding Center in 2012. We now see a firm enter into a consent decree agreement with the courts. The Drug Quality and Security Act, passed in November 2013, created the category of compounding pharmacies known as "outsourcing facilities". We have seen increasing enforcement since 2013. Compounding pharmacies have received the majority of CDER GMP warning letters published in FY 2014 and FY2015. The table below shows this dramatic increase from the metrics in FY 2013.

	FY 2013	FY 2014	FY 2015
Total Drug GMP Warning Letters	42	48	43
Warning Letters to Compounders / Outsourcing Facilities	2 (5%)	27 (56%)	24 (56%)

It would be prudent for ALL compounding pharmacies and outsourcing facilities that manufacture sterile drug product to carefully read the requirements to which Downing Labs LLC must comply. Many of these firms have responded to FDA's forms 483 claiming that they do not need to comply with cGMPs but rather must comply only with Chapter 797 of the U.S. Pharmacopeia ("USP Chapter 797"), which sets forth the standards governing the compounding of sterile injectables. This should go a long way to dissuade firms from assuming this will be an acceptable response to either a form 483 or warning letter.

Lachman Consulting *reports* that of the more than 230 inspections of these facilities posted on the FDA website, almost 90 have received warning letters. With approximately 40% of the inspected sites receiving warning letters this suggests that this industry sector has not fully understood the standards against which they are now being evaluated. The FDA has *published* a web page that focuses on enforcement actions against compounding pharmacies including warning letters, company responses, and forms 483. These are updated frequently to include press releases and FDA letters requesting recalls. It makes for interesting reading for those who follow this segment of the marketplace.

In a *Press Release* dated January 11, 2016 FDA announced that Downing Labs LLC (previously NuVision Pharmacy) of Dallas, Texas, it's co owners and the pharmacist in charge have entered into a consent decree agreement. FDA took a *series of actions* that started in April 2013 and included repeated inspections and requests for recall of product for lack of sterility assurance. Note that the firm did not receive a warning letter as part of the enforcement actions taken by FDA.

The Consent decree agreement into which the firm entered requires they not produce sterile products until they have met requirements that are to be confirmed by a third party prior to re-inspection by FDA. The firm is required to remediate all GMP deficiencies including developing a system to received and manage reporting of adverse events including communication of these events, as appropriate, to FDA. The FDA provides the option to collect fines of $10,000 per day per violation if requirements are not met. Downing Labs LLC *addresses* the agreement on their website.