The 503B Industry Recognizes RCA's Sterile Compounding Expertise

- CDER has held meetings with affected 503B registrants; including RCA Executive Leadership
- International Academy of Compounding Pharmacists (IACP) has recognized RCA as an industry expert and corporate partner
- Compounders on Capitol Hill (CCH) has invited RCA as a thought-leader participant
- RCA has been credited by Unique Pharmaceuticals as their valued independent third party cGMP expert key to remediating FDA's sterility assurance concerns relating to sterile drug compounding
- Washington, D.C. "Big FDA Law" Firms turn to RCA Experts for Sterile Compounding Expertise

RCA Understands the 503B Challenges

The interim guidance document, *Current Good Manufacturing Practice —Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act,* was issued July 2014. In this guidance, a registered Outsourcing Facility:

- Must comply with cGMP requirements (21 CFR Parts 210 and 211; 2004 Aseptic Guidance and various PDA technical reports)
- Will be inspected by FDA on a risk-based schedule
- Must meet certain other conditions to be exempt from New Drug Approval requirements and the requirements for adequate directions for use
- Report to FDA twice a year information about the products they compounded during the previous six months
- Report adverse events & specific labeling requirements

RCA Knows Where FDA Is Searching…

115 Companies - 886 total observations during 2011 – May 12, 2015

Subpart A – General Provisions	0/886 = 0%
Subpart B – Organization and Personnel	95/886 = 10.7%
Subpart C – Buildings and Facilities	231/886 = 26.1%
Subpart D – Equipment	50/886 = 5.6%
Subpart E – Control of Components and Drug Product Containers and Closures	58/886 = 6.6%
Subpart F – Production and Process Controls	132/886 = 15%
Subpart G – Packaging and Labeling Controls	14/886 = 1.6%
Subpart H – Holding and Distribution	3/886 = .3%
Subpart I – Laboratory Controls	224/886 = 25.3%
Subpart J – Records and Reports	78/886 = 8.8%
Subpart K – Returned and Salvaged Drug Products	0/886 = 0%