Statement for the Record of Avella
Energy and Commerce Health Subcommittee Hearing
"Examining Implementation of the Compounding Quality Act"
January 30, 2018

Avella of Deer Valley, Inc. and affiliated entities including Advanced Pharma Inc., D/B/A Avella of Houston (collectively, "Avella") are pleased to submit written testimony to the "Examining Implementation of the Compounding Quality Act" hearing before the Energy and Commerce Health Subcommittee. Avella has been, and continues to be, a strong supporter of the Compounding Quality Act ("the Act"). However, as a currently registered 503B, and as an entity that also dispenses compounded prescriptions under 503A, Avella would like to raise some concerns with the current implementation and enforcement landscape in the compounding world.

Avella currently serves the needs of thousands of patients and providers by providing both dispended and office use, through its 503B facility, compounded medications throughout the United States. Founded in 1996 as a single pharmacy located in Phoenix, Arizona, Avella has since expanded to include two national distribution facilities and community-based pharmacies in eight states while serving patient and/or provider needs in all 50 states. In February 2014, Avella's Deer Valley location was an early registrant with FDA as an Outsourcing Facility in accordance with Section 503B the Food, Drug and Cosmetic Act ("FFDCA"). Today, Avella is a national specialty and compounding pharmacy with unique expertise in ophthalmology treatments, and was the first ophthalmology pharmacy in the nation to earn the Pharmacy Compounding Accreditation Board's Seal of Accreditation. Because of the unique nature of ophthalmology and our hospital clients, a large portion of the medications Avella provides are customized to meet specific patients' unique medical needs.

As this Subcommittee is well aware, patient safety and product quality are a top priority for the industry. Avella, and others, are working tirelessly to lead the industry in such standards to help ensure that a health crisis, like that of the New England Compounding Center ("NECC"), which resulted in 64 deaths and hundreds of injuries due to contaminated sterile injectables, never happens again. For this reason, Avella expresses a number of concerns related to FDA's current implementation and enforcement pathways that could have an impact on patient safety.

I. Varying cGMP Standards Will Impact Product Quality and Put Patients at Risk

FDA's recently published a 2018 Compounding Priorities Plan ("2018 Plan") outlines a risk-based approach for the applicability of current Good Manufacturing Practice ("cGMP") standards for 503B facilities. Specifically, in the 2018 Plan, FDA stated that it wanted to encourage traditional compounders operating under Section 503A of the FFDCA to register as outsourcing facilities by applying varying degrees of cGMP standards to a facility based on the size and scope of the outsourcing facility's operations. Thus, "smaller compounders that compound limited volumes of drugs, and presumably present lower risks, may decide to register as outsourcing facilities."

Avella disagrees with this approach and advocates that instead, one, consistent cGMP standard should apply to all outsourcing facilities no matter the size of the entity or the volume of products

24416 North 19th Avenue
Phoenix, AZ 85085
main (623) 742-1700 **fax** (623) 434-3661

Avella
Health via excellence™

that the entity compounds. Application of varying cGMP standards will only create confusion within the industry, stress the FDA's already limited resources, and significantly raise potential risk to patients. Most importantly, a lesser cGMP standard for small facilities has the potential to impact the quality of drug produced by those entities, and could result in patient harm. For example, if smaller entities are exempt from certain product testing requirements, a sub-standard product may be produced and administered to a patient in the same manner that caused NECC. In turn, an outsourcing facility subject to the higher cGMP standards would have the testing processes in place to identify such an issue. In reviewing this issue, Avella asks that Congress take the time to ask themselves a simple question: if the medication was being injected into your family member, would you want to have the assurance that the preparation was appropriately tested or to take a chance because the facility is a smaller one and not required to have a rigorous testing program?

For this reason, Avella believes that varying cGMP standards will only serve to create more risk in the marketplace and could result in another NECC-like tragedy.

II. A Risk-based Approach to FDA Oversight Could Prevent Future Patient Harm

Section 503B of the FFDCA mandates a risk-based inspection frequency, including consideration of certain risk factors such as compliance history, compounding risk level, and previous inspection history. Avella advocates that this portion of the statute be fully implemented as inspections are a key way to identify non-compliance and risky operations. If the most high-risk outsourcing facilities are identified, and inspected on a more frequent basis, there is a better likelihood that high-risk behavior will be corrected and patient harm may be prevented.

III. Memorandum of Understanding

In its 2018 Plan, FDA indicated that it planned to loosen the MOU standards to make it more feasible for states to sign the MOU, including altering the draft definition of "inordinate amount" from 30 percent or more of all drug dispensed to greater than 50 percent during the calendar month. In addition, distributing inordinate amounts would no longer trigger state action, but would instead trigger certain reporting requirements. Although the 30 percent and 50 percent thresholds appear to be arbitrarily determined, Avella advocates for clarification as to how such a calculation will be made on patient scripts (as opposed to office use). Further, FDA has expressed its goal to encourage more compounders to register as outsourcing facilities, so those entities that believe they will distribute inordinate amounts have an opportunity to does so as FDA-registered outsourcing facilities and should be held to the proper cGMP standards established and regulated by FDA.