- LCDR Lannister is an outstanding officer who exemplifies the Corps values in every aspect of his role as a Senior Regulatory Management Officer (O-5 billet). He has expanded the impact of his position and I highly recommend him for the promotion to Commander.

- Agency Lead for 2018 development of updated guidance for Gastroesophageal Reflux Disease Activity Index for industry and stakeholders – last draft had been issued in 2003. Responsible for stakeholder identification, regulation research, and writing the first draft. Subsequently, the agency has implemented a new review policy that more appropriately identifies subject selection for industry, which helped to increase the first-time acceptance of studies and decreases review time to ultimately approve new drug products. Since release of the guidance, the agency has seen a 15 % increase in first cycle review approvals for these products.

- Division representative to address a congressional inquiry regarding a key nightshade metabolite causing the contamination and possible lethal accumulation of drug byproduct in > 300 approved finished drug products. LCDR Lannister served as a primary author for the relevant sections of the response to the inquiry and moderated a series of multi-office meetings to coordinate a prompt response.

Leadership:

-Acting Chief, Project Management Staff (Supervisory) for 120 days from Sept 2018 to January 2019*.* He was selected for this position due to his additional training in the Wine and Drug Administration (WDA) Emerging Leaders program, as well as his high level of expertise and communication skills commensurate with that of more seasoned officers. Oversaw 15 project managers and administrative staff which included personnel issues, performance reviews for civilian and PHS officers, and workload output all while maintaining his RPM workload. Even though the division received a 5% increase in submissions while operating at 80% of normal staffing during this time frame, all mandated drug application reviews were completed on or ahead of schedule.

- Coordinator, WDC Project Management Training Program: Primary author and trainer for >50% of WDA project management workshop training modules developed from 2018-19 and created paired mentoring system for new hires to be matched with a senior project management mentor. Training and mentoring program utilized by 62 newly hired project managers in FY2019. Responsible for updating modules biennially and in response to legislative changes.

Mission:

-Advanced WDA’s Office of New Drugs mission of providing clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics by serving as an Invited Speaker and Panelist at the 2019 Global Drug Information Association (DIA) International Conference (>2k in attendance), where he educated representatives from the pharmaceutical manufacturing industry on the WDA’s position on GERD medication application development and submission requirements.

- At the request of the Director, he provided critical input toward the creation of an updated Vision and Mission Statement for the Division of Project Management, as required by congressional mandates that deemed necessary changes in the project management process for drug applications. This impacted >70 project managers responsible for managing >180 drug applications annually.