FDA and DoD Shelf Life Extension Program of Pharmaceutical Products: Progress and Promises
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Purpose
Every pharmaceutical product marketed in the USA has an expiration date also referred to as shelf life. Performance of the drug product beyond the manufacturer set shelf life has been a subject of study over several decades. Studies have shown that drug products can retain their shelf life quality characteristics such as potency and efficacy, several years beyond the expiration date if stored properly. The Department of Defense (DOD) shelf life extension program (SLEP) was established to maintain the availability of the national drug stockpiles for military operations and civilian readiness for national disasters without the need to fully replace the stockpiles. FDA has developed a systematic approach to shelf life extension of drugs by laboratory testing of the original and aged products beyond expiry to predict the continued stability of these products. SLEP is very important in maintaining both national security and Public welfare by confirming that pharmaceutical stockpiled products meet quality standards after the “expiration date”. SLEP research is an example of regulatory science that is needed to best ensure product performance past the original shelf-life.

Methods
FDA administers SLEP for DoD as a comprehensive testing and evaluation program designed to justify the extension of drug products beyond the labeled expiration date. Depending on the drug product, these tests (generally USP compendial methods) include assays for potency, impurities, preservatives, dissolution, physical appearance, pH, and water content.

Results
Results from 1122 lots (96 drug products) were evaluated. 84% of the lots were extended for an average of 57 months past the original expiration date. Of the 946 lots extended, 14% were eventually terminated due to failure. The remaining drug lots are still active or discontinued by the military. 22 Drug Products showed no signs of stability failure (at least 5 lots of each tested). 10 Drug Products were unstable with most lots failing initial extension.

Conclusion
The SLEP program and its database are a unique national resource that may ultimately serve as a scientific platform for drug product research that has the potential to support FDA’s broader product quality initiatives and address US and Global Public Health issues.