
Shelf Life Extension Program means big savings for U.S. military

BY PATRICK E. CLARKE

When the U.S. military stockpiles items, they do it in a big way. If stockpiled drugs are past their expiration date and have to be destroyed, it can cost the Department of Defense and the taxpayers millions of dollars.

Enter the Shelf Life Extension Program, begun in 1985, at the request of the Air Force. All military branches now participate in the testing program that determines a new expiration date for stockpiled drugs.

Donna Porter, who is the shelf life project manager in the Office of Regulatory Affairs, estimated that about 35 different drugs are currently tested through the program. “When the military requests a drug product for testing, I research it—look at the packaging and get long-term stability and accelerated stability data,” said **Job Taylor**, a chemist in the Division of Product Quality Research. Taylor then develops a testing protocol for one of the FDA field labs to use.

The principle upon which the program is based is annual real-time testing to provide data to extrapolate how long that lot can be stored, and then a new expiration date is determined. “In some cases we use the process of artificial aging to assist with the initial prediction of extended life,” Taylor said. The three main

labs doing the testing are the ORA district laboratories in Detroit, Philadelphia and San Juan, Puerto Rico.

Porter emphasized that consumers should abide by the expiration date set by the manufacturer. “You cannot compare shelf-life testing, which is done with product lots that have not been opened and are stored under labeled storage conditions, to consumer-purchased prescription products, which are often not in ideal storage conditions,” she said.

Taylor noted that the main drugs tested are military-specific “such as atropine sulfate and pralidoxime chloride, which are antidotes used in case of a nerve gas attack.”

Biological drugs and blood products are not tested, and any drugs known to be unstable are not tested. “Sometimes it’s not cost-effective to test if the military doesn’t have sufficient quantities of a drug,” Porter said.

One example of a drug where the expiration date was extended, at great savings, is the antibiotic ciprofloxacin.

Drugs that pass testing are initially extended one or two years. “Then one year later a retest is given,” Porter said. “If the retest data are OK—the drug can be extended another year. We will re-test until we’ve hit the limit on extensions or else the military no longer has the product available for testing.”