

## **WHITE PAPER**

### **ON**

#### **AIR FORCE INVOLVEMENT IN THE DEPARTMENT OF DEFENSE (DOD)/FOOD AND DRUG ADMINISTRATION (FDA) SHELF LIFE EXTENSION PROGRAM (DOD/FDA SLEP)**

The Department of Defense/Food and Drug Administration Shelf Life Extension Program is a key component of the Medical Readiness Strategic Plan (MRSP) as developed by the Department of Defense Health Affairs DOD (HA) and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources. The Program's focus is to save replacement costs of date sensitive Prepositioned War Reserve Stock (PWRS) by extending its useful life. The following organizations participate in the program: the FDA evaluates the materiel for shelf life extension by testing samples submitted from the Services, the Joint Readiness Clinical Advisory Board (JRCAB), formerly the Defense Medical Standardization Board (DMSB), oversees the program and acts as an interface between the Services and the FDA; and the Army, Navy, Air Force, and Marines fund the program, manage the Program, and receive the benefit of deferred materiel replacement costs.

### **HISTORY**

Prior to the advent of the program, the Military Services were investing substantial funds in replacement costs for stores of potency dated war reserve materiel. Replacement costs for this materiel in 1986 totaled \$2.5 million. One of the methods suggested to limit and defer PWR materiel replacement costs was to test this materiel for extension of its useful life.

In July of 1985, representatives from the Air Force Surgeon General's Office and the FDA met to determine the feasibility of establishing a program to test PWR materiel for extension. An agreement was reached at this meeting to establish a pilot project to test the concept. The Air Force identified a list of items representing stock costing \$3,000 or more which was within 12 to 18 months of its expiration. The FDA screened the list and determined they could establish test protocols for 56 of the listed items. Samples of the 56 items were sent to FDA for testing.

The FDA testing required eight months. Final test results were far better than expected. Eighty percent of the items tested, and 84 percent of all lots tested, were extended. Although the FDA was conservative in their estimates, some of the tested items were granted three-year extensions.

In January 1986, an interagency agreement was signed forming the DOD/FDA Shelf Life Extension Program. The JRCAB was tasked as the Quad-Service focal point for the Program. Testing of items submitted by the four services and DSCP (DSCP no longer participates in the program) was not started until Fiscal Year (FY) 1987. During FY 87, four new projects were initiated which realized a total replacement cost deferral of \$3,084,077. Through the years since FY 87, the program has expanded. In FY 91, the FDA had to increase dedicated Program resources (facilities and personnel) to support the program's requirements for new projects and retest projects. In FY 98, the Air Force alone had approximately \$8.6M (including atropine and 2 PAM chloride autoinjectors) of stock tested through the program.

### **FDA TESTING**

The FDA, as the proponent for quality control of medical materiel for DOD, performs the required testing of all items entered into the DOD/FDA SLEP. The FDA uses original manufacturer's test data on each item to establish a protocol for testing. Accelerated testing (also called stress testing) is the method used most to predict the extension period. Under an accelerated testing protocol, the test is designed to increase the rate of chemical or physical degradation of the drug substance by using exaggerated storage conditions. Each

item is “stressed” (placed in chambers which maintain a temperature of 45 percent centigrade and 75 percent humidity) for 90 days. The potency of the stressed samples are compared with the standard for each item, and, through this comparison, the FDA estimated the extendible life of the product. The FDA testing process, from the time the JRCAB presents the project’s candidate list until the project’s extension information is received by the JRCAB, requires approximately eight months.

The testing the FDA conducts is comprehensive and scientifically sound. The FDA bases their expiration date extensions on conservative estimates of the useful life of the product as substantiated by the test results. The FDA grants the extensions for all DOD facilities having the materiel as specified by lot number, expiration date, and manufacturer. Although the focus of the program is primarily the extension of PWR materiel, extensions are not limited to this materiel.

The FDA will not test all items presented to them as program candidates. Traditionally, biological and nutritional products are not accepted for testing. The FDA has determined the items listed in Table I will not be included in the FDA/DOD SLEP. The FDA is capable of establishing a protocol and testing most other PWR items.

## **AIR FORCE MEDICAL LOGISTICS OFFICE INVOLVEMENT**

The Air Force Medical Logistics Office (AFMLO) manages the DOD/FDA Shelf Life Extension Program for the AFMS. All Air Force-owned war reserve stock is rotated when possible; however, war reserve quantities greatly exceed peacetime use in many instances. AF medical activities are required by regulation to project the quantity of potency dated assets not used at their expiration six months prior to this date. Items having sufficient quantities projected at time of expiration are reported to the Procurement Team at AFMLO for possible shelf life extension.

AFMLO’s Procurement Team personnel evaluate each activity’s report for items to enter into the DOD/FDA SLEP. The Army, Navy, and Air Force Logistics Field Agencies nominate national stock numbers (NSNs) and submit them to the Joint Readiness Clinical Advisory Board (JRCAB) as Program candidates. AFMLO’s selection criteria for a candidate (per AFMAN 23-110, Vol 5 para 13.4) is whether the materiel is, a chemical defense item, military unique/significant, not military unique with over \$1,000 dollar value per lot, per location, and has six months or less shelf life.

The JRCAB maintains a database of DOD/FDA SLEP candidate items. Items having the greatest dollar value, chemical and biological defense items, military unique and/or military significant items and other pharmaceuticals used in Air Force readiness assemblages in the database are forwarded by the JRCAB to the FDA as potential program candidates. Historically, 45-55 items on each list are sent as candidates to the FDA and the item with the lowest dollar value on this list usually has a value of \$20,000 to \$30,000.

The JRCAB forwards four or five lists per year to the FDA in descending dollar value order, to initiate new projects. The FDA selects a total of 40 to 45 NSNs for testing. At present, the test selection criteria are as follows: the item cannot be a biological; an FDA test protocol must be established; and, the manufacturer’s data for the item does not indicate previous instability.

The FDA sends the JRCAB a request for test item samples. The JRCAB then requests these samples from the appropriate service field agency. Upon receipt of the JRCAB message, AFMLO sends requests for samples to the appropriate Air Force facilities. The FDA requires sample receipt within 60 days of the request. If an item’s samples are not received in that time, the item is dropped from the project, and the testing on the samples received begins.

After testing and evaluation of test results is completed by the FDA, the results are forwarded to the JRCAB which forwards them to the Services’ Logistics Field Operating Agency. AFMLO formulates a message compiling the FDA test results and sends that message world wide to Air Force medical activities. Any activity having items with the lot number and expiration date within the message may extend that

materiel to the specified new expiration date. AFMLO will also send a message asking that materiel which the FDA determined the expiration date could not be extended be destroyed. Activities holding materiel to be extended must remark that materiel with its new FDA approved expiration date as described in AFMAN 23-110, Vol 5 paragraph 13.5. The reported quantities extended are used to determine the benefit of the Program with regard to replacement cost deferral. The same lot numbers are subjected to yearly retest and further extensions until the participants advise JRCAB to remove the NSN from the project, or the item fails testing.

**SUMMARY**

The DOD/FDA SLEP is a program designed to delay replacement costs of potency dated war reserve materiel. The Air Force has been very successful in this program. There have been 45 initial projects and approximately 130 retest projects established. In FY 98, the Air Force extended \$8,595,032 worth of stock through an investment of \$107,326 for a \$80:1 return on investment. Stated differently, for every \$1 spent on testing, the Air Force avoided spending \$80 for the replacement of stocks.

**Air Force Results 95-99**

	FY95	FY96	FY97	FY98	FY99
Cost For Testing	\$107,226	\$71,993.36	\$79,469	\$107,326	\$212,564
Cost Avoidance (Extended Materiel)	\$5,511,636	\$4,574,462	\$3,196,625	\$8,595,032	\$6,721,744
Return on Investment Ratio (ROI) *	51.4	63.54	40.22	80.08	31.62**

\*\* Testing Not Complete