

# **Pharmaceutical Products and the DoD/FDA Shelf Life Extension Program**

## **Introduction**

The Department of Defense (DoD)/Food and Drug Administration (FDA) Shelf Life Extension Program is a key component of the Medical Readiness Strategic Plan (MRSP) as developed by DoD Health Affairs and the Military Medical Departments in response to Congressional concern over the conservation of military medical resources. The program's focus is to defer drug replacement costs of date sensitive Pre-positioned War Reserve Stock (PWRS) by extending its useful life. The following organizations participate in the program: FDA, Joint Readiness Clinical Advisory Board (JRCAB), Army, Navy, Air Force, and Marine Corps. The FDA evaluates candidate materiel for shelf life extension by testing samples submitted from the 4 Services, while the JRCAB (formerly the Defense Medical Standardization Board) coordinates the program and acts as the interface between the Services and FDA. 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 introduction of the program, the Services were investing significant funds in replacement costs for pharmaceutical products of potency dated war reserve and depot stocked pharmaceuticals. Replacement costs for these drugs in 1986 totaled \$2.5 million. One of the methods suggested to limit and defer PWRS and depot drug replacement costs was testing for potential extension of its useful life.

In July 1985, representatives from the Air Force Surgeon General's Office and the FDA met to determine the feasibility of testing drugs for extension. An agreement was reached at this meeting to establish a pilot project for testing. The Air Force identified a list of items representing stock costing \$3,000 or more and within 12 to 18 months of its expiration. The FDA screened the list and determined establishment of test protocols for 56 of the listed items. Samples of the items were sent to the FDA for testing. After 8 months of testing, the final results exceeded expectations. A total of 80% of the items were tested, and 84% of all lots tested were extended. Although the FDA was conservative in their estimates, some of the tested items were granted 3-year extensions.

In January 1986, an interagency agreement was signed forming the DoD/FDA SLEP. The DMSB (now the JRCAB) was tasked as the Quad-Service focal point for the program. Testing of items submitted by the Services and DSCP (DSCP no longer participates) was not started until FY 87. By FY 91, the program had grown enough for the FDA to increase dedicated program resources (facilities and personnel) supporting requirements for new and retest projects.

## **FDA Testing**

The Food and Drug Administration (FDA), as the proponent for quality control of medical materiel for DoD, performs 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. The accelerated testing protocols are 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 chamber which maintains a temperature of 45 degrees centigrade and 75% humidity) for 90 days. The potency of the stressed samples is compared with the standard for each item, and using the comparison, the FDA estimates the extendable life of the product. The FDA testing process, from the time the JRCAB presents the project's candidate list until the results are received by the JRCAB, requires approximately 8 months.

The FDA will not test all items presented to them as program candidates. Biological products, nutritional products, and products with a history of testing failures (i.e., water purification tablets and Mefloquine®) are not accepted for testing.

The testing conducted by the FDA 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 that has been stored under appropriate conditions.

## **The Current SLEP Process**

All war reserve stock should be rotated with peacetime operating stocks when possible; however, war reserve quantities exceed peacetime use in most instances. Activities are required to project quantities of products for the program a minimum of 16, not to exceed 18, months prior to the product's expiration date. The U.S. Army Medical Materiel Agency (USAMMA) is the executive agent for the preparation and dissemination of DoD/FDA SLEP messages which are available for viewing at [www.armymedicine.army.mil/usamma](http://www.armymedicine.army.mil/usamma). Select "DOD Medical Materiel Quality Control Program" on the side bar, then follow the appropriate prompts to access SLEP messages. Individual service representatives may be accessed using hot links from the JRCAB web page [www.medicine.army.mil/jrcab](http://www.medicine.army.mil/jrcab).

Each Service representative (AFMLO, USAMMA, NAVMEDLOGCOM) evaluates their respective activity's report for items to enter into the DoD/FDA SLEP. Products that are nominated as candidates for the program are submitted to the JRCAB. The JRCAB maintains a database of candidate items which is used to select products submitted to the FDA for inclusion in an upcoming project. The FDA assigns a project number and then sends the list of project products and lot numbers, a list of lot numbers that have been cancelled from the project, and a list of Service-specific test item sample requirements to the JRCAB. The JRCAB then sends the information received from the FDA out to the

Services for distribution to respective facilities. The FDA requires sample receipt within 60 days of the request. If an item's samples are not received in 60 days, the item is dropped from the project and testing on the samples that were received begins. Timely submission of samples is critical to successful completion of a project.

Upon completion of testing, the FDA forwards the results to the JRCAB, which forwards them to each respective Service. Any DoD activity having items with the lot number and expiration date within the realm of the test results may extend specified materiel to the new expiration date. Once a product has been tested, it will be re-tested annually until the product either fails testing or is depleted. Additionally, each fiscal year a list of expired, or soon to expire, drugs is compiled from the JRCAB maintained central database to establish new projects in addition to the retest projects carried over from the previous fiscal year.

The focus of the program since its inception has changed. The switch from a depot supply system to a prime vendor supply system has focused the program on PWRS materiel. The prime vendor system has reduced the need for centrally controlled warehousing of drugs and, therefore, reduced the pool of products that are eligible for testing. Additionally, all Medical Treatment Facilities within DoD have the ability to return goods for credit or replacement of expiring stocks of medication in individual facility inventories. Return goods assure replacement of expired products with little or no cost to the facility.

### **Data Integrity**

Automated systems require accurate information input for quality outcomes. The SLEP database is no exception to this rule. It is absolutely critical that all the required fields in the database are entered accurately. Each piece of information is vital to the outcome and results of the testing process. The cost to each Service is based, in part, upon the quantities of products that have been entered by field activities and are apportioned across the Services based upon fair share. If any Service changes quantities for any reason after that product has been entered into a project, it has an impact on the cost the FDA charges for the testing. The reason that quantity changes have an impact is because the FDA bases their charges upon quantities on the front end and then does a reconciliation of actual costs on the back end. Quantities that have changed during the testing process will be accounted for at the conclusion of that testing cycle, and the FDA charges can ultimately be less or greater than the up front estimates depending on quantity changes. If the information is not correct to begin with, the cost can change significantly requiring budget reconciliation problems.

### **Program Guidelines:**

1. Only drugs in FSC 6505 are eligible for this program.
2. Submit eligible candidate products to your respective Service representative (i.e. AFMLO, USAMMA, NAVMEDLOGCOM) at least 16 months and not more than 18 months prior to product expiration.

3. Focus on military significant drug products (use return goods programs for other drug products).
4. Provide accurate information (NSN, expiration date, lot number, manufacturer, quantity per lot number). Additionally, the storage conditions of each product at the unit level should be reported.
5. Always provide manufacturer; not the distributor, of the drug product.
6. Ensure that you use the correct unit of issue. Provide tablet and capsule quantities as a package unit and not each tablet or capsule. (e.g. one bottle of 100 count ciprofloxacin tablets is “one” and not “100”).
7. Products specifically excluded (biologicals, nutritional products, water purification tablets, Mefloquine®) from testing should not be submitted.
8. When samples for a specific product and lot number are requested from your facility, send them promptly to address specified for testing. Delays in submission are directly proportional to delays in results or may even result in cancellation of a test project.
9. Keep your respective Service representative informed of changes to quantities on hand.
10. Facilities will be informed of test results as soon as the tests are complete.

### **Conclusion**

The DoD/FDA Shelf Life Life Extension Program has been a successful Quad-Service program since its introduction. Since 1992 the program has allowed the Services to avoid annual replacement costs of over \$372 million worth of medications. Thanks to all who have worked hard to make the program a success and with continued efforts the SLEP will continue to be a valuable asset to DoD.