



# Defense Health Agency

## PROCEDURES MANUAL

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Director, MEDLOG

SUBJECT: Shelf-Life Extension Program

References: See Enclosure 1

1. PURPOSE. This Defense Health Agency-Procedures Manual (DHA-PM) based on the authority of References (a) through (c), and in accordance with the guidance of References (d) through (k), establishes the DHA procedures to manage and provide guidance on the Shelf-Life Extension Program (SLEP) within the Military Health System and contingency operations. Additionally, this DHA-PM provides guidance on general operations of the Department of Defense (DoD)/Food and Drug Administration (FDA) SLEP to non-DoD program participants.

2. APPLICABILITY. This DHA-PM applies to the DHA Enterprise (components and activities under the authority, direction, and control of the DHA) to include: assigned, attached, allotted, or detailed personnel, and the Military Departments (MILDEPs).

3. POLICY IMPLEMENTATION. It is DHA's instruction, pursuant to Reference (f), to provide authority to the DHA Medical Logistics Division (MEDLOG) to be the executive manager for the DoD/FDA SLEP, oversee the program, and act as the single interface for other federal agencies between SLEP and the FDA. The following organizations enter into inter-agency agreements with DHA MEDLOG to participate in the SLEP program: Army, Navy, Air Force, Marine Corps, Coast Guard, Defense Logistics Agency, Department of Health and Human Service's (HHS) Strategic National Stockpile, Veterans Administration Emergency Preparedness Program, National Guard Bureau, Federal Bureau of Investigation, Department of Homeland Security, and the Department of State. Service specific guidance with regard to the administration of SLEP inter-agency agreements (IAAs) lies with the following component agencies to include, Army Medical Logistics Command, Naval Medical Logistics Readiness Command (commonly referred to as, NMLRC-DET FORT DETRICK), Air Force Medical Readiness Agency, and the US Coast Guard.

4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Director, Medical Logistics (MEDLOG). When Activities are unable to comply with this publication the activity may request a waiver that must include a justification, to include an analysis of the risk associated with not granting the waiver. The activity director or senior leader will submit the waiver request through their supervisory chain to the Director MEDLOG to determine if the waiver may be granted by the Director, DHA or their designee.

7. RELEASABILITY. **Cleared for public release.** This DHA-PM is available on the Internet from the Health.mil site at: <https://health.mil/Reference-Center/Policies> and is also available to authorized users from the DHA SharePoint site at: <https://info.health.mil/cos/admin/pubs/>.

8. EFFECTIVE DATE. This DHA-PM:

a. Is effective upon signature.

b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

9. FORMS

a. Standard Form (SF) 1080, Voucher for Transfers Between Appropriations and Funds is available at: <https://www.gsa.gov/Forms/TrackForm/32759>.

b. The following Department of Defense (DD) forms are available at: [https://www.esd.whs.mil/Directives/forms/dd0001\\_0499/](https://www.esd.whs.mil/Directives/forms/dd0001_0499/).

(1) DD Form 448, Military Interdepartmental Purchase Request (MIPR)

(2) DD form 2875, System Authorization Access Request (SAAR)

c. The DD Form 448-2, Acceptance of MIPR is available at: [DD Form 448-2, "Acceptance of MIPR" \(whs.mil\)](#)

d. The DHA Form 130, GFEBS Direct Charge Funding Request is available at: [DHA Forms Library](#)

e. The following Fiscal Service (FS) Forms are available at: <https://fiscal.treasury.gov/g-invoice/resources.html>

(1) FS Form 7600A, General Terms and Conditions

(2) FS Form 7600B, Agreement Between Federal Program Agencies for Intragovernmental Reimbursable, Buy/Sell Activity

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#### Enclosures

1. References
2. Responsibilities
3. Procedures

#### Appendices

1. List of Program Participants
2. Figures

#### Glossary

TABLE OF CONTENTS

ENCLOSURE 1: REFERENCES.....	6
ENCLOSURE 2: RESPONSIBILITIES.....	7
DIRECTOR, DEFENSE HEALTH AGENCY .....	7
MEDICAL LOGISTICS, DIRECTOR, DEFENSE HEALTH AGENCY.....	7
PEO MEDICAL SYSTEMS/CHIEF INFORMATION OFFICER, INFORMATION OPERATIONS, DEFENSE HEALTH AGENCY .....	7
DEPARTMENT OF DEFENSE SHELF-LIFE EXTENSION PROGRAM MANAGER .....	8
RESOURCE MANAGER, DEFENSE HEALTH AGENCY .....	9
SUPPORT LEAD AGREEMENTS MANAGER, DEFENSE HEALTH AGENCY .....	9
SECRETARIES, MILITARY DEPARTMENTS .....	9
AGENCY SHELF-LIFE EXTENSION PROGRAM MANAGER (NON-MILITARY DEPARTMENT) .....	10
DIRECTORS, DIRECT CARE COMPONENTS .....	10
DIRECTORS, MILITARY MEDICAL TREATMENT FACILITIES .....	10
SHELF-LIFE EXTENSION PROGRAM UNIT MONITORS.....	10
ENCLOSURE 3: PROCEDURES.....	11
BACKGROUND .....	11
FINANCIAL PLANNING AND MANAGEMENT .....	11
ADDITION OF NEW PRODUCT (PREVIOUSLY NOT TESTED) .....	13
INVENTORY MANAGEMENT .....	14
IDENTIFICATION FOR LOT NUMBER TESTING .....	16
SAMPLE HANDLING AND SHIPPING .....	17
PRODUCT TESTING .....	17
TEST RESULT PROCESSING .....	18
LABEL GENERATION OF EXTENDED PHARMACEUTICALS .....	19
OUT-OF-CYCLE LABEL PROCESSING .....	20
PHARMACEUTICAL DISPOSAL .....	21
ADDITIONAL INFORMATION.....	21
TRAINING INFORMATION .....	21
APPENDICES	
LIST OF PROGRAM PARTICIPANTS .....	23
FIGURES.....	24
GLOSSARY .....	31
PART I: ABBREVIATIONS AND ACRONYMS .....	31
PART II: DEFINITIONS.....	31

FIGURES .....24

1. Financial Planning and Management.....24
2. New Product Addition to Shelf-Life Extension Program Process.....25
3. Shelf-Life Extension Program Inventory Management Process.....26
4. Shelf-Life Extension Program Identification for Testing Process.....27
5. Shelf-Life Extension Program Sample Handling Process .....28
6. Processing of Shelf-Life Extension Program Test Result Process .....29
7. Shelf-Life Extension Program Out-of-Cycle Label Request Process.....30

ENCLOSURE 1

REFERENCES

- (a) DoD Directive 5136.01, “Assistant Secretary of Defense for Health Affairs (ASD(HA)),” September 30, 2013, as amended
- (b) DoD Directive 5136.13, “Defense Health Agency (DHA),” September 30, 2013
- (c) DHA-Procedural Instruction 5025.01, “Publication System,” April 1, 2022
- (d) DoD Instruction 4000.19, “Support Agreements,” December 16, 2020
- (e) DoD Instruction 6430.02, “Defense Medical Logistics Program,” August 23, 2017
- (f) United States Code, Title 10, Section 1073c
- (g) DoD Manual 4140.27, Volume 2, “DoD Shelf-Life Management Program: Materiel Quality Control Storage Standards,” July 6, 2016, as amended
- (h) Memorandum of Agreement between Tricare Management Activity and the Health and Human Services Supply Service Center, February 1, 2013
- (i) United States Code Title 21, Chapter 9 (also known as the “Federal Food, Drug, and Cosmetic Act, 1938”)
- (j) Code of Federal Regulations, Title 21
- (k) Code of Federal Regulations, Title 40

ENCLOSURE 2

RESPONSIBILITIES

1. DIRECTOR, DHA. The Director, DHA, will establish a comprehensive, FDA compliant SLEP that acts as the single interface between the FDA and program participants from the MILDEPs and federal agencies outside of DoD.
  
2. MEDICAL LOGISTICS, DIRECTOR, DHA. The Director MEDLOG must exercise management responsibility for MEDLOG shared services, functions, and activities, and develop management models to deliver MEDLOG product lines in the most effective, efficient manner, while reducing the cost to DoD health care. Specific to SLEP, Director MEDLOG must:
  - a. Implement an FDA-compliant program to act as the single interface between the SLEP Participant and the FDA in accordance with References (a) through (k).
  
  - b. Establish a MEDLOG SLEP Management team consisting of a DHA Program Manager and program support staff.
  
  - c. Establish a MEDLOG SLEP Resource Management team consisting of a Resource Manager and financial support staff.
  
  - d. Establish metrics and standards, monitors execution performance and reports SLEP, and initiative compliance to the Director, DHA.
  
  - e. Ensure operational support to Combatant Commands (CCMD) to optimize materiel readiness.
  
3. PEO MEDICAL SYSTEMS/CHIEF INFORMATION OFFICER (CIO), INFORMATION OPERATIONS (J-6), DHA. The PEO MEDICAL SYSTEMS/CHIEF INFORMATION OFFICER (CIO), INFORMATION OPERATIONS (J-6), DHA must:
  - a. Support the DHA MEDLOG Information Technology Program Management Office/ Joint Medical Logistics Functional Development Center (JMLFDC).
  
  - b. Fully execute the SLEP funds provided by DHA MEDLOG to sustain the SLEP technical information technology capability in perpetuity.
  
  - c. Continue coordination and planning for final details on activities required to transition SLEP capabilities into LogiCole/Reporting and Analytics (R&A), formerly known as Joint Medical Asset Repository.

d. Update the LogiCole/R&A SLEP module to support current and future SLEP business processes.

e. Establish access to R&A data based on Need-to-Know at the SLEP Unit level. This is necessary to allow other federal agencies and SLEP participants to perform specific SLEP Unit, customer inventory, or project management inquiries in R&A.

f. Assist DHA MEDLOG in transition and stakeholder training activities on the use of the JMLFDC systems to support SLEP Capabilities.

g. Ensure SLEP can print/send labels requests for specific FDA shelf-life extensions for one or more National Stock Number/Lots in an FDA project for one or more designated units.

h. Provide ongoing resources and customer technical support to DHA MEDLOG specific to LogiCole/R&A and subsequently, LogiCole daily technical operations of the SLEP within JMLFDC in perpetuity.

i. Establish access to LogiCole/R&A via DoD Common Access Card or Personal Identity Verification card for external federal agencies. This is necessary to allow other federal agencies and SLEP participants to perform SLEP Inventory or Project Management inquiries in R&A.

4. DoD-SLEP PROGRAM MANAGER. The DoD-SLEP Program Manager must:

a. Manage and provide daily oversight to the MEDLOG SLEP team, including program resource management requirements.

b. Have access to all program management reports and alerts, monitor SLEP participant compliance of established performance metrics, standards, and reports for Director MEDLOG, as needed.

c. Review and revise this DHA-PM as needed in accordance with Reference (e).

d. Oversee and maintain visibility and ensure accountability on materiel managed within SLEP.

e. Update test results and dispositions on stock-based FDA guidance to program participants.

f. Provide cost estimates and conduct coordination meetings with SLEP participants, at the middle of each fiscal quarter (November, February, May, and August).



5. RESOURCE MANAGER, DHA. The Resource Manager, Assistant Director-Support (AD-S) Business Operations Division must:

- a. Serve as the General Fund Enterprise Business System administrator and finance analyst for SLEP.
- b. Review and process annual SLEP participant funding via DD Form 448, Military Interdepartmental Request, IAAs or Purchase Order, and SF 1080, "Voucher for Transfers between Appropriations and/or Funds," billing invoices for each SLEP participant.
- c. Review Task Orders and Billing statements prepared by the SLEP Program Analyst.
- d. Validate funding availability for each SLEP participant and request additional funding if warranted by final project cost estimate.
- e. Review signed IAAs for updated annual estimated program costs for each SLEP participant.

6. SUPPORT LEAD AGREEMENTS MANAGER, DHA. The Support Agreements Manager or designee must:

- a. Review IAAs between DHA and all SLEP participants.
- b. Provide DHA MEDLOG approved/endorsed IAAs and/or other appropriate forms (Such as DHA Form 130 or DD Form 448 or DD Form 448-2).

7. SECRETARIES, MILITARY DEPARTMENTS. The Secretaries, MILDEPs will ensure effective MILDEPs collaboration with DHA in the execution and development of SLEP policies and procedures and support to CCMDs. The MILDEPs will also identify a service representative who can perform the following duties:

- a. Serve as the administrator of the SLEP for their MILDEP.
- b. Have access to all inventory assigned to the MILDEP.
- c. Manage inventory, receive test status changes, sample requests, reports, and other alerts.
- d. Provide operational funding as defined by the DoD SLEP Program Manager.
- e. Ensure all SLEP pharmaceuticals are maintained in a controlled environment under conditions recommended by the manufacturer.

8. AGENCY PROGRAM MANAGERS (NON-MILDEP). Agency Program Managers (non-MILDEP) must collaborate and comply with DHA in the execution and development of SLEP responsibilities, procedures, and standards outlined in this DHA-PM.

- a. Serve as the administrator of the SLEP for their Agency.
- b. Have access to all inventory assigned to the Agency.
- c. Manage inventory, receive test status changes, sample requests, reports, and other alerts.
- d. Provide operational funding as defined by the DoD SLEP Program Manager.
- e. Ensure all SLEP pharmaceuticals are maintained in a controlled environment under conditions recommended by the manufacturer.

9. DIRECTORS, DIRECT CARE COMPONENTS (DCC). The Directors, DCC must ensure military medical treatment facilities (MTF) comply with applicable DoD-SLEP policies and procedures and/or Service-specific guidance.

10. DIRECTORS, MTFs. Directors, MTFs must ensure compliance with SLEP policies and procedures and/or Service-specific guidance.

11. SHELF-LIFE EXTENSION PROGRAM UNIT MONITORS. The SLEP Unit Monitor must:

- a. Generate a Designated/Appointment Letter for SLEP Unit Monitor.
- b. Maintain, account for, relabel, ship, and destroy materiel at the site of physical SLEP inventory.
- c. Have access to all inventory assigned to the unit monitor.
- d. Manage inventory, receive test status changes, sample requests, reports, and other alerts.

ENCLOSURE 3

PROCEDURES

1. BACKGROUND

a. The DoD Shelf-Life Extension Program is an internal component of the Medical Readiness Strategic Plan. The Federal government maintains significant pre-positioned stocks of critical medical materiel, to include pharmaceuticals. Prior to introduction of the program, the Services were investing significant funds in replacement costs for potency dated pharmaceutical products (pre-positioned stocks, war reserves and depot stocked pharmaceuticals). One of the methods suggested to limit expenditures and defer drug replacement costs for this materiel was to test the expiring inventory to verify that it was still within the specifications of the product's official monograph.

b. In July of 1985, representatives from the Air Force Surgeon General's Office and the FDA met to determine the feasibility of testing drugs for possible extension. An agreement resulted from this meeting to establish a pilot project. Although FDA was conservative in their estimates, some of the tested items were granted extensions of up to 3 years beyond their initial expiration date.

c. In January of 1986, a signed IAA created the DoD SLEP. The program's original focus was to defer drug replacement costs of date-sensitive Prepositioned War Reserve Stock items by testing and extending their useful product life. The DoD Medical Standardization Board (DMSB) was tasked as the DoD focal point for the program. Testing of items submitted by the Services and by the Defense Logistics Agency (DLA) began during fiscal year 1987. Over the next 3 years, the program grew considerably and the FDA dedicated program resources (facilities and personnel) to the support requirements for new testing as well as retesting projects. The DMSB SLEP roles were incorporated into the Defense Medical Materiel Standardization Program in 2011 and later placed under the direction of the DHA MEDLOG Directorate in 2013.

d. DHA MEDLOG consolidates all requirements from program participants and identifies expiring lot numbers that are viable candidates for testing by the FDA for possible extension. If the test results warrant extending the expiration date of the product, the FDA grants approval to re-label the products with an extended expiration date. The program results in significant costs avoidance for the participants.

2. FINANCIAL PLANNING AND MANAGEMENT

a. DoD SLEP Program Manager develops annual SLEP Cost Estimate/Spend Plan at the start of the 4th quarter, in preparation for the next fiscal year.

- b. DHA Logistics Plans and Readiness Division Chief reviews and approves SLEP Cost Estimate/Spend Plan.
- c. DoD SLEP Program Manager reviews SLEP participation status and generates FS Form 7600A, General Terms and Conditions or IAA form as necessary for agencies/organizations whose IAAs with DHA has expired, or soon to expire.
- d. DoD SLEP Program Manager submits FS 7600A to DHA Support Agreements Section for review and approval.
- e. FS Form 7600As are provided to SLEP participants for review and approval.
- f. FS Form 7600As signed and executed by DHA and SLEP participants before funding is disbursed.
- g. SLEP Participants submit signed funding document (FS Form 7600B, Agreement Between Federal Program Agencies for Intragovernmental Reimbursable, Buy/Sell Activity and DD Form 448, MIPR) to DoD SLEP Program Manager.
- h. Signed funding documents (FS Form 7600B and DD Form 448) are provided to DHA Resource Manager, AD-S Business Operations Division to process MIPR acceptance and returns to DoD SLEP Program Manager
- i. DoD SLEP Program Manager provides MIPR acceptance document (DD 448-2, Acceptance of MIPR) to SLEP participants.
- j. DoD SLEP Program Manager prepares project cost estimates. “Project” is the term used for testing of a particular drug. Each drug is represented by a project. SLEP project estimates are provided to SLEP participants who are included in a project.
- k. DoD SLEP Program Manager enters and maintains project and financial information.
- l. Sample Collection, Product Testing, Approval, and Certification are external to financial management process and are defined in detail in subsequent paragraphs within this section.
- m. DoD SLEP Program Manager conduct mid-year SLEP review (at the start of the 3<sup>rd</sup> quarter).
- n. DoD SLEP Program Manager receives monthly invoices from SLEP labeler (HHS Program Support Center Perry Point).
- o. DoD SLEP Program Manager enters label invoice and validates funding availability, requests additional funding as necessary.
- p. DoD SLEP Program Manager requests SF 1080 for SLEP project testing from the FDA.

q. DoD SLEP Program Manager provides SF 1080 to Resource Manager, AD-S Business Operations Division for processing.

r. The AD-S Business Operations Division processes invoice payment in Defense Finance and Accounting Service.

3. ADDITION OF A NEW PRODUCT (NOT PREVIOUSLY TESTED)

a. SLEP Service/Agency Program Manager submits a request to DoD SLEP Program Manager to add a new product to SLEP.

b. DoD SLEP Program Manager reviews request and enters into a system of record.

c. DoD SLEP Program Manager determines if the product meets the following entrance criteria:

(1) SLEP addition is directed by Service/Agency higher-level authority.

(2) Pharmaceutical is pre-positioned and/or contingency stock.

(3) Total inventory value per lot is at least \$10,000.00.

(4) Product was not requested and denied within the last 12 months.

d. If the pharmaceutical meets all the program requirements, DoD SLEP Program Manager contacts FDA to determine if it can be added to SLEP. Proceed to paragraph 3.i. of this enclosure.

e. If product does not meet the entrance criteria, DoD SLEP Program Manager notifies the SLEP Service/Agency Program Manager.

f. SLEP Service/Agency Program Manager may submit an exemption request to the entrance criteria based on national security interest, market availability, service priority, etc. DoD SLEP Program Manager has the discretion to grant exemption.

g. If exemption is granted, proceed to paragraph 3.i. of this enclosure.

h. If exemption is not granted, SLEP Service/Agency Program Manager is notified. Product is not added to SLEP. Process is completed.

i. FDA determines testing capability for the product. Testing capability is defined as protocol (design and parameters), personnel, and equipment to perform the test.

j. If FDA has the testing capability:

- (1) FDA notifies the DoD SLEP Program Manager.
- (2) DoD SLEP Program Manager adds product to SLEP.
- (3) SLEP Service/Agency Program Manager is notified. Process is completed.

k. If FDA does not have the testing capability, FDA will determine if testing capability can be developed. Requesting Service/Agency has the option of funding the development of testing capability.

l. If testing capability can be developed:

- (1) FDA provides a cost estimate to DoD SLEP Program Manager.
- (2) DoD SLEP Program Manager notifies SLEP Service/Agency Program Manager and provides cost estimate.

m. If Service/Agency funds testing capability development:

- (1) DoD SLEP Program Manager notifies and provides funding document to FDA.
- (2) Product is added to SLEP. Process is completed.

n. If Service/Agency does not fund testing capability development:

- (1) DoD SLEP Program Manager notifies FDA.
- (2) Product is not added to SLEP. Process is completed.

o. If testing capability cannot be developed:

- (1) FDA notifies DoD SLEP Program Manager.
- (2) DoD SLEP Program Manager notifies SLEP Service/Agency Program Manager.
- (3) Product is not added to SLEP. Process is completed.

4. INVENTORY MANAGEMENT. SLEP participant updates System of Record with lot number information.

a. System of Record is the application used by the SLEP participant. There are currently three approved systems. SLEP participants will refer to their SLEP Service/Agency Program Manager for the approved system of use.

(1) Defense Medical Logistics Standard Support (DMLSS)

(2) Theater Enterprise-Wide Logistics System (TEWLS)

(3) LogiCole/R&A

b. A product's lot number information includes:

(1) National Stock Number

(2) Name of Product

(3) Lot Number

(4) Expiration date

(5) Quantity on hand

(6) Dollar value

(7) National Drug Code (NDC)

c. New lot number entered in system of record will be fed into R&A.

d. If the new lot number has an inventory value of less than \$10,000.00 per lot, the lot number is retained in the system of record until the total SLEP aggregate value of the lot number reaches the \$10,000.00 threshold. The lot number will be included in the data refresh.

e. If the new lot number has an inventory value of greater than or equal to \$10,000.00 per lot, an automated notification will be sent to the DoD SLEP Program Manager for new lot number approval.

f. DoD SLEP Program Manager reviews lot number and verifies information entered. DoD SLEP Program Manager verifies the submission of the digital image.

g. If a photograph was uploaded, DoD SLEP Program Manager approves the new lot number. If photograph was not uploaded, proceed to paragraph 3.a.(i) of this enclosure.

h. R&A sends system auto-generated request to user for a digital image of the new lot number.

i. User uploads digital image of new lot number into R&A with the following minimum lot number information:

- (1) Manufacturer
- (2) Name of Product
- (3) Lot Number
- (4) Expiration date
- (5) NDC

j. Return to paragraph 3.a.(f) of this enclosure.

#### 5. IDENTIFICATION FOR LOT NUMBER TESTING

a. Lot number testing is initiated by the following actions:

- (1) DoD SLEP Program Manager reviews inventory and identifies lot number for testing.
- (2) SLEP Service/Agency Program Manager submits a request to the DoD SLEP Program Manager to test a lot number.

b. Testing criteria is based on the following (not listed in any specific order):

- (1) SLEP approved product
- (2) Expiration date (within three months)
- (3) Total SLEP aggregate lot value no less than \$10,000.00.
- (4) Service/Agency priority
- (5) Mission requirement (readiness/availability)
- (6) Lot number testing history (within the last 12 months)
- (7) Military unique items take precedence over commercially available items

c. If the lot number has been previously tested, the DoD SLEP Program Manager will submit a retest project request to the FDA.



- d. If the lot number has not been previously tested, the DoD SLEP Program Manager will submit a new project request to the FDA.
- e. FDA will respond with sample requirements (quantity of lot numbers to be tested).
- f. DoD SLEP Program Manager will have an approved test project and sample requirements.
- g. Process is completed.

6. SAMPLE HANDLING AND SHIPPING

- a. DoD SLEP Program Manager reviews inventory to identify project testing samples.
- b. DoD SLEP Program Manager notifies SLEP Service/Agency Program Manager of lot number sample requirements.
  - (1) Samples of controlled substances are sent to the FDA Laboratory, 300 River Place, Suite 5900, Detroit, Michigan 48207. Units/activities are responsible for compliance to their respective controlled substance handling protocols. Units/activities are responsible for all shipping costs.
  - (2) Samples of non-controlled substances are sent to the FDA, 12420 Parklawn Drive, Room 3144, Rockville, Maryland, 20857. Units/activities are responsible for compliance to their respective pharmaceutical handling protocols.
  - (3). Units/activities are responsible for all shipping costs.
- c. Service/Agency Program Manager selects units/activities to provide project test lot samples based on:
  - (1) On-hand inventory
  - (2) Location of unit/activity
- d. FDA receives samples and notifies DoD SLEP Program Manager.
- e. Process is completed.

7. PRODUCT TESTING. The Program Manager, Office of Regulatory Affairs, FDA will conduct scientific testing of pharmaceuticals submitted by SLEP participants using established protocols and will analyze the results to determine appropriate shelf-life extensions of stockpiled pharmaceuticals. The FDA will, per agreement:

- a. Design an appropriate testing and evaluation program to determine if scientific data supports the extension of labeled expiration dates on specified medical products.
- b. Identify samples to be submitted by the DoD components/authorized partners for evaluation/testing in accordance with DoD/authorized partners' priorities.
- c. Perform the testing and evaluation to determine if scientific data supports extending labeled expiration dates of medical products.

#### 8. TEST RESULT PROCESSING

- a. FDA sends project results notification letter to DoD SLEP Program Manager.
- b. If testing failed:
  - (1) DoD SLEP Program Manager changes lot status in LogiCole to “Failed Testing – Return for credit or destroy”.
  - (2) R&A sends automated alert message to SLEP participants.
  - (3) SLEP participants will dispose of expired pharmaceuticals according to Service/Agency-specific policies and procedures, and update inventory in applicable system of record (i.e., LogiCole, DMLSS, TEWLS).
  - (4) Process is completed.
- c. If shelf-life is extended:
  - (1) DoD SLEP Program Manager changes lot status in LogiCole to “Tested - Extended” and enters new expiration date.
  - (2) R&A sends automatic alert message to SLEP participants.
- d. DoD SLEP Program Manager validates inventory of lot number has been updated within the last 90 days.
- e. If inventory has not been updated within the last 90 days:
  - (1) Lot number extension label order requirements are suspended.
  - (2) Units/organizations with extended lots are notified and required to update their respective inventories in the system of record.
  - (3) DoD SLEP Program Manager validates inventory has been updated.

(4) Extension label order requirements suspension is lifted. Proceed to paragraph 6.g. of this enclosure, below.

f. If inventory is current, DoD SLEP Program Manager submits extension label requirements to HHS Perry Point, Supply Chain Management Services (PSC). Program Support Center, Perry Point, Maryland 21902. SLEP items extended will be relabeled, down to the unit of issue, per Service/Agency-specific policies and procedures.

9. LABEL GENERATION OF EXTENDED PHARMACEUTICALS. The Quality Assurance Specialist and Office Automation Assistant of HHS PSC will, per IAA:

a. Produce, perform quality control management, and ship extension labels to DoD Activity Address Code (DoDAAC) reporting SLEP inventory at the direction of the DoD SLEP Program Manager or designee.

b. Perform all functions relative to quality assurance, quality control surveillance of label production, management consistent with Good Manufacturing Practice, and security of sensitive items and/or information throughout all aspects of label management and production.

(1) Printed labels will have a life expectancy of at least three years before application and, after application, must adhere to the product for at least three additional years and be resistant to damage when exposed to severe heat (140°F), moisture or cold (32°F) environments.

(2) The labels must adhere to all products maintained by SLEP participants to include the following types of surfaces: glass, wood, plastic, and paper. The label should be removal resistant, such that it is destroyed in attempt to remove it after application. Additionally, labels must comply with Reference (h). The labels will be made with run and fade resistant ink.

(3) All documents relative to production of extension labels including quality control will be readily accessible to DoD SLEP Program Manager upon request.

(4) All reproduction of labels due to errors discovered by proofing or quality control is done at the expense of HHS PSC.

(5) The exception to the above is if the DoD SLEP Program Manager requests label reproduction due to a correction of data in the SLEP application.

c. Accommodate variations (Lot number and Expiration date) of each base label order placed. Quantities of labels distributed to SLEP participants must be exactly what was requested, for both case package and individual items.

d. Distribute labels to SLEP participants in shrink-film wrap in quantities indicated on print order.

(1) Reinforce each package to prevent curling, wrinkling, etc. Multiple items shipped to the same destination may be packed together but must be able to be separated. Each lot number will be shrink-film wrapped separately before packing and will have appropriate envelopes or packages to insert single or multiple copies of labels displaying the extended expiration date.

(2) Each shipment will include a label instruction page. Shipments filling less than a shipping container must be packaged with materials of sufficient strength, durability, and in such a manner that guarantees the product will not be damaged and the package will not open or split during shipment.

(3) Packages must be under 40 pounds. All shipments must be sent by common carrier in such a manner to allow the DoD SLEP Program Manager to track and trace its delivery (e.g., through Federal Express, United Parcel Service, or United States Postal Service traceable mail). No federal endorsement is intended.

(4) All information related to distribution and shipment of the items (i.e., tracking numbers) will be furnished by electronic file transfer to the DoD SLEP Program Manager immediately upon initiation of shipment. Potential methods of electronic file transfer include, but are not limited to: Government posted website, file transfer protocol, and agency hosted file transfer protocol server.

e. Begin label production only on receipt of a production order issued by the DoD SLEP Program Manager or delegate. The production of labels will occur immediately upon request, which will not follow a routine or schedule, and the entire order must be shipped within 30 days of order receipt. Exceptions will be granted on a case-by-case basis (e.g., a backlog of orders created because of lack of funding or agreement in place).

f. Keep all records regarding label management for SLEP extension labels on file following Service/Agency records management guidance.

g. DoD SLEP Program Manager sends extension label notification via email to appropriate SLEP participants.

h. SLEP Unit Monitor confirms extension label receipt via email response.

i. Process is completed.

## 10. OUT-OF-CYCLE LABEL PROCESSING

a. SLEP participants send request to reprint extension labels to DoD SLEP Program Manager.

- b. DoD SLEP Program Manager validates inventory and unit profile DoDAAC, contact information, address, etc.).
- c. DoD SLEP Program Manager sends extension label to HHS PSC.
- d. HHS PSC prints and ships extension labels to DoDAAC reporting SLEP inventory.
- e. DoD SLEP Program Manager sends extension label notification status to appropriate SLEP participants.
- f. SLEP Unit Monitor confirms extension label receipt.
- g. Process is completed.

11. PHARMACEUTICAL DISPOSAL. The facility should dispose of pharmaceuticals in accordance with Reference (k), if applicable; otherwise, the facility should adhere to applicable Service/Agency requirements in disposing of the pharmaceuticals subject to this document.

12. ADDITIONAL INFORMATION. Online access is now available to the DoD/FDA SLEP. Registration is required for access to the LogiCole/R&A: <https://logicole.health.mil/>.

- a. All SLEP participants must register for an R&A account via <https://logicole.health.mil/>.

b. SLEP participants may also be required to register for a LogiCole account. Coordinate with Service/Agency Program Manager for access requests. DD Form 2875, System Authorization Access Request (SAAR) is required.

13. TRAINING INFORMATION. The following online training modules are available in Joint Knowledge Online:

- a. Required LogiCole/R&A training:

- (1) DHA-US414 LogiCole/R&A SLEP Initial Registration
- (2) DHA-US417 LogiCole/R&A SLEP Unit Monitor or,
- (3) DHA-US419 LogiCole/R&A SLEP Service/Agency Representative or,
- (4) DHA-US418 LogiCole/R&A DoD-SLEP Program Manager

b. Additional LogiCole/R&A training for Service/Agency Program Manager or Access Managers:

- (1) DHA-US416 LogiCole/R&A SLEP Service/Agency Program Manager
- (2) DHA-US415 LogiCole/R&A SLEP Access Control
- (3) DHA-US309 LogiCole/R&A Access Management

APPENDIX 1

LIST OF PROGRAM PARTICIPANTS

Per DoDM 4140.27, Vol 1, para. 7.7a, the following are the Program participants:

United States Air Force

Air Force Medical Readiness Agency, Medical Logistics

Air Force Medical Readiness Agency, Medical Readiness

Air National Guard

Ninth Air Force (Air Forces Central)

United States Army

United States Army Medical Materiel Agency

United States Marine Corps

United States Navy

United States Coast Guard

Defense Health Agency

Medical Logistics Pandemic Stockpile Program

Army National Guard

National Capital Region

Defense Logistics Agency-Troop Support

Office of the Assistant Secretary of Defense for Health Affairs

Office of the Assistant Secretary for Preparedness and Response–Division of Strategic National  
Stockpile

Federal Bureau of Investigation

United States Department of State

United States Department of Homeland Security

United States Department of Veterans Affairs

APPENDIX 2

FIGURES

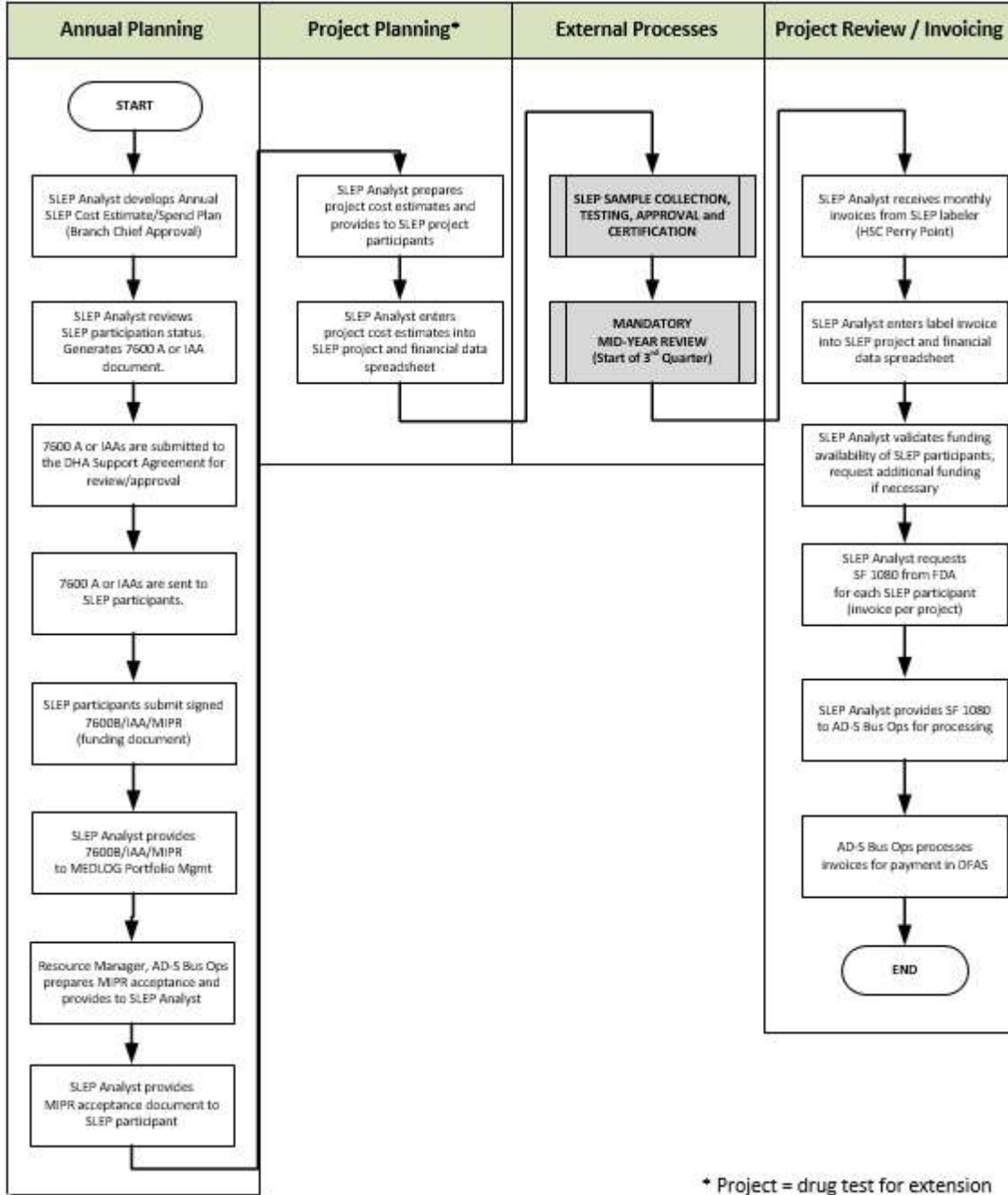


Figure 1. Financial Planning and Management



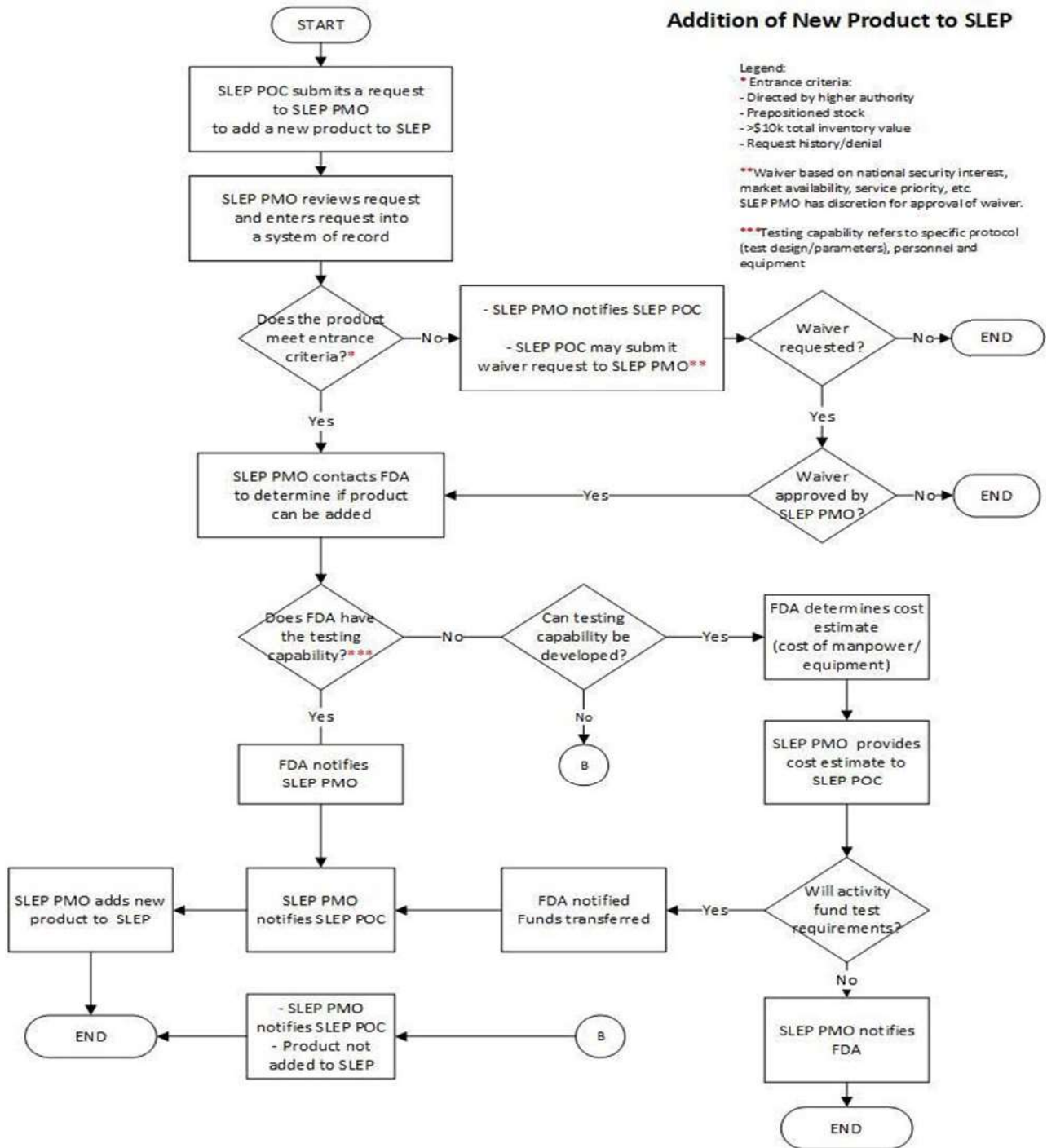


Figure 2. New Product Addition to Shelf-Life Extension Program Process

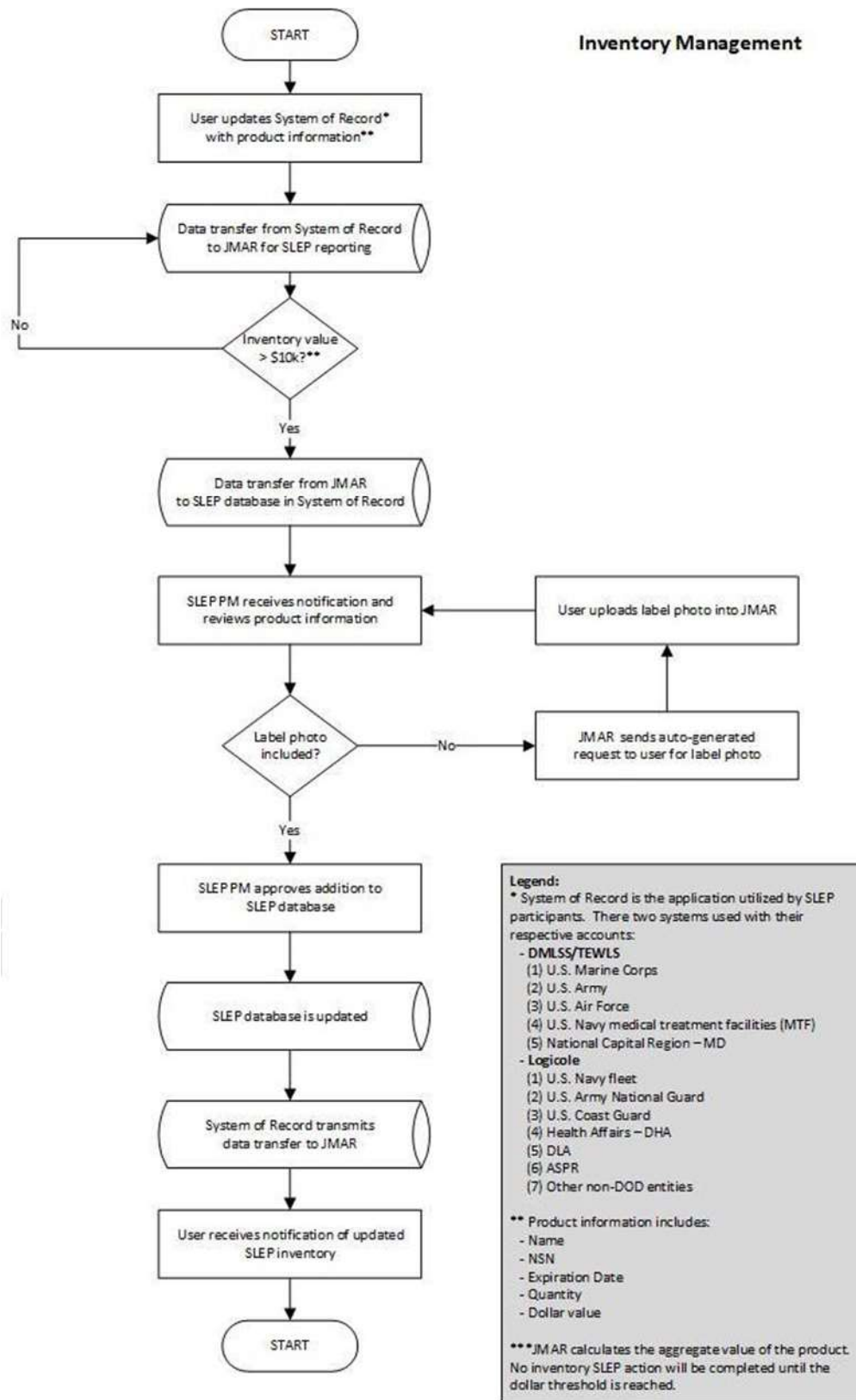
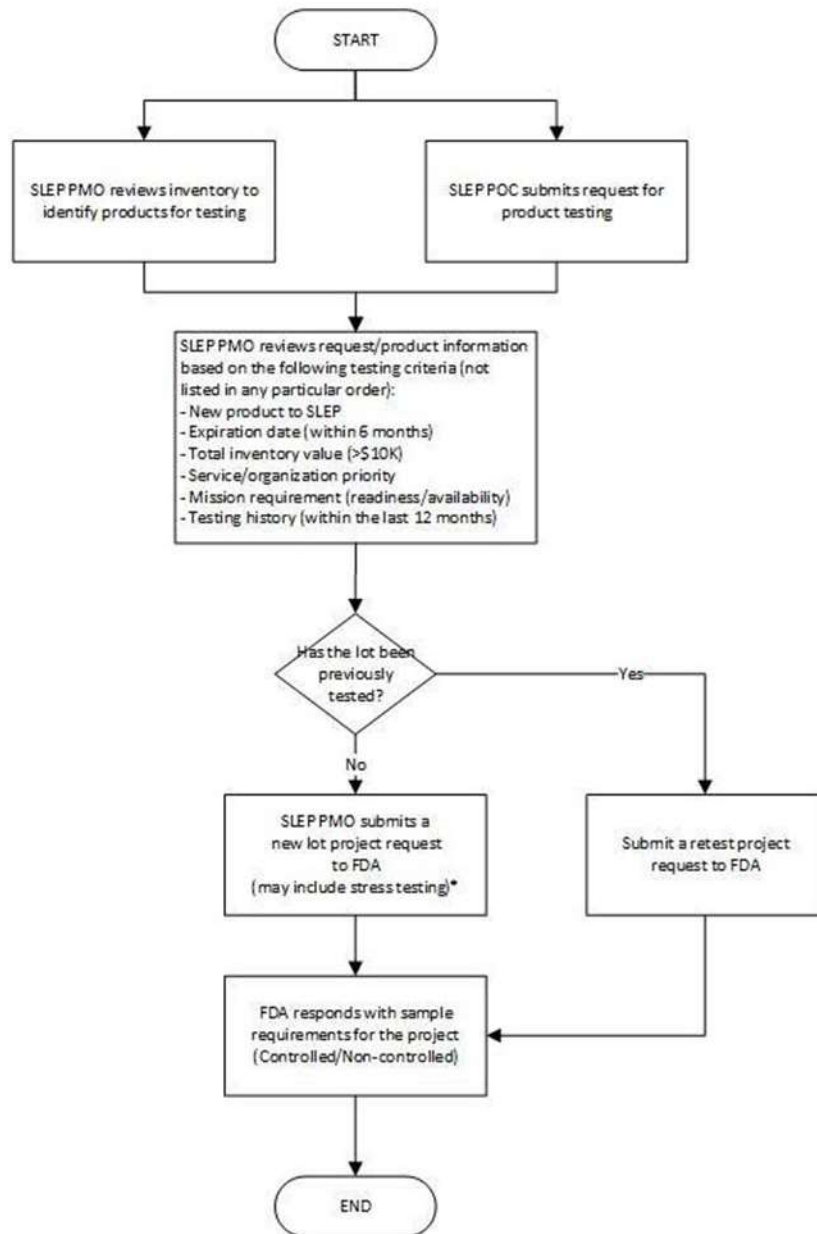


Figure 3. Shelf-Life Extension Program Inventory Management Process

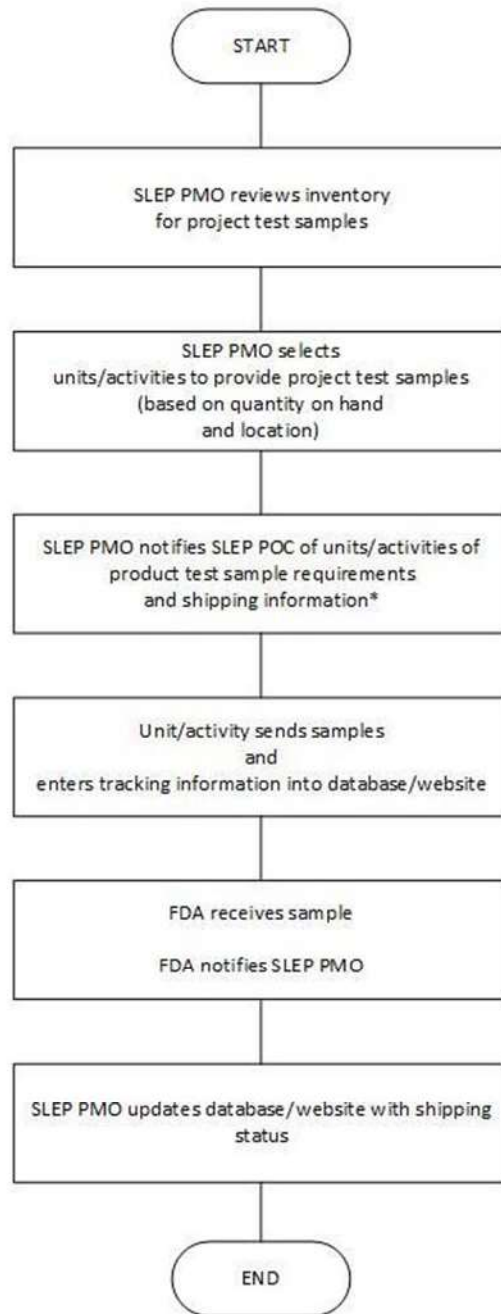
### Identification for Product Testing (SLEP)



\*FDA determines if stress testing is indicated. Stress testing extends testing period by up to 90 days.

Figure 4. Shelf-Life Extension Program Product Identification for Testing Process

**Sample Handling**



- \*
  - Controlled products are sent to the FDA Testing Laboratory in Detroit, MI. Units/activities are responsible for compliance to their respective controlled products handling protocols.
  - Standard tests (non-controlled) are performed in the FDA Testing Laboratory in Rockville, MD
  - Units are responsible for cost for shipping

Figure 5. Shelf-Life Extension Program Sample Handling/Shipping Process

**Test Result Processing**

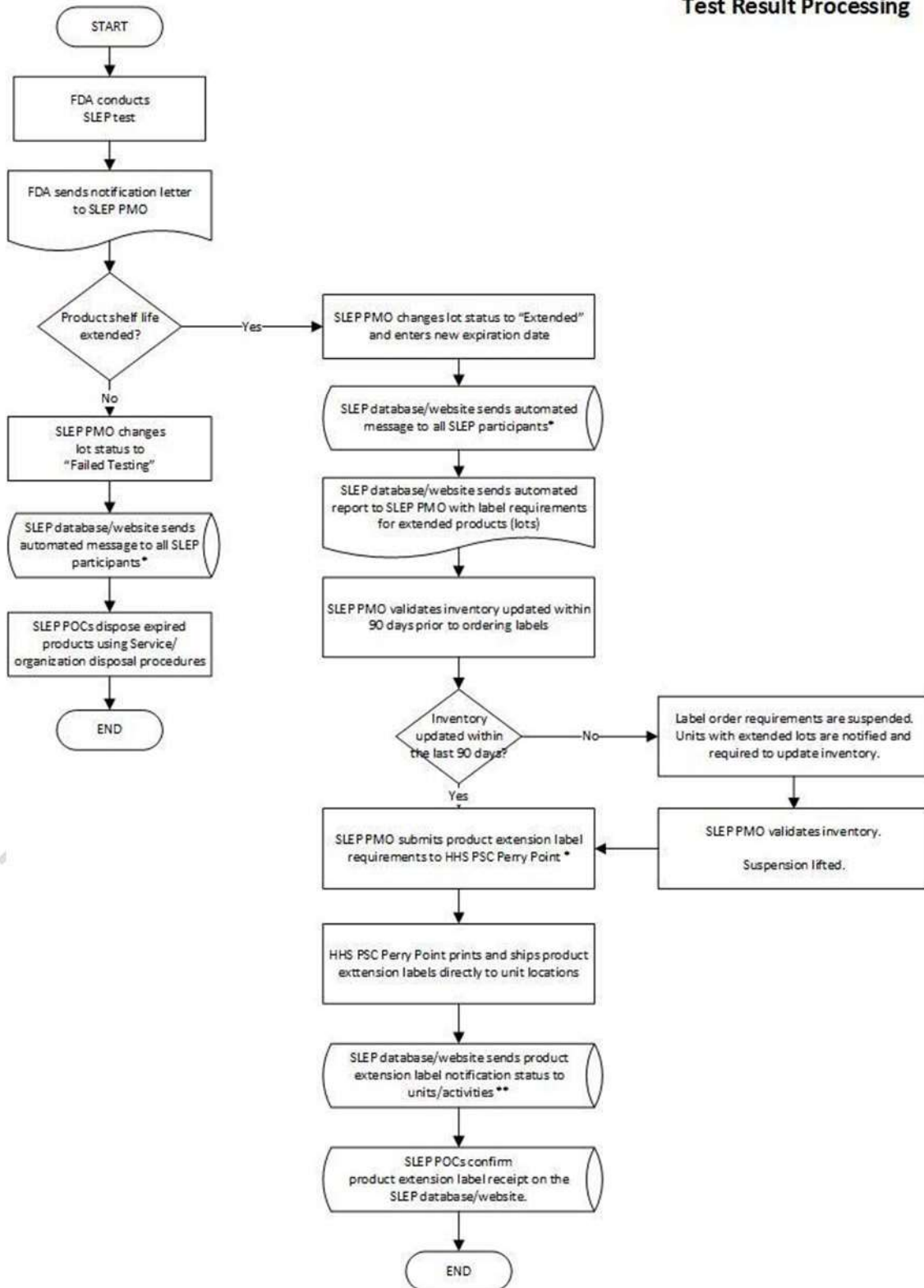


Figure 6. Processing of Shelf-Life Extension Program Test Result Process

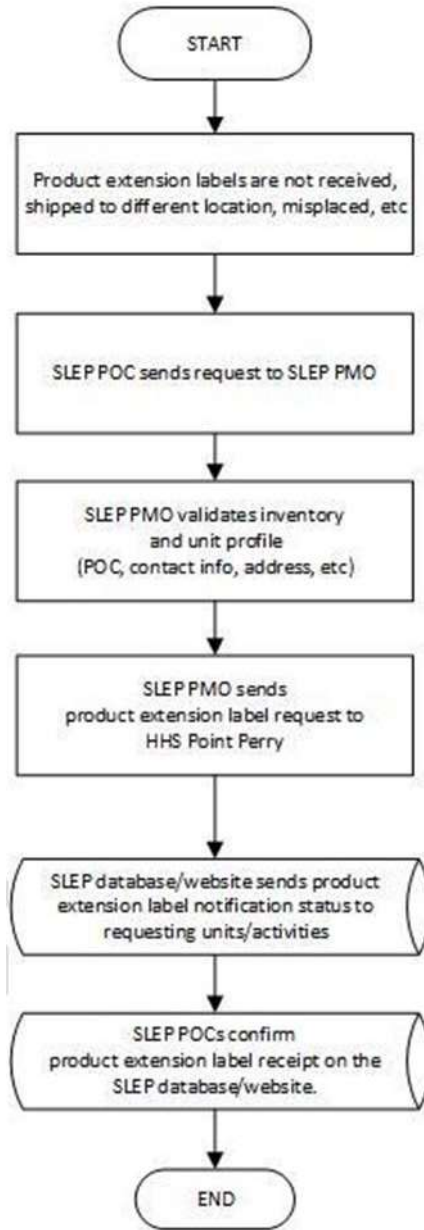


Figure 7. Shelf-Life Extension Program Out-of-Cycle Label Request Process

## GLOSSARY

### ABBREVIATIONS AND ACRONYMS

AD-S	Assistant Director-Support
CCMD	Combatant Commands
DHA	Defense Health Agency
DHA-PM	Defense Health Agency-Procedures Manual
DMLSS	Defense Medical Logistics Standard Support
DoDAAC	Department of Defense Activity Address Code
FDA	Food and Drug Administration
HHS	Health and Human Services
IAA	Inter-Agency Agreement
JMLFDC	Joint Medical Logistics Functional Development Center
MEDLOG	Medical Logistics
MILDEP	Military Department
MIPR	Military Interdepartmental Purchase Request
MTF	military medical treatment facility
PSC	Perry Point, Supply Chain Management Services
R&A	Reporting & Analytics (formerly Joint Medical Asset Repository)
SLEP	Shelf-Life Extension Program
TEWLS	Theater Enterprise-Wide Logistics System

### PART II. DEFINITIONS

DCC. Activities under the authority, direction, and control of DHA: Direct Reporting Markets, Small Market and Stand Alone Military Treatment Facility Organization, Defense Health Agency Regions, and MTFs/Dental Treatment Facilities/Veterinary Treatment Facilities

LogiCole. Is the technical refresh of DMLSS, transitioning all MEDLOG applications into a single, web-based application supporting all medical logistics functions in the Military Health System.