



Defense Health Agency

PROCEDURES MANUAL

NUMBER 6430.05

October 5, 2021

DAD-MEDLOG

SUBJECT: Shelf-Life Extension Program (SLEP)

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 (n), establishes the DHA procedures to manage and provide guidance on the SLEP within the Military Health System and contingency operations. Additionally, this DHA-PM provides guidance on general operations of the DoD/Food and Drug Administration (FDA) SLEP to non-DoD program participants.
2. APPLICABILITY. This DHA-PM applies to Defense Health Agency (DHA), DHA components (activities under the authority, direction, and control of DHA), Military Departments (MILDEPs), and Military Medical Treatment Facilities (MTFs).
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, DLA, Department of Health and Human Service's Strategic National Stockpile (SNS), Veterans Administration Emergency Preparedness Program, National Guard Bureau, Federal Bureau of Investigation, Department of Homeland Security, and the Department of State (DOS). Service specific guidance with regard to the administration of SLEP inter-agency agreements lies with the following component agencies to include, Army Medical Logistics Command (AMLC), Naval Medical Logistics Command (NMLC), Air Force Medical Readiness Agency (AFMRA), and the US Coast Guard (USCG).
4. RESPONSIBILITIES. See Enclosure 2.

5. PROCEDURES. See Enclosure 3.

6. PROPONENT AND WAIVERS. The proponent of this publication is the Deputy Assistant Director (DAD), 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 DAD-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/SitePages/Home.aspx>.

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. The following Department of Defense (DD) forms are available at: https://www.esd.whs.mil/Directives/forms/dd0001_0499/.

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

(2) DD Form 448-2, Acceptance of MIPR

b. DD Form 1144, Support Agreement is available at <https://www.acq.osd.mil/dpap/pacc/cc/TAB%20F%20-%202016-P001%20DD%20Form%201144%20rev1.pdf>.

c. Fiscal Service (FS) Form 7600A, General Terms and Conditions is available at: <https://fiscal.treasury.gov/files/forms/GT&C-Form-7600-A.pdf>.

d. FS Form 7600B, Agreement Between Federal Program Agencies for Intragovernmental Reimbursable, Buy/Sell Activity is available at: https://www.gsa.gov/cdnstatic/Integrated_Technology_Services/GSA-form-7600B%2008_19_2020.pdf.

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

/S/
RONALD J. PLACE
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Director

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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,” August 24, 2018
- (d) DoD Instruction 4000.19, “Support Agreements,” December 16, 2020,
- (e) DoD Instruction 6430.02, “Defense Medical Logistics Program,” August 23, 2017
- (f) 10 USC 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, Parts 175.105, 210, and 211
- (k) Code of Federal Regulations, Title 40, Parts 266.500-510 (Subpart P)

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. DAD-MEDLOG. The DAD 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, DAD 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 to optimize materiel readiness.

3. DHA, CHIEF INFORMATION OFFICER/DAD, INFORMATION OPERATIONS. The DHA, Chief Information Officer/DAD, Information Operations must:
 - a. Support the MEDLOG Information Technology Program Management Office (PMO)/ 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/Joint Medical Asset Repository (JMAR).

 - d. Update the LogiCole/JMAR SLEP module to support current and future SLEP business processes.

e. Establish access to JMAR 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 JMAR.

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/JMAR and subsequently, LogiCole daily technical operations of the SLEP within JMLFDC in perpetuity.

i. Establish access to LogiCole/JMAR 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 JMAR.

4. DoD-SLEP DHA PROGRAM MANAGER. The DoD-SLEP DHA 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 DAD-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 beginning of each quarter (January, April, July, and October).

5. SLEP DHA RESOURCE MANAGER. The SLEP Resource Manager, DHA Portfolio Management Section 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 Military Interdepartmental Request, Interagency Agreement or Purchase Order, and FDA Standard Form (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. Process quarterly SF 1080 labeling invoice payments submitted by SLEP customers.
- f. Review signed interagency agreements for updated annual estimated program costs for each SLEP participant.

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

- a. Review interagency agreements (IAAs) DHA and all SLEP participants.
- b. Provide DHA MEDLOG approved/endorsed IAAs and/or other appropriate forms.

7. SECRETARIES, MILITARY DEPARTMENTS (MILDEPs). The Secretaries, MILDEPs will ensure effective MILDEPs collaboration with DHA in the execution and development of SLEP policies and procedures and support to combatant commands. 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 DHA Program Manager.
- e. Ensure all SLEP pharmaceuticals are maintained in a controlled environment under conditions recommended by the manufacturer.

9. SLEP AGENCY PROGRAM MANAGERS (NON-MILDEP). SLEP 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 DHA Program Manager.
- e. Ensure all SLEP pharmaceuticals are maintained in a controlled environment under conditions recommended by the manufacturer.

10. MARKET, SMALL MARKET AND STAND-ALONE MEDICAL TREATMENT FACILITY ORGANIZATION, AND DEFENSE HEALTH AGENCY DIRECTORS. The Market, Small Market and Stand-Alone Medical Treatment Facility Organization, and Defense Health Agency Region Directors must ensure MTFs comply with applicable DoD-SLEP policies and procedures and/or Service-specific guidance.

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

12. SLEP UNIT MONITOR. The SLEP Unit Monitor must:

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

ENCLOSURE 3

PROCEDURES

1. BACKGROUND

a. The DoD/FDA Shelf Life Extension Program is an internal component of the Medical Readiness Strategic Plan (MRSP). 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 interagency agreement created the DoD/FDA Shelf Life Extension Program (SLEP). The program's original focus was to defer drug replacement costs of date-sensitive Prepositioned War Reserve Stock (PWRS) 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 (DMMSP) in 2011 and later placed under the direction of the Defense Health Agency, Medical Logistics (MEDLOG) Division 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 remark the products with an extended expiration date. The program results in significant costs deference for the participants.

2. FINANCIAL PLANNING AND MANAGEMENT

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

b. DHA Readiness Branch Chief reviews and approves SLEP Cost Estimate/Spend Plan.

- c. SLEP Analyst reviews SLEP participation status and generates FS 7600A Form or Interagency Agreement (IAA) form as necessary for agencies/organizations whose IAAs with DHA has expired, or soon to expire.
- d. SLEP Analyst submits FS 7600A to DHA Support Agreements Section (DHA-CAE) for review and approval.
- e. FS 7600As are provided to SLEP participants for review and approval.
- f. FS 7600As signed and executed by DHA and SLEP participants before funding is disbursed.
- g. SLEP Participants submit signed funding document (FS 7600B or SF 1080, Military Interagency Purchase Request (MIPR) Form) to SLEP Analyst.
- h. Signed funding documents (FS 7600B or SF 1080) are provided to DHA MEDLOG Portfolio Management Section to process MIPR acceptance and returns to SLEP Analyst.
- i. SLEP Analyst provides MIPR acceptance document to SLEP participants.
- j. SLEP Analyst 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. SLEP Analyst 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. SLEP Analyst conduct mandatory mid-year SLEP review (at the start of the 3rd quarter).
- n. SLEP Analyst receives monthly invoices from SLEP labeler (PSC Perry Point).
- o. SLEP Analyst enters label invoice and validates funding availability, requests additional funding as necessary.
- p. SLEP Analyst requests SF 1080 for SLEP project testing from the FDA.
- q. SLEP Analyst provides SF 1080 to DHA Portfolio Management for processing.
- r. DHA Portfolio Management 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 SLEP PMO to add a new product to SLEP.
- b. SLEP PMO reviews request and enters into a system of record.
- c. SLEP PMO 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, SLEP PMO contacts FDA to determine if it can be added to SLEP. Proceed to paragraph 2.i. of this enclosure.
- e. If product does not meet the entrance criteria, SLEP PMO notifies the SLEP Service/Agency Program Manager.
- f. SLEP Service/Agency Program Manager may submit a waiver request based on national security interest, market availability, service priority, etc. SLEP PMO has the discretion to grant waiver.
- g. If waiver is granted, proceed to paragraph 2.i. of this enclosure.
- h. If waiver 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 SLEP PMO.
 - (2) SLEP PMO 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 SLEP PMO.

(2) SLEP PMO notifies SLEP Service/Agency Program Manager and provides cost estimate.

m. If Service/Agency funds testing capability development:

(1) SLEP PMO 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) SLEP PMO notifies FDA.

(2) Product is not added to SLEP. Process is completed.

o. If testing capability cannot be developed:

(1) FDA notifies SLEP PMO.

(2) SLEP PMO notifies SLEP Service/Agency Program Manager.

(3) Product is not added to SLEP. Process is completed.

3. 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

(2) Theater Enterprise-Wide Logistics System

(3) LogiCole/JMAR

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

c. New lot number entered in system of record will be fed into the JMAR.

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 SLEP DHA Program Manager for new lot number approval.

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

g. If a photograph was uploaded, SLEP DHA Program Manager approves the new lot number. If photograph was not uploaded, proceed to paragraph 3.a.(9) of this enclosure.

h. JMAR 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 JMAR with the following minimum lot number information:

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

j. Return to paragraph 3.a.(6) of this enclosure.

4. IDENTIFICATION FOR LOT NUMBER TESTING

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

(1) SLEP PMO reviews inventory and identifies lot number for testing.

(2) SLEP Service/Agency Program Manager submits a request to the SLEP PMO to test a lot number.

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

(1) Lot number to SLEP

(2) Expiration date (within six months)

(3) Total inventory value (greater than \$10,000.00 (>\$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 SLEP PMO will submit a retest project request to the FDA.

d. If the lot number has not been previously tested, the SLEP PMO will submit a new project request to the FDA.

e. FDA will respond with sample requirements (quantity of lot numbers to be tested).

f. SLEP PMO will have an approved test project and sample requirements.

g. Process is completed.

5. SAMPLE HANDLING AND SHIPPING

a. SLEP PMO reviews inventory to identify project testing samples.

b. SLEP PMO selects units/activities to provide project test lot samples based on:

(1) On-hand inventory

(2) Location of unit/activity

c. SLEP PMO 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, MI 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.

d. Units/activities are responsible for all shipping costs.

e. FDA receives samples and notifies SLEP PMO.

f. Process is completed.

6. 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.

7. TEST RESULT PROCESSING

a. FDA sends project results notification letter to SLEP PMO.

b. If testing failed:

(1) SLEP PMO changes lot status in LogiCole to "Failed Testing."

(2) JMAR sends automated message to SLEP participants.

(3) SLEP participants will dispose of expired pharmaceuticals and update inventory according to Service/Agency-specific policies and procedures.

(4) Process is completed.

c. If shelf-life is extended:

(1) SLEP PMO changes lot status in LogiCole to “Extended” and enters new expiration date.

(2) JMAR sends automatic message to SLEP participants.

d. SLEP PMO 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) SLEP PMO 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, SLEP PMO submits extension label requirements to HHS PSC. Program Support Center, Perry Point, MD 21902. SLEP items extended will be relabeled, down to the unit of issue, per Service/Agency-specific policies and procedures.

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

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 DHA Program Manager or designee.

b. Perform all functions relative to quality assurance, quality control surveillance of label production, management consistent with Current 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 DHA 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 DHA 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 DHA 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 DHA 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. SLEP PMO 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.

9. OUT-OF-CYCLE LABEL PROCESSING

a. SLEP participants send request to reprint extension labels to SLEP PMO.

b. SLEP PMO validates inventory and unit profile DoDAAC, contact information, address, etc.).

c. SLEP PMO sends extension label to HHS PSC.

d. HHS PSC prints and ships extension labels to DoDAAC reporting SLEP inventory.

e. SLEP PMO sends extension label notification status to appropriate SLEP participants.

f. SLEP Unit Monitor confirms extension label receipt.

g. Process is completed.

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

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

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

a. DHA-US309 LogiCole/JMAR Access Management

- b. DHA-US414 LogiCole/JMAR SLEP Initial Registration
- c. DHA-US415 LogiCole/JMAR SLEP Access Control
- d. DHA-US416 LogiCole/JMAR SLEP Service/Agency Program Manager
- e. DHA-US417 LogiCole/JMAR SLEP Unit Monitor
- f. DHA-US418 LogiCole/JMAR DoD-SLEP Program Manager
- g. DHA-US419 LogiCole/JMAR SLEP Service/Agency Representative

APPENDIX 1

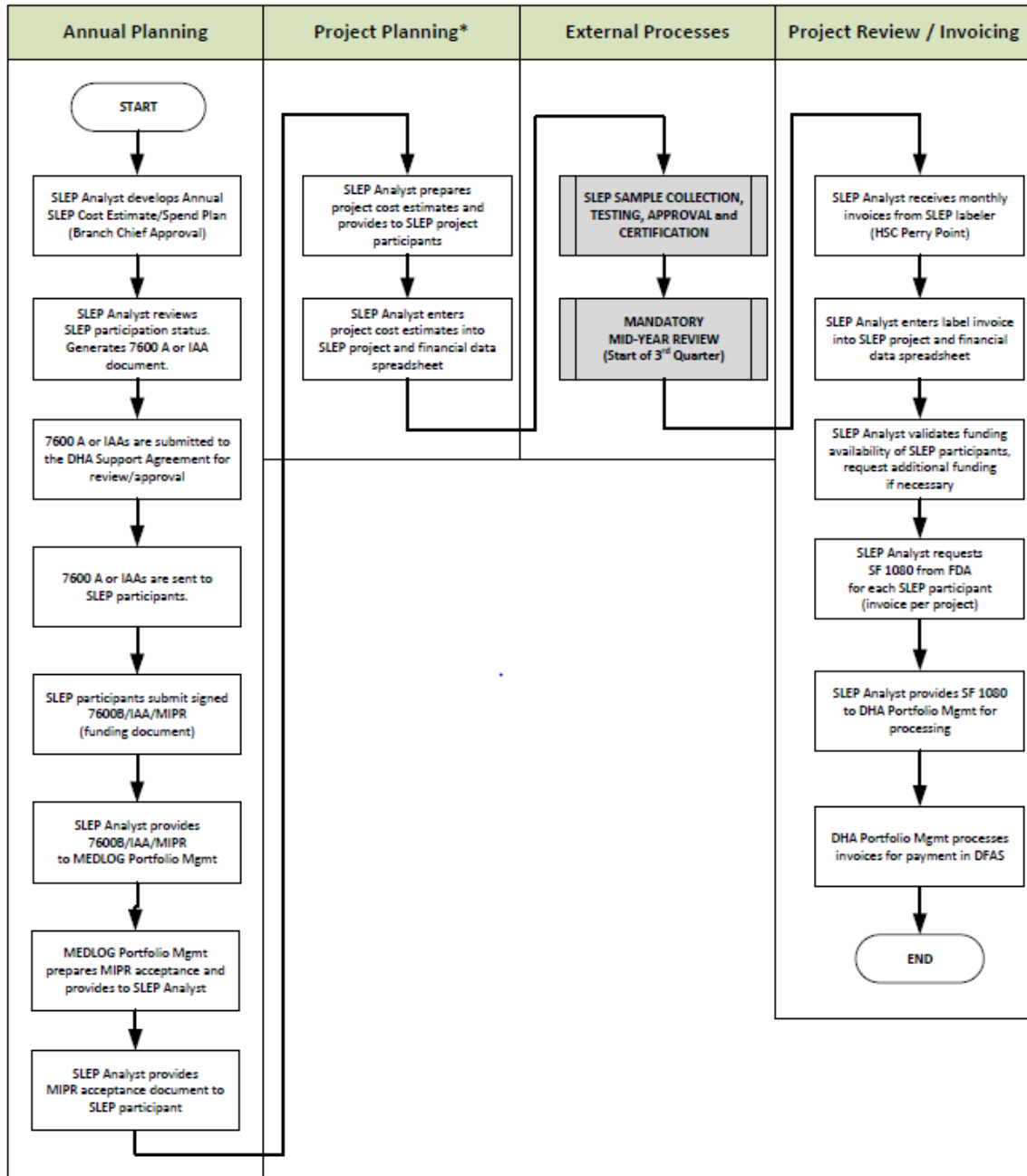
LIST OF PROGRAM PARTICIPANTS

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

United States Air Force
United States Army
United States Marine Corps
United States Navy
United States Coast Guard
Army National Guard
National Capital Region
Defense Logistics Agency
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



* Project = drug test for extension

Figure 1. Financial Planning and Management

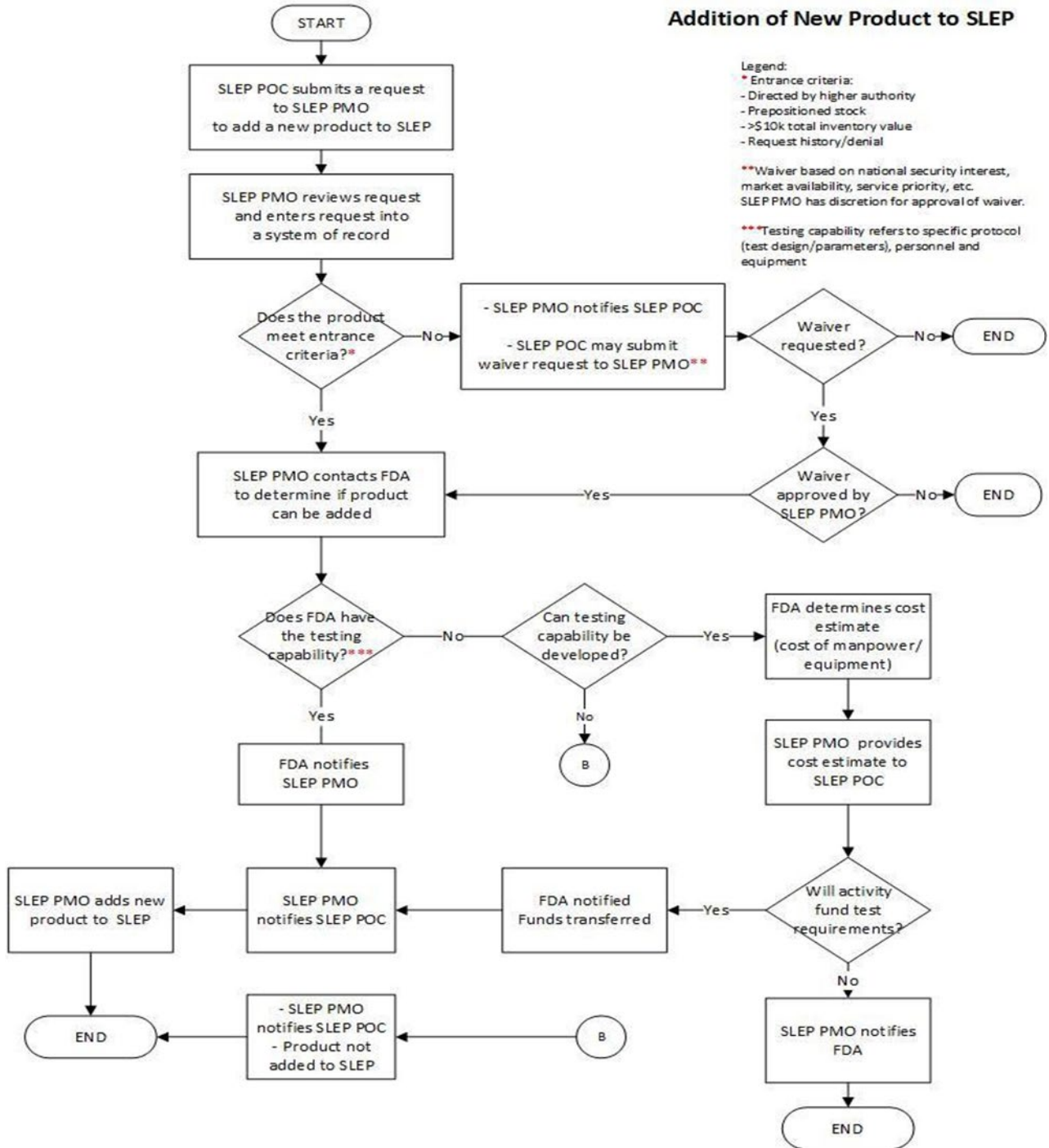


Figure 2. New Product Addition to Shelf Life Extension Program Process

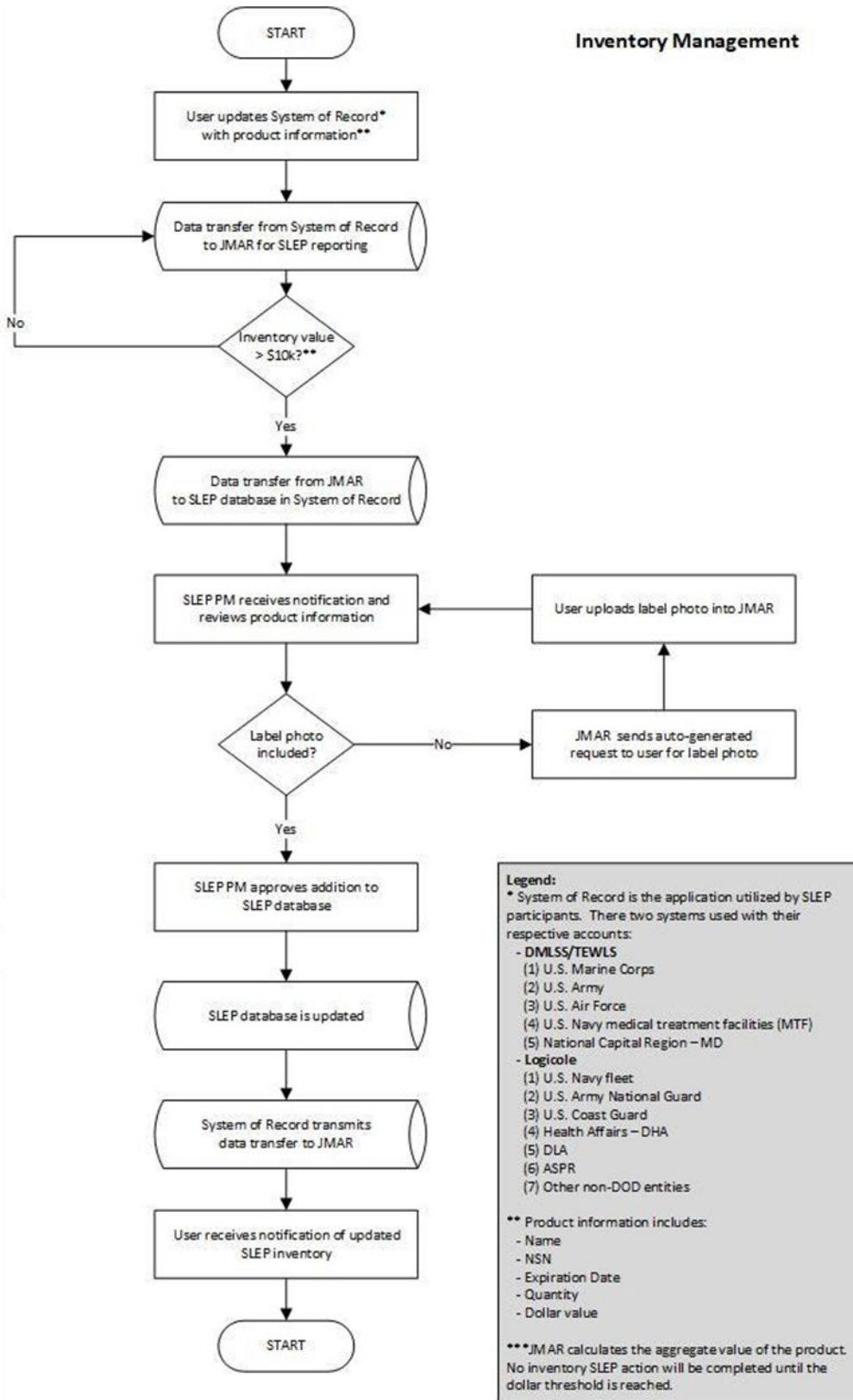
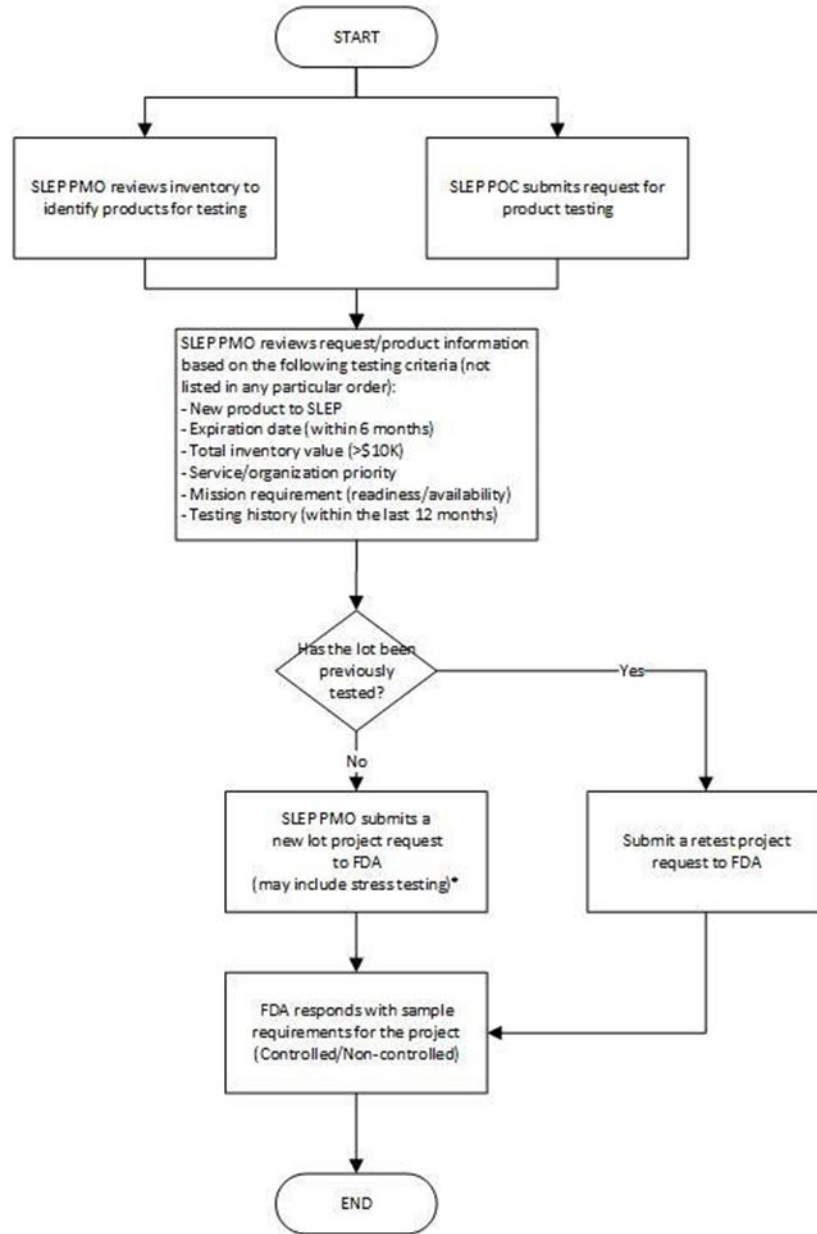


Figure 3. Shelf

Life Extension Program Inventory Management Process

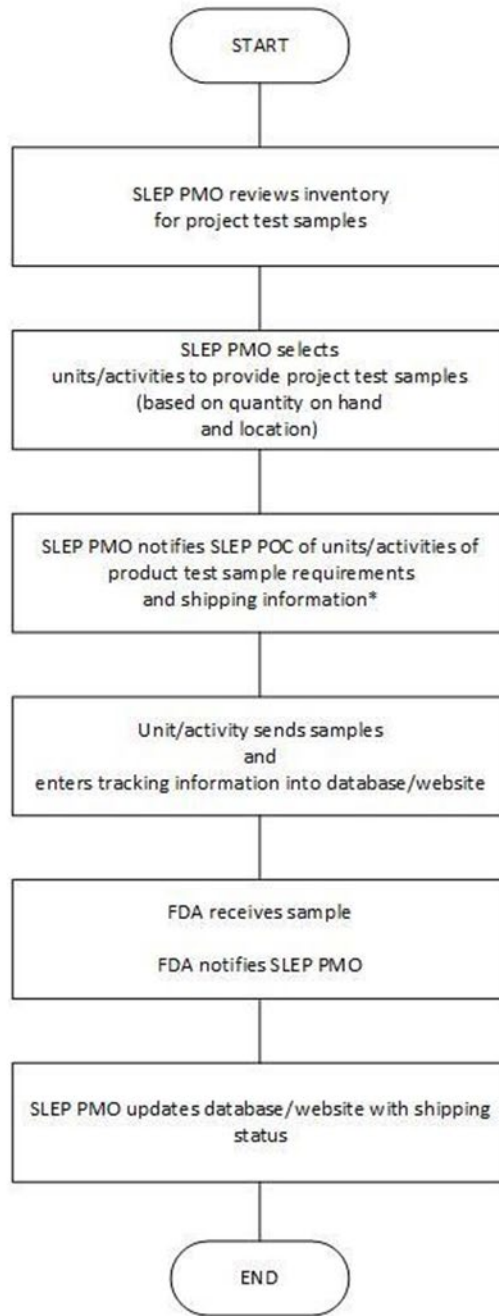
Identification for Product Testing (SLEP)



*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

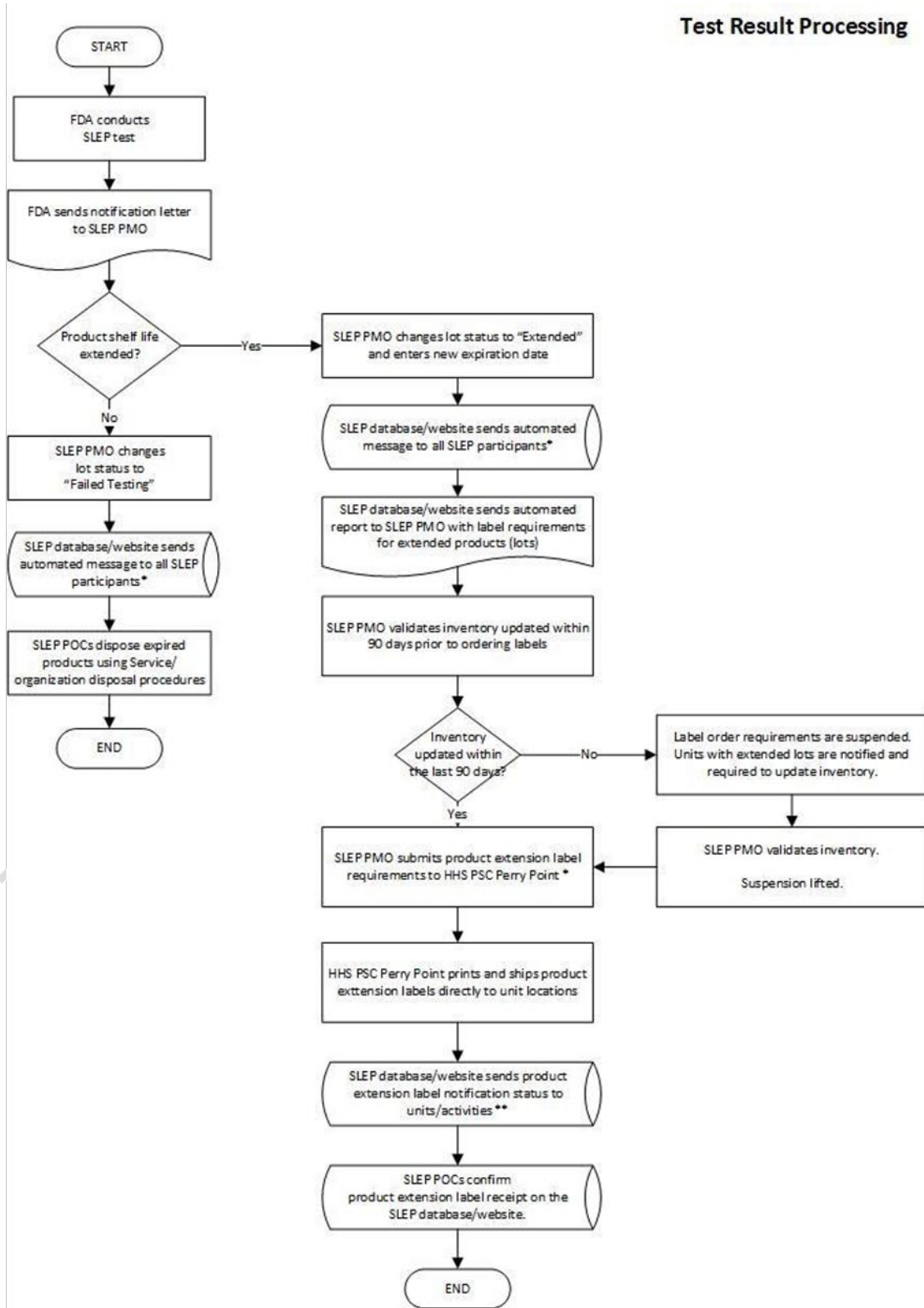


Figure 6. Processing of Shelf-Life Extension Program Test Result Process

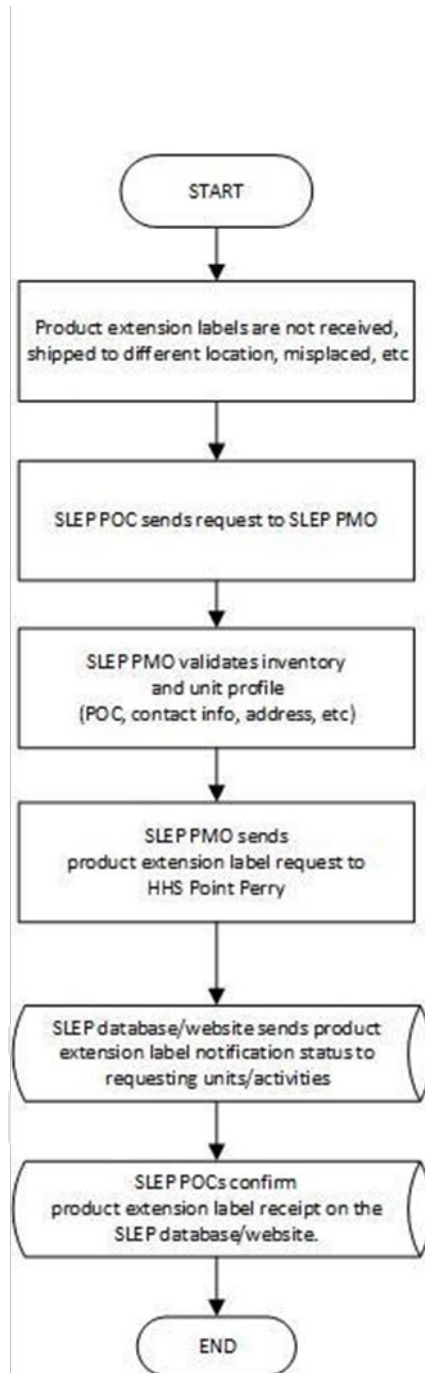


Figure 7. Shelf-Life Extension Program Out-of-Cycle Label Request Process

GLOSSARY

ABBREVIATIONS AND ACRONYMS

DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PM	Defense Health Agency-Procedures Manual
DoDAAC	Department of Defense Activity Address Code
FDA	Food and Drug Administration
HHS	Health and Human Services
IAA	Inter-Agency Agreement
JMAR	Joint Medical Asset Repository
JMLFDC	Joint Medical Logistics Functional Development Center
MEDLOG	Medical Logistics
MILDEP	Military Department
MIPR	Military Interdepartmental Purchase Request
MTF	Military Medical Treatment Facilities
PMO	Program Management Office
PSC	Perry Point, Supply Chain Management Services
SLEP	Shelf-Life Extension Program

PART II. DEFINITIONS

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