



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

IN REPLY REFER TO
BUMEDINST 6710.71A
BUMED-M4
27 Apr 2015

BUMED INSTRUCTION 6710.71A

From: Chief, Bureau of Medicine and Surgery

Subj: NAVY MEDICINE PHARMACEUTICALS SHELF LIFE EXTENSION PROGRAM

Ref: (a) MOA TMA-20120-S-0020 between TMA and NAVMEDLOGCOM "Participation in the DoD/FDA Shelf Life Extension Program (SLEP)" of Mar 2013
(b) Interagency Agreement between Health and Human Services Food and Drug Administration, Office of Regulatory Affairs and Defense Medical Material Program Office, IAG NO. 224-13-4010 of Oct 2012

Encl: (1) Sample Appointment Letter

1. Purpose. To issue policies and guidelines for the management, disposal, and relabeling of dated pharmaceuticals. This is a complete revision and must be read in its entirety.
2. Cancellation. BUMEDINST 6710.71.
3. Scope. This instruction applies to all Navy and Marine Corps activities having Shelf Life Extension Program (SLEP) pharmaceuticals.
4. Background. The Department of Defense (DoD)/Food and Drug Administration (FDA) SLEP is a key component of the medical readiness strategic plan as developed by the DoD Health Affairs and the Military Medical Departments, per references (a) and (b). The program's focus is to defer drug replacement costs of date sensitive military significant medical pharmaceuticals by testing and extending their useful life. The following organizations participate in the subject program:
 - a. The FDA evaluates candidate pharmaceuticals under the SLEP by testing samples submitted from the Services.
 - b. Defense Health Agency (DHA), Medical Logistics (MEDLOG) Division oversees the program and acts as the liaison between the Services and the FDA.
 - c. Army, Navy, Air Force, Marine Corps, and other federal participants fund and manage the program, and receive the benefit of deferred pharmaceutical replacement costs.
5. Guidelines
 - a. All ships, stations, and medical treatment facilities (MTF) with pharmaceuticals shall enter their on-hand inventory of chemical, biological, radiological, nuclear pharmaceutical,

pandemic influenza, and anti-malaria pharmaceuticals into the SLEP web-based program upon receipt. Register for SLEP at:

https://slep.dmsbfda.army.mil/portal/page/portal/SLEP_PAGE_GRP/User_Registration.

b. Each unit shall have at least two registered users in the SLEP system; the contact information, including mailing address, shall be kept up to date. Commands that centrally manage inventory at a higher level will be exempt from this requirement.

c. Ensure all on-hand inventories of stockpiled pharmaceuticals are accurately entered into the SLEP database. Update inventory records every 90 days even if on-hand quantities have not changed.

d. Currently approved pharmaceuticals for testing are outlined at:
https://slep.dmsbfda.army.mil/portal/page/portal/SLEP_PAGE_GRP/SLEP_HOME_NEW.
Once logged into the SLEP web site, click on "Product Info," then click on "Candidates currently tested in SLEP" and the list will be made available.

e. Maintain all SLEP pharmaceuticals in a controlled environment under conditions recommended by the manufacturer. Lots stored outside of the manufacturers recommended storage parameters must be immediately disclosed to Naval Medical Logistics Command (NAVMEDLOGCOM) (e-mail to: usn.detrick.n-medlogcom.mbx.shelf-life-extension-program@mail.mil) to be tracked and separately tested.

f. When physical samples are requested, the samples are shipped to designated locations as requested. DHA MEDLOG SLEP Web site will provide the specific details and shipping address for each lot number.

g. SLEP test results are listed in the SLEP system along with the test result messages; extensions are granted to SLEP participants with declared inventory only. If inventory is not declared in the SLEP database, extension labels will not be generated and pharmaceuticals will need to be replaced. Only pharmaceutical grade extension labels are authorized for use on extended inventories.

h. Items that have reached their expiration date will be marked to show the reason for suspension and secured to prevent use or loss.

i. Disposal of all medical items that have reached their expiration date or end of the estimated storage life and are not extendable must be disposed of properly per federal, state, and local policies. Outdated pharmaceuticals may be eligible for return utilizing the MTFs contracted reverse distribution service provider.

6. Action

a. Relabeling is required for all declared inventories that are extended under the DoD/FDA SLEP. Items showing expired dating will not be dispensed at any time. Affixed extension labels will show lot number, current expiration date, and FDA test project number.

(1) The SLEP system will automatically request labels based on the on-hand quantity declared by each site's inventory records when extensions are granted. Label orders will be suspended for SLEP participants that have not updated their inventory within the past 90 days.

(2) Labels will be mailed directly to the address listed in the SLEP database for each site. Unit mailing addresses shall be kept current.

b. The FDA will permit SLEP participants to label only the outer cartons of products with the updated information so long as they remain in centralized storage. Pharmaceuticals must be relabeled completely by local medical staffs, down to the individual units of issue, before being distributed, issued, or dispensed outside centralized storage or to individuals.

c. Commanding Officers (COs) will appoint in writing, at least two SLEP representatives, in the rank of E6 and above (or the civilian equivalent), to accurately enter all on-hand inventories of stockpiled pharmaceuticals into the SLEP database and ensure that inventory records are updated every 90 days. Refer to enclosure (1) for sample appointment letter.

d. Navy Medicine COs will forward appointment letters to NAVMEDLOGCOM. Contact information is listed below:

Navy Shelf Life Extension Program Manager
<mailto:usn.detrick.n-medlogcom.mbx.shelf-life-extension-program@mail.mil>
(301) 619-3085 (DSN 343)

e. Fleet Forces Command and Pacific Fleet COs will forward appointment letters to the Fleet Forces Command SLEP point of contact (POC). Contact information is listed below:

Fleet Medical Logistics Officer
U.S. Fleet Forces Command
1562 Mitscher Avenue, Suite 250
Norfolk, VA 23551-2487
Phone: 757-836-6027 or DSN: 836-6027
Fax: 757-836-5520
USFFSLEP@navy.mil

f. Marine Corps COs will forward appointment letters to the Marine Corps SLEP POC. Contact information is listed below:

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U.S. Marine Corps Medical Logistics Officer
Logistics Policy & Capabilities Branch (LPC-2)
Installation & Logistics
Headquarters Marine Corps
3000 Marine Corps Pentagon: Room 2E211
Washington, DC 20350-3000
Office: 571-256-7115; (DSN: 260-7115)

7. Points of Contact. If assistance is needed with the Navy's SLEP System, please refer any questions to the NAVMEDLOGCOM SLEP Manager at (301) 619-3085 (DSN: 343-3085) or via e-mail at usn.detrick.n-medlogcom.mbx.shelf-life-extension-program@mail.mil. For assistance with the Marine Corps' SLEP System, please refer any questions to the U.S. Marine Corps Medical Logistics Officer at (571) 256-7115 (DSN: 260-7115).

8. Records. Records created as a result of this instruction, regardless of media and format, shall be managed per SECNAV M-5210.1 of January 2012.



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Distribution is electronic only via the Navy Medicine Web site at:
<http://www.med.navy.mil/directives/Pages/default.aspx>

BUMEDINST 6710.71A
27 Apr 2015

Sample Appointment Letter

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From: Commanding Officer, [Name of Unit]
To: LT Jane Doe, USN

Subj: APPOINTMENT AS THE SHELF LIFE EXTENSION PROGRAM OFFICER

Ref: (a) BUMEDINST 6710.71A

1. Per reference (a), you are hereby appointed as the Shelf Life Extension Program (SLEP) Representative for [name of unit].
2. You are required to ensure that all on-hand inventories of stockpiled pharmaceuticals are accurately entered into and updated in the SLEP database every 90 days; even if on-hand quantities have not changed.
3. You are charged to carry out the duties noted above and all other duties as it pertains to your role as the SLEP Representative.
4. This appointment letter supersedes all other previously dated appointment letters for this DODDAC. Please refer any questions to [Rank Name M. Full] at DSN [### - #####] or via e-mail at [Name.Full@mail.mil].

(Signature)
NAME M. FULL

Enclosure (1)