

Federal Shelf Life Extension Program

Fact Sheet

Overview

The federal [Shelf Life Extension Program \(SLEP\)](#) extends the expiration dates on qualifying drugs and other materiel in federal stockpiles. SLEP is administered by the U.S. Department of Defense (DoD) in cooperation with the [U.S. Food and Drug Administration \(FDA\)](#).¹ The program is an acknowledgement that the actual shelf life of drugs and other medical products may be longer than their stated expiration date, depending on their storage conditions. The purpose of SLEP is to defer replacement costs of stockpiled drugs by extending their useful life.

The program was established in 1986 through an interagency agreement between the DoD and the FDA in response to a Congressional directive to address U.S. Air Force drug stockpiles.² This initial SLEP program was intended to extend the useful shelf life of medicines with limited commercial use (e.g., chemical agent antidotes) or which the government held in such large quantities that the manufacturer would not accept them for credit when the drugs expired.³ Since then, other federal agencies have entered into a memorandum of agreement with the DoD to participate in SLEP, including other branches of the military, the [Strategic National Stockpile \(SNS\)](#), the Department of Veterans Affairs (VA), the U.S. Postal Service, and the Bureau of Federal Prisons.²

SLEP is currently available only for federally-maintained stockpiles, although there have been ongoing deliberations between the federal government and the states about extending SLEP to state-maintained stockpiles or creating a separate SLEP-like program for state stockpiles. (See “State Stockpiles” discussion below.)

Note: As of March 2012, Congress is in the process of reauthorizing the [Pandemic and All-Hazards Preparedness Act \(PAHPA\)](#), which may impact a number of laws and programs described below. Please see [ASTHO EUA Current Issues Winter 2012](#) for more information about reauthorization and its potential impact on EUAs and related issues.

How SLEP Works

SLEP is a fee-for-service program. Participating agencies are required to pay for the FDA’s periodic, comprehensive testing and analysis of the drugs and other medical materiel in the SLEP process. Items eligible for SLEP are tested by the FDA. Products that pass testing are granted extended expiration dates but must undergo ongoing testing to monitor their continued shelf life.⁴ Products that fail testing at any time are destroyed.⁴ Products that do not receive additional extensions of their expiration dates or are not tested for SLEP are destroyed at their final expiration dates.⁴ Maintaining controlled storage conditions appropriate for the product(s) is an important factor in the SLEP process.

Agency Roles and Responsibilities

The program is operated by the DoD [Defense Medical Materiel Program Office \(DMMPO\)](#) (formerly the Defense Medical Standardization Board [DMSB]) and regularly interacts with the FDA and agencies participating in SLEP.^{2,5} The DMMPO/DoD role in SLEP is to conduct programmatic and administrative functions, including but not limited to: (1) identifying products eligible for testing to FDA; (2) updating the SLEP expiration database; (3) conducting a cost-benefit analysis of extending a drug’s expiration date; (4) ordering labels for relabeled drugs; and (5) billing participant agencies.²

The FDA is responsible for testing and evaluating drugs for SLEP. Specifically, the FDA: (1) determines the appropriate tests and methods for the candidate drugs; (2) conducts tests on samples of the candidate drugs; (3) analyzes test results and determines whether and for how long extension is possible; and (4) performs other research to address SLEP issues.²

Items Eligible for SLEP

Not every item stockpiled is a candidate for SLEP. Because of the costs involved in testing, the program is primarily designed for large stockpiles of drugs and medical materiel that are housed in environmentally controlled facilities.² FDA-approved prescription drugs are most frequently designated for SLEP testing by program participants. Biological products such as vaccines, serums, and nutritional products or items with a history of poor SLEP performance are not eligible for testing.^{2,4} Items where testing would be time or cost prohibitive are not accepted.⁴ The focus on testing has been on products that are militarily significant, have limited commercial use, are purchased in large quantities (e.g., antivirals), or are used only if there is an event requiring their administration.²

SLEP Process

The procedure to determine whether a drug or other medical materiel is eligible for extension under SLEP involves testing by the FDA. If an extension is granted, the approval document identifies the length of the extension and relabeling requirements. Products under SLEP are regularly retested and must be destroyed if at any time they fail testing.²

- **Initial Testing and Analysis**—SLEP participants are required to maintain updated information about their inventories of stockpiled medical materiel in an access-restricted SLEP online database. DMMPO staff review participants' online inventories of products set to expire within 180 days and identify potential items for SLEP testing.⁴ The FDA then requests samples from participants. Representative samples of the drugs nominated for participation in SLEP are taken from specific lot numbers at one stockpile location and shipped to an FDA field laboratory for testing.² The FDA tests the samples for continued safety and potency using methods from the U.S. Pharmacopeia (USP)⁶ or the drug manufacturer's test methodology.² The FDA then analyzes the test results to determine if the lot sampled can be extended and for how long.² The FDA sends its determination to the DMMPO, which provides the results to the SLEP participant requesting the test.² The time from nomination for testing to reported results is approximately six months.⁴
- **Extension and Retesting**—The FDA can issue an expiration date extension for a maximum of up to two years for the first time a lot is tested under SLEP.² The FDA grants extensions for the specific lot number(s) tested based on the assumption that all lots at all stockpile locations have been stored according to Current Good Manufacturing Practices (CGMPs),⁷ including requirements for environmentally controlled storage conditions.² FDA retests the same lot annually or semi-annually to confirm the expiration date extension granted or to permit further extension.² No product will be extended beyond 10 years from the original manufacturer's expiration date.⁴
- **Relabeling**—Products granted an expiration date extension must be relabeled according to CGMPs and other FDA regulations.² The term "labeling" means all labels and other writing, printing, or graphics on any item, container, wrapper, or accompaniment to the item such as an insert in the item's packaging.¹ The Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations set out the specific labeling information required for an item covered under the FD&C Act. Items that are not relabeled are considered misbranded if they are sold, distributed, or dispensed and therefore are in violation of the FD&C Act.⁴ However, the FDA can exercise its enforcement discretion in certain situations and has done so in the past.⁸ In a June 2010 letter to the CDC, the FDA stated that it would not take enforcement action regarding relabeling requirements for specific antiviral drugs at non-SNS stockpiles (i.e., state, local, or regional caches) if shelf-life-extended items are held under their labeled storage conditions and are relabeled prior to dispensing.^{8,9} The FDA's past exercise of its enforcement discretion related to relabeling of drugs in non-SNS stockpiles does not guarantee that it will act similarly in the future.

Practice Notes

- Identify the agency and office responsible for managing your state's SNS and other medical stockpiles.
- Understand the systems your state has in place to deal with shelf-life-extended products, including storage, relabeling, and dispensing.
- Identify how your state's laws and regulations may affect the dispensing of shelf-life-extended items and where your state laws may be preempted by federal laws.
- Identify how your state educates healthcare providers, pharmacists, and other persons dispensing shelf-life-extended products.

EUA and SLEP

An [Emergency Use Authorization \(EUA\)](#) is a type of permission under FD&C Act §564 that allows for the use of an unapproved medical product or an unapproved use of an approved medical product (drugs, biologics [e.g., vaccines], and devices [e.g., diagnostics]) during certain types of emergencies. Products extended under SLEP through the exercise of FDA enforcement discretion receive a new expiration date that is different than the one originally contained on the product's labeling and is considered a deviation from the item's prior approved use. Similarly, some SNS products may have been stored in conditions that exceeded labeled temperature ranges. Currently, an EUA is required to ensure that SLEP-extended drugs are not in violation of the FD&C Act. (See also [ASTHO Current Issues and Updates—Summer 2011—Evolving Policy Issues](#).) During the H1N1 influenza pandemic in 2009, Tamiflu (in capsules and suspension form) that was held in the SNS, much of which had been tested and extended under SLEP, was distributed to states and localities.² The FDA issued an EUA that allowed the use of these products beyond the labeled expiration date without requiring that they be relabeled.

State Stockpiles

States have developed and maintained their own stockpiles of medicines and supplies in addition to those provided by the federal government through the SNS. In preparation for a pandemic, the federal government offered states a 25 percent subsidy to purchase additional antivirals through the SNS program. However, stockpiles held by states, whether purchased with state or federal funds, are not eligible for SLEP.¹⁰ In 2006, the [National Strategy for Pandemic Influenza: Implementation Plan](#) directed the HHS, the DoD, the VA, and the states to explore expanding SLEP to state stockpiles.¹¹ Similarly, in a report about antiviral strategies for a pandemic, the Institute of Medicine recommended that the SLEP program be extended to other public and private stockpiles.¹⁰ That report also suggested using the information gained through SLEP to facilitate the use of properly stored recently expired drugs held outside SLEP.¹⁰ These recommendations acknowledged the high cost of replacing expired stockpiles and the potential scarcity of the drugs during a severe pandemic as important reasons for seeking to extend the drugs' expiration dates.¹⁰

Incorporating States into SLEP

An FDA-led interagency workgroup that included the DoD, the CDC, and the VA determined that including state antiviral stockpiles in SLEP is not currently feasible.² Reasons cited for the decision included programmatic, resource, quality, and legal considerations:

- **Programmatic Issues**—At the program level, a large increase in the number of SLEP participants could adversely affect program efficiency.² To address efficiency concerns, the workgroup suggested that consolidating additional SLEP participants would facilitate the collection of samples and funding.²
- **Resource Issues**—Expanding SLEP to state stockpiles would require significant additional funding at both the federal and state levels. The DMMPO and the FDA would require additional funding and personnel to accomplish SLEP administration and testing above participant fees collected.² Like the current federal participants in SLEP, state and local governments would have to pay for initial and ongoing testing by SLEP.
- **Quality Issues**—State and local stockpiles would be required to have quality control programs in place that would address issues such as facility design, environmental conditions for stored materiel, maintenance, and security.² State and local programs would also need the capacity to label and relabel shelf-life-extended products and to conduct recordkeeping, tracking, and monitoring activities on the stockpiled materiel.² The workgroup also noted that the federal government would need to monitor state stockpile program compliance through regular inspections.²
- **Legal Issues**—The current SLEP program is operated under the enforcement discretion of the FDA; the SLEP program is not expressly authorized in statute or regulation. As such, there will be concerns over potential liability for entities (e.g., state/local governments) participating in SLEP.² Before SLEP could be extended to the states, an appropriate mechanism for incorporating states into SLEP would have to be determined¹ and liability concerns evaluated and addressed.

Developing a SLEP-Like Program for States

In addition to evaluating the feasibility of including states in SLEP, the HHS has been analyzing the feasibility of creating a separate SLEP-like program for extending state stockpiles. The [Biomedical Advanced Research and Development Authority \(BARDA\)](#) within the HHS [Office of the Assistant Secretary for Preparedness and Response \(ASPR\)](#) has been evaluating the infrastructure necessary to support a new program for states and analyzing the comparative cost effectiveness of shelf-life testing to repurchasing for state inventories.¹² Cost factors to be considered include laboratory testing, storage site inspection, state personnel, relabeling for extended products, destruction for products not extended, and transportation for products being tested or destroyed.¹² The HHS, BARDA, and the states conducted a detailed analysis with state-specific data in 2011, but no results have been released as of March 2012.¹²

How the Program Affects States

SLEP currently impacts states primarily through SNS deployments containing medicines that have received, or subsequently receive, shelf-life extensions. Shelf-life-extended products that have an expired label date or that have been relabeled may cause concern among healthcare providers and the public about the safety and efficacy of the extended items. Liability fears can arise among healthcare providers and others dispensing the shelf-life-extended items. Furthermore, complications can arise in determining what products are eligible for SLEP when SNS assets have been mixed with non-SNS assets in state, local, or regional stockpiles.

While extending expiration dates potentially saves money for states by reducing the frequency of replacing expired stockpiled medicines, if state stockpiles are eventually included in the federal SLEP or a similar program for states, states will also have to consider the logistical, personnel, and financial implications of participating in such an initiative.

Sources and Notes

¹ U.S. Army. Shelf Life Extension Program website. Accessed January 31, 2012.

² Leissa B. Food and Drug Administration. "Shelf Life Extension Program" presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm. Accessed January 31, 2012.

³ Courtney B et al. "Maximizing State and Local Medical Countermeasure Stockpile Investments Through the Shelf Life Extension Program." *Biosecurity and Bioterrorism*. Vol. 7 No. 1. 2009.

⁴ Defense Medical Materiel Program Office. "Extending the Shelf Life of Critical Chemical, Biological, Nuclear, and Radiological (CBRN) Medical Materiel Using the FDA/DOD Shelf Life Extension Program." January 24, 2006. Available at https://slep.dmsbfda.army.mil/slep/slep_info_paper_JAN_2006.doc. Accessed January 31, 2012.

⁵ U.S. Department of Defense. Defense Medical Materiel Program Office website and DMMPO SLEP webpage. Both accessed January 31, 2012.

⁶ See U.S. Pharmacopeia website: "The United States Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the quality, purity, identity, and strength of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration..." Available at www.usp.org/aboutUSP/. Accessed January 31, 2012.

⁷ See FDA website "Drug Applications and Current Good Manufacturing Practice (CGMP) Regulations" which states that "The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have." Available at www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm090016.htm. Accessed January 31, 2012. See also 21 CFR Part 210 (CGMP in Manufacturing, Processing, Packing, or Holding of Drugs) and 21 CFR Part 211 (CGMP for Finished Pharmaceuticals).

⁸ Borio L. Food and Drug Administration. July 25, 2011 Letter to William G. Burel, CDC et al regarding answers to questions raised during December 2010 *Federal, State, and Local Public Health Preparedness* meeting in Baltimore, MD. Available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm234336.htm. Accessed January 31, 2012.

⁹ Hamburg M. Food and Drug Administration. June 22, 2010 Letter to Thomas R. Frieden, Centers for Disease Control and Prevention regarding disposition of certain antiviral drugs—Zanamivir and Oseltamivir Phosphate. Available at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm216249.htm>. Accessed March 9, 2012.

¹⁰ Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic. Institute of Medicine. *Antivirals for Pandemic Influenza: Guidance on Developing a Distribution and Dispensing Program*. National Academies Press. 2008.

¹¹ Homeland Security Council. *National Strategy for Pandemic Influenza: Implementation Plan*. May 2006.

¹² Tegeris J. Dept. of Health and Human Services. "Cost Comparison: Shelf Life Extension Program (SLEP) vs. Repurchase for State Stockpiles." Presentation at *Federal, State, and Local Public Health Preparedness* meeting. Baltimore, Maryland. December 14-15, 2010. Available at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm247676.htm. Accessed January 31, 2012.

¹³ Lyon RC et al. Stability profiles of drug products extended beyond labeled expiration dates. *J Pharm Sci* 2006;95(7):1549-1560.

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