August 17, 2011

TO: Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention

FROM: /Lori S. Pilcher/
Acting Deputy Inspector General for Audit Services

SUBJECT: Audit of the Centers for Disease Control and Prevention's Shelf-Life Extension Program (A-04-11-01001)

The attached final report provides the results of our audit of the Centers for Disease Control and Prevention's Shelf-Life Extension Program. We conducted the audit in response to an Office of Inspector General (OIG) Hotline complaint.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that the Office of Inspector General (OIG) post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to contact me at (202) 619-1175 or through email at Lori.Pilcher@oig.hhs.gov. Please refer to report number A-04-11-01001 in all correspondence.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

AUDIT OF THE SHELF LIFE EXTENSION PROGRAM (SLEP) AT THE CENTERS FOR DISEASE CONTROL AND PREVENTION

Daniel R. Levinson
Inspector General

August 2011
A-04-11-01001

Office of Inspector General

http://oig.hhs.gov

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Notices

THIS REPORT IS AVAILABLE TO THE PUBLIC

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Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

INTRODUCTION

BACKGROUND

To ensure preparedness for war or other contingencies, the Department of Defense (DoD) maintains significant pre-positioned reserves of critical medical material. The Shelf Life Extension Program (SLEP) is a joint DoD and Food and Drug Administration (FDA) program. It was created to enable DoD to defer drug replacement costs by delaying the replacement of certain drugs that have useful lives beyond their expiration dates.

The Centers for Disease Control and Prevention (CDC) maintains the Strategic National Stockpile (Stockpile), which contains significant amounts of pre-positioned drugs for use in responding to emergencies throughout the United States. Although each of the drugs has an expiration date set by the manufacturer, if a drug is stored properly, its shelf life can be extended beyond that date. In 2002, CDC entered into an interagency agreement with DoD to use the SLEP to defer the costs of replacing the Stockpile inventory. Under the agreement, FDA tests SLEP-eligible drugs[1] that are stored in the Stockpile inventory to determine whether the drugs' useful lives can be extended beyond their original expiration dates.

FDA evaluates drugs for shelf-life extension by testing samples that CDC submits. The Defense Medical Standardization Board (DMSB) coordinates the program and is the interface between the SLEP participants[2] and FDA. Each week, CDC updates its drug inventory and uploads that information to DMSB's automated database. DMSB reviews the inventory to identify drugs nearing their expiration and presents FDA and CDC with a list of drugs (including their lot numbers) that are potential candidates for testing. CDC then provides DMSB and FDA with a list of drugs ranked by priority for testing. Finally, FDA determines which drug lots it will test and sends CDC a request for samples of drugs from the specified lots. FDA does not test all items presented to it as candidates for testing because it does not have sufficient laboratory resources. Also, FDA does not normally test any lot of material valued at less than $10,000.

We conducted this audit in response to an Office of Inspector General Hotline complaint.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

The objective of our audit was to determine whether CDC was using the SLEP to extend the expiration dates of Stockpile drugs.

[1] The Defense Medical Standardization Board (DMSB) advises CDC on which drugs are SLEP-eligible. (The shelf lives of some drugs cannot be extended.)

[2] Participants are CDC and components of DoD.

Scope

The scope of our audit was SLEP-eligible Stockpile drugs that expired during the period February 28, 2007, through June 30, 2010. We performed fieldwork from March through May 2011 at CDC in Atlanta, Georgia.

Methodology

To accomplish our objective, we reviewed applicable CDC policies and interviewed CDC Stockpile officials to gain an understanding of the SLEP policies and procedures and testing process.

We also reviewed the interagency agreement that CDC has with DoD for CDC's participation in the SLEP.

From a list of SLEP-eligible drugs that CDC stores, we indentified for review a population of 1,463 drug lots that expired during the period February 28, 2007, through June 30, 2010. We judgmentally selected 17 drug lots, one for each of the 14 SLEP-eligible drugs in the Stockpile.[3]

For each selected drug lot, we determined whether CDC prioritized and entered the drug lot into the automated database and whether FDA agreed to test the drug lot. If FDA tested the drug lot, we determined whether CDC followed up on the results by either relabeling drugs in the lot with a new expiration date, destroying the drug lot, or returning the drug lot to the manufacturer, as appropriate. We reviewed CDC's internal controls to the extent necessary to accomplish the objective of our audit. We limited our review to obtaining an understanding of CDC's controls and specific responsibilities under the SLEP.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our finding and conclusions based on our audit objective.

RESULTS OF AUDIT

CDC used the SLEP to extend the expiration dates of Stockpile drugs when possible. Of the 17 SLEP-eligible drug lots included in our sample, FDA did not accept 9 lots for testing. CDC destroyed or returned these drug lots to the drug manufacturer for credit. FDA tested the remaining eight drug lots and extended their expiration dates. CDC had relabeled or was in the process of relabeling these eight drug lots at the conclusion of our audit.

[3] Some drugs come in multiple forms (for example, powder and capsule). One of the 14 SLEP-eligible drugs came in two forms and one came in three forms, for a total of 17 drug lots.