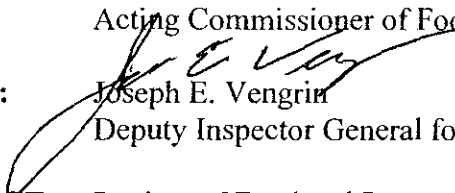




SEP 20 2004

TO: Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs

FROM: 
Joseph E. Vengrin
Deputy Inspector General for Audit Services

SUBJECT: Review of Food and Drug Administration's Bone Mass Study
(A-03-03-00378)

Attached is our final report in response to a March 21, 2003 letter from the Commissioner of Food and Drugs, requesting that we perform a review of a clinical study that examined dietary supplements' ability to increase bone mass.

The objectives of our limited-scope review were to determine if the Food and Drug Administration (FDA) (1) could do more to locate or account for the study's allegedly missing medical folders and (2) had an accurate and supportable financial report of the study's transactions.

Regarding the missing medical folders, we believe that any additional search would not be useful. The exact number of folders and their contents may never be known because FDA did not establish clear responsibilities for creating, updating, and filing the folders in question. The lapse also poses an ongoing risk that medical information on the subjects involved in the study could be released without their authorization.

Regarding the financial accounting issue, FDA provided us a spreadsheet that it had prepared to report the study's financial transactions. We reviewed all supporting documentation for the transactions shown, which totaled \$496,704, and determined that the spreadsheet contained:

- Inaccurate Entries:

- ⇒ FDA recorded only \$5,987 as being paid to Oak Ridge Associated Universities (Oak Ridge) for the study coordinator's services, but in a phone conversation with us, Oak Ridge acknowledged receipt of \$54,423. At the time of our fieldwork, FDA had requested only \$5,987 in reimbursement from the Army, which funded the study.
- ⇒ FDA did not record \$6,144 of general and administrative (G&A) costs in the study's financial accounting spreadsheet and calculated G&A costs using a rate that had not been updated since 1991. These costs had not been billed to the Army.

- Unsupported Entries:
 - ⇒ FDA paid the Natick Soldier Center (Natick) \$261,331 for calcium tablets and nutrient bars via numerous disbursements without adequate supporting documentation.
 - ⇒ FDA charged the study \$1,529 for supplies with no supporting documentation.

We made a number of recommendations related to the financial findings, and FDA agreed with them.

If you have any questions or comments about this report, please call me, or have your staff call Peter J. Koenig, Acting Assistant Inspector General for Grants and Internal Activities, at (202) 619-1175 or through e-mail at Peter.Koenig@oig.hhs.gov. Please refer to report number A-03-03-00378 in all correspondence.

Attachment

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF FOOD AND DRUG
ADMINISTRATION'S BONE MASS
STUDY**



**September 2004
A-03-03-00378**

Office of Inspector General

<http://oig.hhs.gov>

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



EXECUTIVE SUMMARY

BACKGROUND

In March 2003, the Commissioner of Food and Drugs (the Commissioner), Food and Drug Administration (FDA), asked the Office of Inspector General (OIG) to review certain aspects of a clinical study conducted by one of its employees and to assess the integrity of FDA's overall processes for conducting clinical trials. We address the clinical study in this report. As agreed with FDA officials, we will report on the second part of the request at a later date. That work is ongoing and examines FDA's clinical trial management in greater depth.

The purpose of the clinical study, originally estimated to cost \$774,447, was to evaluate the effects of nutritional bars and supplements on the bone mass of up to 320 participating midshipmen at the United States Naval Academy (academy). The Department of the Army funded the study, which was approved by the Research Involving Human Subjects Committee, an FDA institutional review board (IRB). An FDA employee served as the principal investigator (PI) and worked with a co-PI from the Henry M. Jackson Foundation (foundation). Results of psychological and medical tests were to be kept in medical folders on the subjects with adequate safeguards.

The FDA halted the study in May 2001 because of low participation. Afterward, the onsite co-PI reportedly moved the medical folders from the academy to his office in the National Naval Medical Center, Bethesda, Maryland (naval center). In November 2002, officials of the foundation told FDA that they could not account for all of the midshipmen's medical folders. The FDA launched an inspection and an investigation of the matter, and requested a review by OIG.

OBJECTIVES

Based on the Commissioner's request regarding the bone mass study, our objectives were to determine whether FDA (1) could do more to locate or account for the study's allegedly missing medical folders and (2) had an accurate and supportable financial report of the study's transactions.

SUMMARY OF FINDINGS

Finding 1: Additional search for missing folders would not be useful

We believe that it would not be useful to continue to search for folders thought to be missing from the study. Based on our review of various FDA documents that indicated FDA had not established clear responsibilities for creating, updating, and filing the midshipmen's medical folders, the exact number of folders and their contents may never be known. Establishing such responsibilities is critical in order to adequately protect human subjects involved with research, as required by the Federal regulation at 45 CFR 46.111(a)(7). This lapse in accountability—a weakness we are examining on an FDA-

wide basis during the second part of the Commissioner's request—means that the midshipmen's medical information could be accessed without proper authorization. A recently completed FDA internal investigation supported this finding.

Finding 2: FDA did not have an accurate and fully supported financial report to account for the transactions related to the study

Regarding the financial accounting issue, FDA provided us a spreadsheet that it had prepared to report the study's financial transactions. We reviewed all supporting documentation for the transactions shown, which totaled \$496,704, and determined that the spreadsheet contained:

- Inaccurate Entries:
 - ⇒ FDA recorded only \$5,987 as being paid to Oak Ridge Associated Universities (Oak Ridge) for the study coordinator's services, but in a phone conversation with us, Oak Ridge acknowledged receipt of \$54,423. At the time of our fieldwork, FDA had requested reimbursement from the Army for only \$5,987.
 - ⇒ FDA did not record \$6,144 of general and administrative (G&A) costs in the study's financial accounting spreadsheet and calculated G&A costs using a rate that had not been updated since 1991. These costs had not been billed to the Army.
- Unsupported Entries:
 - ⇒ FDA paid the Natick Soldier Center (Natick) \$261,331 for calcium tablets and nutrient bars via numerous disbursements without adequate supporting documentation.
 - ⇒ FDA charged the study \$1,529 for supplies with no supporting documentation.

Without a reliable accounting of the study, there cannot be assurance that all of the study's financial resources have been expended properly or as intended.

RECOMMENDATIONS

We recommend that FDA:

1. locate documentation for the discrepancy in payment of \$48,436 (\$54,423 minus \$5,987) for the study coordinator; bill the Army, as appropriate; and prepare an adjusting entry to properly record those payments to the study

2. bill the Army an additional \$6,144 for unclaimed G&A costs incurred on the study
3. obtain adequate documentation from Natick to support the numerous payments totaling \$261,331 for calcium tablets and nutrient bars
4. provide documentation to support the \$1,529 for supplies or refund this amount to the Army
5. develop and implement effective management controls to properly record and report the costs of studies similar to this one

FDA COMMENTS

FDA agreed with our recommendations in a response dated June 17, 2004 (Appendix C). The comments responded to a draft report we provided on May 11, 2004.

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INTRODUCTION

BACKGROUND

OIG Request

As part of an effort to assure the integrity of FDA's clinical trial program, the Commissioner asked OIG in March 2003 to review certain issues related to an FDA clinical study involving a dietary strategy to maximize bone mass and the agency's overall process for conducting clinical trials. Regarding the bone mass study, the subject of this report, the Commissioner was concerned about the apparent loss of medical folders of some study participants and the study's financial accounting.

Bone Mass Study

In September 1998, FDA entered into an interagency agreement with the Army to conduct a study, originally estimated to cost \$774,447, to develop methods for improving bone mass in young men and women to lower the incidence of fractures. The proposed 2-year study involved midshipmen at the academy supplementing their diets with calcium and other specific nutrients associated with bone growth, strength, and mineralization. The dietary supplements took the form of calcium tablets and nutrient bars.

An employee of the FDA Center for Food Safety and Applied Nutrition (food center) served as the principal investigator. The FDA PI worked with a co-PI from the Henry M. Jackson Foundation, a private foundation for the advancement of military medicine. In July 1999, the academy offered the opportunity for up to 320 midshipmen to participate in the study. As part of their agreement to participate, the midshipmen underwent various medical and psychological tests. Based on available signed consent forms, 260 midshipmen initially volunteered to participate. Although 260 consent forms were signed, FDA could not establish the number of midshipmen who actually participated in the study.

The co-PI provided onsite oversight of the study at the academy. The co-PI worked with the study coordinator, who scheduled blood and urine collections and distributed the dietary supplements to the midshipmen. A study assistant created the midshipmen folders, which were to hold such documents as signed informed consent forms, psychological and anxiety questionnaires, medication and food intake records, and fitness for duty summaries.

The study experienced a high participant dropout rate from the outset. In May 2001, FDA terminated the feeding, urine collections, and blood testing components of the study because the PI said she could no longer obtain statistically meaningful data with so few participants.

In mid-May 2001, the co-PI transferred the midshipmen's folders to his office at the naval center in Bethesda, Maryland. Sometime after May 2001—we did not identify the

date—the co-PI vacated his office at the naval center. We determined from interview records with naval medical center officials that Navy personnel moved the midshipmen’s records to another office and back again during a painting project on the premises. In November 2002, foundation representatives turned over these study folders to FDA. Shortly before this exchange, a regulatory affairs specialist with the foundation informed FDA that some of the study folders were missing. FDA later determined that at least 92 of the folders could not be accounted for. As of March 2004, a definitive number of folders created or unaccounted for remained unknown.

Financial Accounting for the Study

The FDA Office of Acquisitions and Grants Services (grants office) presented OIG with a financial report of the study in the form of a summary spreadsheet prepared for the specific purpose of our review. The spreadsheet contained financial data obtained from several FDA offices, including the food center, the Office of Financial Management, and the FDA grants office. The spreadsheet showed that FDA billed the Army for reimbursement in the amount of \$496,704.

According to FDA, no one person had overall financial responsibility to account for the study. Instead, the food center office, the Office of Financial Management, and the FDA grants office worked together as a team in providing financial data for the study’s spreadsheet.

FDA Concerns About the Study

FDA’s concern about the study led to an inspection of the PI’s conduct of the study by FDA’s Office of Regulatory Affairs and an investigation by the agency’s Office of Internal Affairs. Both examinations, which resulted in restricted reports, noted accountability issues with the study.

The Commissioner asked OIG to perform an independent review of the study to serve as a critical component in helping FDA assure the integrity of its clinical trials. The Commissioner also requested OIG to review the integrity of the agency’s overall processes for conducting clinical trials. OIG is performing the overall review separately in fiscal year (FY) 2004 and will include the results in an upcoming report.

Based on available signed consent forms, FDA has notified the midshipmen about the allegedly missing medical folders.

OBJECTIVES, SCOPE, AND METHODOLOGY

Objectives

Based on the Commissioner's request regarding the bone mass study, our objectives were to determine whether FDA (1) could do more to locate or account for the study's allegedly missing medical folders and (2) had an accurate and supportable financial report of the study's transactions.

Scope

Based on FDA's request dated March 21, 2003, our scope was limited and had two parts: FDA's efforts to account for the allegedly missing folders and the accuracy and supportability of the study's financial spreadsheet dated June 12, 2003.

Our audit periods varied with each objective. For the allegedly missing folders, we reviewed FDA's efforts through April 17, 2003, the date of our entrance conference. We later expanded our period to include reports of investigation issued May 20, 2003, December 16, 2003, and March 9, 2004 by the FDA's Office of Internal Affairs.

For the financial spreadsheet, we reviewed FDA's supporting documentation for transactions executed during FYs 1998-2002. Although we did not actively search for missing transactions, we did question the amount claimed as payment for the services of a study coordinator. Our work on internal controls was limited to developing an understanding of controls related to the transactions posted to the spreadsheet.

Methodology

To learn about the study and FDA's efforts to account for the midshipmen's medical folders, we interviewed officials and obtained documents from various FDA offices, among them the Office of the Commissioner; the Research Involving Human Subjects Committee (FDA's IRB); the food center; the Office of Regulatory Affairs; the Office of Internal Affairs; the grants office; and the Office of Financial Management. Rather than interview the PI and co-PI directly, we relied on results from the March 6, 2003 inspection report by the Office of Regulatory Affairs and investigation reports dated May 20, 2003, December 16, 2003, and March 9, 2004 from the Office of Internal Affairs.

To determine the accuracy of and support for the study's financial report, we interviewed officials and obtained records for transactions included on the June 12, 2003 financial spreadsheet from the Office of Financial Management, the grants office, and the food center. We reviewed interagency agreements, purchase orders, journal vouchers, invoices, FDA's billing documents to the Army, and related documents to verify the accuracy, validity, and allocability of costs to the study shown on the spreadsheet. Also, we spoke with an Oak Ridge official who provided us documentation that supported activities reimbursed by the study.

We discussed our financial findings with FDA officials and provided them a discussion draft report of those findings on December 16, 2003. We provided a subsequent draft report on May 11, 2004 that included a discussion of the medical folders, and FDA agreed with our recommendations in a response dated June 17, 2004 (Appendix C). FDA's comments are incorporated, as appropriate, into this final report.

We conducted our review in accordance with generally accepted government auditing standards.

RESULTS OF REVIEW

FINDING 1: ADDITIONAL SEARCH FOR MISSING FOLDERS WOULD NOT BE USEFUL

We believe that it would not be useful to continue to search for folders thought to be missing from the bone mass study. FDA documents that we reviewed, including inspection and investigation reports prepared by FDA's Office of Regulatory Affairs and Office of Internal Affairs, showed that FDA had not established clear responsibilities for creating, updating, and filing the study folders. As a result, the exact number of folders and their contents may never be known. Establishing such responsibilities is critical in order to adequately protect human subjects involved with research, as required by the Federal regulation at 45 CFR 46.111(a)(7). This lapse in accountability—a weakness we will examine on an FDA-wide basis during the second part of the Commissioner's request—means that the midshipmen's medical information could be accessed without proper authorization. A recently completed FDA internal investigation supported this finding.

Principal Investigators Are To Follow Certain Requirements When Conducting Research With Human Subjects

The PIs involved with the study were responsible for maintaining the integrity and confidentiality of information related to the subjects enrolled. When research involves human subjects, the Federal regulation at 45 CFR 46.111(a)(7) requires that there be "adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." Consistent with that regulation, the study's informed consent form, approved by FDA, the Army, and the Navy, stated that the study subjects' medical folders were to be kept confidential and maintained in a secure location accessible only to study officials.

There Was Inadequate Accountability for Study Folders

From the study's outset, FDA did not ensure adequate accountability for the midshipmen's study folders, and we were not able to determine the reason for this lapse. Clear responsibilities were not established as to who would create the folders, how the folders would be created, and at what point of the study folders were to be created. Establishing such responsibilities is critical in order to adequately protect human subjects involved with research, as required by the Federal regulation at 45 CFR 46.111(a)(7).

Accountability was also compromised by the lack of an inventory of folders while the study was underway and by a failure to implement safeguards for the folders' contents, which included the midshipmen's personal medical information obtained through surveys and tests.

Folders May Be Vulnerable

Given the poor accountability associated with the study folders, the exact number of folders and their contents may never be known, and some of the folders may not have been collected. As a result, the folders and their contents are vulnerable to being accessed without permission by unauthorized persons. This is a serious lapse because the folder contents could pertain to sensitive areas of the midshipmen's medical histories.

We have no recommendations regarding the study's folders, and are exploring FDA's clinical trial management in greater depth during a separate review in FY 2004.

FINDING 2: FINANCIAL SPREADSHEET WAS INACCURATE AND NOT FULLY SUPPORTED

FDA did not have an accurate and fully supported financial spreadsheet to account for the study's expenditure of \$496,704. As a result, FDA did not have reliable financial information on the study's transactions, did not charge G&A costs consistently, and may have charged inappropriate or unallocable costs. In our view, these problems arose because no single FDA official provided overall financial management control to ensure that the study's transactions on the spreadsheet were accurate and supported. FDA prepared the spreadsheet for the purpose of our review.

Requirements for Financial Reporting Should Be Followed

To ensure the reliability of financial reporting, an organization should follow the Government Accountability Office's (formerly the General Accounting Office) "Standards for Internal Control in the Federal Government," issued November 1, 1999, which requires that transactions and events be (1) executed properly, (2) recorded accurately and timely, and (3) documented appropriately.

FDA's Financial Spreadsheet Was Inaccurate and Not Fully Supported

FDA's spreadsheet was not accurate and fully supported to account for the \$496,704 expended on the study. For the transactions shown, we reviewed all interagency agreements, purchase orders, journal vouchers, invoices, FDA billing documents to the Army, and related documents to verify the accuracy, validity, and allocability of costs. We also spoke with an Oak Ridge official who provided us documentation that supported activities reimbursed by the study.

We identified two inaccuracies in the report:

- FDA's financial spreadsheet showed payment of \$5,987 to Oak Ridge for the study coordinator's services, but in a phone conversation with us, Oak Ridge acknowledged receipt of \$54,423. At the time of our fieldwork, FDA had sought reimbursement from the Army for only \$5,987.
- We noted a range of accuracy problems with G&A costs. First, FDA's financial spreadsheet did not record \$6,144 of G&A costs, thus underreporting the full cost of the study. (Appendix B shows a breakdown of the costs by fiscal year.) Second, the FDA G&A rate had not been updated since 1991. Using an older rate, FDA risked less than full recovery of G&A costs. Third, FDA did not charge G&A costs consistently. For FYs 1998-1999, the spreadsheet showed no entries at all, while other years showed G&A charges based on amounts other than actual total direct costs, contrary to the interagency agreement with the Army.

We identified two unsupported entries in the report:

- FDA paid Natick \$261,331 for calcium tablets and nutrient bars without seeking supporting documentation. In light of the problems noted with the study, we believe it would have been prudent for FDA to obtain this documentation, such as invoices or receiving reports showing quantities and related money amounts, rather than rely exclusively on the customary drawdown procedures of the Payment Management System. Additional documentation could have better supported the allocability of costs to the study.
- FDA also charged the study \$1,529 for supplies with no supporting documentation.

Management Controls Were Inadequate

FDA's grants office manually prepared the summary spreadsheet for the study with financial data from several offices, but it appeared that no single FDA official provided overall financial management control to ensure that the various inputs to the spreadsheet were accurate and supported. FDA did not follow effective procedures for processing, recording, supporting, or managing the review of transactions posted to the spreadsheet.

Financial Control of the Study's Funds Was Lacking

As a result of the financial problems detailed above, FDA:

- lacked complete financial information on the study's transactions
- charged G&A costs inconsistently

- charged costs that may not have been appropriate or allocable

RECOMMENDATIONS

We recommend that FDA:

1. locate documentation for the discrepancy in payment of \$48,436 (\$54,423 minus \$5,987) for the study coordinator; bill the Army, as appropriate; and prepare an adjusting entry to properly record those payments to the study
2. bill the Army an additional \$6,144 for unclaimed G&A costs incurred on the study
3. obtain adequate documentation from Natick to support the numerous payments totaling \$261,331 for calcium tablets and nutrient bars
4. provide documentation to support the \$1,529 for supplies or refund this amount to the Army
5. develop and implement effective management controls to properly record and report the costs of studies similar to this one

FDA'S COMMENTS

FDA agreed with our recommendations in a response dated June 17, 2004 (Appendix C). The comments responded to a draft report we provided on May 11, 2004.

APPENDICES

RESULTS OF FINANCIAL ACCOUNTING

Cost Category	FDA Spreadsheet Disbursements	OIG Recommended Adjustments	OIG Referrals to FDA for Support	Notes
Supplies	\$53,619	(\$1,529)		a
Dietary Supplements	322,587		\$261,331	b
Purchase Orders	71,261	48,436		c
Travel	901			
Total Direct Costs	\$448,368	\$46,907	\$261,331	
G&A	48,336	6,144		d
Total Costs	\$496,704	\$53,051	\$261,331	

NOTES:

- a. \$1,529 was charged by FDA to the study through journal vouchers without supporting documentation.
- b. \$261,331 paid for calcium tablets and nutrient bars requires adequate supporting documentation.
- c. \$48,436 charged for the study coordinator's services was not recorded or reported by FDA for the study.
- d. \$6,144 was not claimed by FDA for G&A costs. See Appendix B.

UNREPORTED G&A COSTS

FY	(A) OIG Accepted Costs Without G&A Costs Included	(B) FDA's G&A Rate	(C) G&A Costs Calculated by OIG (A X B)	(D) G&A Costs Reported by FDA	(E) Unreported (Overreported) G&A Costs (C - D)
1998	\$43,519	11%	\$4,787	\$0	\$4,787
1999	4,735	11%	521	0	521
2000	348,300	11%	38,313	38,247	66
2001	83,281	11%	9,161	8,331	830
2002	15,440	11%	1,698	1,758	(60)
Totals	\$495,275	11%	\$54,480	\$48,336	\$6,144



Food and Drug Administration
Rockville MD 20857

DATE: JUN 17 2004

TO: Auditor, Office of the Inspector General (OIG)

FROM: Associate Commissioner for Management

SUBJECT: FDA's Comments on OIG Draft Report: "Bone Mass Study—Folders' Accountability," (CIN: A-03-03-00378)

Thank you for the opportunity to review and comment on the OIG draft report, "Bone Mass Study—Folders' Accountability." We appreciate your insights and the thoroughness with which you conducted the audit. In reviewing the report, FDA did not find any inaccuracies regarding the alleged missing folders section of the audit. Despite the lack of any recommendations by the OIG, please be advised that FDA intends to conduct an internal assessment of our clinical study processes to determine if additional management controls are needed. In terms of the financial expenditures section of the audit, the Agency's comments are in the attachments.

If you need additional information, please contact Paul Jones, (301) 827-4812.

A handwritten signature in black ink, appearing to be "Jeffrey M. Weber", with a long horizontal line extending to the right.

Jeffrey M. Weber

Attachments

FDA's Comments on OIG Draft Report: "Bone Mass Study-Folders'
Accountability,"(CIN: A-03-03-00378)
June 17, 2004

RECOMMENDATIONS

1. **Locate documentation for the discrepancy in payment of \$48,436 (\$54,423 minus \$5,987) for the study coordinator and prepare an adjusting entry to properly record those payments to the study.**

FDA Response: FDA concurs with recommendation number one. Although documentation does not exist for the \$48,436.00, FDA will review its current policies and procedures to determine if additional management controls are needed.

2. **Bill the Army an additional \$6,144 for unclaimed G&A costs incurred on the study.**

FDA Response: FDA concurs with recommendation number two. The 11 percent G&A rate has been in place since 1991. FDA will look into whether that rate is still sufficient/appropriate for all reimbursable agreements. Also, FDA plans, in this one instance only, to bill the Army for an additional \$6,114 for unclaimed G&A costs incurred on the study.

3. **Obtain adequate documentation from Natick to support the numerous payments totaling \$261,331 for calcium tablets and nutrient bars.**

FDA Response: FDA concurs with recommendation number three. FDA has provided copies of shipping receipts, documenting receipt of nutrition bars and calcium tablet products. There were actually only 20 disbursement entries for the nutrition bars, including 13 actual bills, and seven electronic payments Intra-Governmental Payment Collection System. The other seven entries were for two credits, therefore, the OIG report should reflect only the 20 payments.

The \$269,000 amount was an estimate based on past experience with the development and manufacture of similar nutrient bars and calcium tablets products. This was the estimated cost used on the FDA IAG with the Army. The \$261,331.06 was the actual amount billed by the Army for the nutrient bars and calcium tablets. The shipping receipts are included for the three separate shipments received for the nutrient bars and calcium tablets relating to the study.

4. **Provide documentation to support the \$1,529 for supplies or refund this amount to the Army.**

FDA Response: If sufficient documentation cannot be provided, FDA will reimburse the Army. In addition, FDA plans to revamp the Project Management Training to put additional emphasis on the financial management of the project.

5. Develop and implement effective management controls to properly record and report study costs similar to this one.

FDA Response: FDA concurs with recommendation number five. FDA has developed and implemented effective management controls to record and report study costs. The Agency provides training on the reimbursable IAG process. The training was directed specifically to the issues and concerns related to the prior year close out and to receive the necessary documents for timely processing. The training entailed processing journal vouchers to ensure that the information was correct and properly stated according to the IAG. Also, the training enables Centers' to manage their own transactions numbers, obtain access to their Center's system (once requested via password). It provided a forum for Centers' budget and extramural staff to ask questions regarding pertinent IAG information. The training also includes the entire reimbursable guidelines, including anti-deficiency and collection of overhead and G&A rates.

As an additional management controls measure, FDA Centers participate in the Partnership for Administrative Quality (PAQ) program, which provides a mechanism for occasional in-house self-assessment reviews of various administrative areas, including Financial Management. The Financial Management checklist includes sections covering Commercial Invoices, Fund Control, IMPAC/Bankcard processes, Timekeeping, etc. These checklists, which are updated annually, were developed to provide a tool for Centers to use in assessing the effectiveness of their administrative operations. PAQ is designed to be flexible, and provides the Centers with latitude to determine which administrative areas to review in a given year, based on need, priority, and availability of resources.

Finally, the role and responsibilities of the Project Officer is post-award administration, set forth in the Project Officer Handbook.