Memorandum

Date SEP - 1 1999

From Deputy Inspector General
for Audit Services

Subject Review of the Food and Drug Administration's Cost Increase for the Arkansas Regional Laboratory (CIN: A-15-98-50002)

To Jane E. Henney, M.D.
Commissioner
Food and Drug Administration

The attached final report provides you with the results of our review of the cost increase incurred on the Food and Drug Administration's Arkansas Regional Laboratory project. This review was requested by Congressman Joe Skeen, Chairman, Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, House Committee on Appropriations, to determine why the Arkansas Regional Laboratory's construction costs exceeded the original budget estimate.

On August 10, 1999, we received FDA's comments on our findings and recommendations contained in our draft report dated May 27, 1999.

Please advise us of any additional actions taken within the next 60 days. If you have any questions, please call me or have your staff contact Joseph J. Green, Assistant Inspector General for Public Health Service Audits, at (301) 443-3582. To facilitate identification, please refer to Common Identification Number A-15-98-50002.

Thomas D. Roslewicz

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF THE FOOD AND DRUG ADMINISTRATION'S COST INCREASES FOR THE ARKANSAS REGIONAL LABORATORY

JUNE GIBBS BROWN
Inspector General

SEPTEMBER 1999
A-15-98-50002

Memorandum

Date SEP - 1 1999

From Deputy Inspector General
for Audit Services

Subject Review of the Food and Drug Administration's Cost Increases for the Arkansas Regional Laboratory (CIN: A-15-98-50002)

To Jane E. Henney, M.D.
Commissioner
Food and Drug Administration

This final report provides you with the results of our review of a cost increase related to the Food and Drug Administration's (FDA) construction of the Arkansas Regional Laboratory (ARL). The current ARL estimate is $37.9 million, which is $10.4 million, or 38 percent, higher than the original estimate of $27.5 million.

OBJECTIVE

The objective of this review was to respond to a request from the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, House Committee on Appropriations, to determine why the ARL project's costs exceeded the original budget estimate.

SUMMARY OF FINDINGS

We determined that the ARL project's cost exceeded the budget estimate by $10.4 million as a result of the following:

- $3.4 million in costs not included in the estimate FDA used as the basis for the budget request.
- $2.1 million due to the architecture and engineering (A&E) firm revising its estimate upward in October of 1996.
- $4.9 million in additional costs attributable to a combination of factors, including: inflation, the A&E firm's unfamiliarity with the Arkansas area, the effects of a "building boom" in Arkansas, the A&E firm's cursory assessment of market conditions, and the inexact nature of construction estimates.

We also identified several management control weaknesses in FDA's oversight of this project, which may have contributed to the agency's underestimating ARL's project costs. Specifically, FDA did not: establish centralized control over the fiscal management of the project at the start of the project; maintain a sound project tracking

system, or obtain a second estimate. Furthermore, the estimate obtained by FDA only included the cost of the construction contract, not total project costs, which may also include items such as construction quality management fees, architect and engineering fees, telecommunications, and construction contingency. We also noted that FDA does not have adequate written policies for budgeting construction projects.

To ensure that the ARL and future FDA construction projects are implemented within anticipated cost ranges, we recommend FDA:

- Establish clear lines of responsibility for future construction projects by assigning responsibility for planning, budget development, and execution of the project to one high-level official within the Office of Management and Systems.

- Implement a system for tracking estimated project costs throughout the budget development stage. The budget tracking system should include management controls to ensure all costs entered into the system, or adjusted, have proper supporting documentation and approval. All costs of the project should be included in the project budget, unless another source of funding has been confirmed.

- Institute a policy to closely review budgets and estimates to ensure completeness and accuracy. Such a policy should ensure that necessary project costs outside of the construction contract are included when developing project budgets. The policy should also include a requirement to obtain a second opinion from a construction management firm for all contracts over a certain dollar threshold.

- Institute general policies regarding developing a construction project budget. The policies should address which organization within FDA should be used to develop project estimates, how to calculate a construction contingency, when a construction quality management company is necessary, and at what point it should be hired.

BACKGROUND

The ARL, now under construction, is part of the FDA's 1994 plan to replace the existing array of 18 field laboratories with 5 large regional laboratories and 4 specialty laboratories.[1] According to FDA, the ARL, to be co-located with FDA's National Center for Toxicological Research (NCTR) in Jefferson, Arkansas, is a full-service

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[1] The five regional laboratories are to be located in the following areas: Bothell, Washington; Irvine, California; Jamaica, New York; Atlanta, Georgia; and Jefferson, Arkansas. The specialty laboratories will be in Winchester, Massachusetts; Philadelphia, Pennsylvania; Cincinnati, Ohio; and San Juan, Puerto Rico.

laboratory that will be most heavily involved in foods and animal drug and feed work. This includes both micro and chemistry for foods and drug residue work for the Center for Veterinary Medicine. The FDA expects the facility to be available for use by the Office of Regulatory Affairs (ORA) in Fiscal Year (FY) 2000, and plans to have all of its laboratories operational by 2014.

In its budget request for FY 1998, which FDA officials state was formulated in January, 1996, FDA estimated ARL project costs would be $27.55 million. On January 30, 1998, the Department of Health and Human Services (HHS) notified Congress that it planned to reprogram $10.4 million from within the FDA's Buildings and Facilities appropriation to cover the increase in ARL project costs.

The FDA provided Congressman Skeen, Chairman of the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, House Committee on Appropriations, with explanations for the construction cost increases--from $27.55 million to $37.9 million. For example, in its January 30, 1998 reprogramming request to Congressman Skeen, the agency attributed the increases to rising construction prices in the Arkansas area. The agency provided additional documentation to the Congressman's office attributing the increase to escalating construction costs including subcontracting, masonry, and steel.

The FDA's explanations for the cost increases did not offer full justification to the Congressman and his staff. Thus, in February of 1998, Congressman Skeen wrote to the Secretary of HHS, requesting that the Office of Inspector General (OIG) examine why the FDA's original cost estimate was almost 40 percent too low.

Several FDA components have played a role in the ARL project. There was no one FDA official in charge of the overall management and coordination of the project at its outset; rather, the project was planned and is being carried out by a partnership of the following agency offices:

- The ORA: responsible for participating in the design of the building to ensure the building can support ORA program activities. The ORA also assisted in the development of the project budget.

- The Office of Facilities Acquisitions and Central Services (OFACS): responsible for administering contracts for A&E, construction quality management, and construction.

- Division of Facilities Planning, Engineering, and Safety (a division of OFACS): responsible for planning the project, developing the project budget, and overseeing the construction.

- The NCTR: according to FDA, "assisted ORA in the development of the Program of Requirements for the project in FY 1994 which included a construction cost estimate."

- The Office of Financial Management: responsible for developing budget requests for funding and processing the requests through the budget cycle.

In FY 1994, FDA contracted with an A&E firm to design the ARL project and develop the estimated construction contract price (ECCP) of the ARL. Because an ECCP is only an estimate of the cost of the actual construction contract itself, FDA was responsible for estimating all of the other essential cost elements of the building project, such as A&E fees, construction contingency, construction quality management service, telecommunications, and security.

OBJECTIVE, SCOPE, AND METHODOLOGY

Our review was limited to addressing Congressman Skeen's request that we determine why the ARL project's costs exceeded the budget estimate by almost 40 percent, from $27.55 million to $37.9 million. Our review of management controls addressed only those controls affecting the cost increase. Our review was conducted at the FDA offices in Rockville, MD, from April of 1998 to February of 1999, in accordance with generally accepted government auditing standards.

To understand the original cost estimate, and the subsequent increase, we interviewed FDA officials and reviewed documentation provided by FDA officials and professionals at the A&E firm hired to prepare the ECCP. To verify FDA's explanations for the cost increases, we contacted independent parties, including the Federal Government's General Services Administration (GSA), which is responsible for many Government construction projects; and Bethlehem Steel. To determine the construction climate nationwide and in Arkansas, we performed research on Internet web sites such as: Construction Monthly Online, The Institute for Economic Advancement at the University of Arkansas at Little Rock, the University of Arkansas at Little Rock, and the City of Little Rock Office of Economic Development.

We briefed the staff of the Subcommittee on Agriculture, Rural Development, FDA and Related Agencies, House Committee on Appropriations, on our findings in the fall of 1998.

DETAILED FINDINGS

The $10.4 million ARL cost increase was caused by a variety of factors. We identified the primary factors as follows:

- $3.4 million in costs not included in the estimate FDA used as the basis for the budget request.

- $2.1 million due to the A&E firm revising its estimate upward in October of 1996. At FDA's request, the A&E firm re-examined its estimate, an action which resulted in an upward budget revision of $2.1 million in October of 1996.

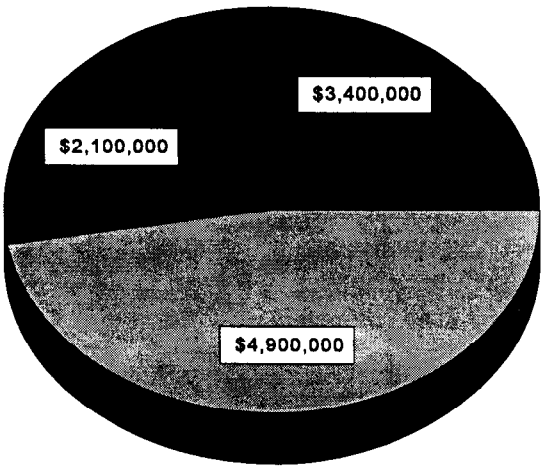
- $4.9 million in additional costs attributable to a combination of factors, including: inflation, the A&E firm's unfamiliarity with the Arkansas area, the effects of a "building boom" in Arkansas, the A&E firm's cursory assessment of market conditions, and the inexact nature of construction estimates.

We also identified several management control weaknesses in FDA's oversight of this project which may have contributed to FDA's underestimating ARL project costs. Specifically, FDA did not: establish centralized control over the fiscal management of the project, maintain a sound project tracking system, or obtain a second estimate. Furthermore, the estimate obtained by FDA only included the cost of the construction contract, not total project costs. We also noted FDA does not have adequate policies for budgeting construction projects.

ARL COST INCREASES DUE TO SEVERAL FACTORS

We determined that the $10.4 million cost increase resulted from a number of factors as shown in the graph below.

Factors Resulting In $10.4 Million Cost Increase



FDA Did Not Include Certain Costs in its Original Estimate

We identified $3.4 million in project costs that FDA did not include in its original budget. It appears that FDA did not adequately plan for the source of funding for the following costs:

- *$0.7 million in ongoing A&E services:* An earlier appropriation covered most of the costs of A&E services; however, the remaining balance of $0.7 million was not included. We believe such costs should have been included in the project estimate, unless other sources of funding had been established.

- *$1.2 million in telecommunications and security systems costs:* Since these costs are essential to operating the building, we believe they should have been included in the project estimate, unless other sources of funding had been established.

- *$1.3 million in additional construction contingency costs:* Before preparing the reprogramming letter, FDA decided to double its original construction contingency estimate from 5 percent to 10 percent (from $1.3 million to $2.6 million). Based on our research, including discussions with officials at GSA, the 10 percent estimate is more reasonable for a Government construction project. The 10 percent figure probably should have been included in the original estimate. The FDA did not have any documents explaining why it originally believed a 5 percent contingency would be sufficient or why the contingency needed to be doubled to 10 percent.

- *$0.2 million for a demolition contract:* We believe these costs should have been included in the original estimate unless other sources of funding had been established. This demolition work had been performed before the general contractor for ARL began its work, and we could not determine FDA's reasons for not including these costs.

The A&E Firm Revised the Construction Contract Estimate

The A&E firm revised its estimate upward in October of 1996, increasing estimated costs by $2.1 million. The A&E firm could not place a dollar figure on each of the factors contributing to this increase, but indicated most of the increase resulted from:

- A reduction in the market discount factor. The original estimate included a market discount factor of 15 percent; but, by the October estimate, the A&E

firm reduced this discount to 8 percent, thereby increasing the estimate of the cost of the construction contract.[2]

- An increase in the estimated manhours necessary to complete the job due to a decrease in labor productivity levels.

- Inflation due to completing the project in phases, which pushed parts of the project back a year.

A Combination of Other Factors Led to Additional Increase

It was not possible to place a dollar figure on each of the factors contributing to the remaining $4.9 million increase; however, we believe it can be attributed to the following factors:

- *Limited work performed to determine market conditions*: For example, the A&E firm established its market discount factor on the basis of limited discussions with just two contractors familiar with the Arkansas area. The A&E firm did not have any documentation to show how the market factor was calculated.

- *Unfamiliarity with the Arkansas area:* The A&E firm was not familiar with the Arkansas area and had not done any prior work in Arkansas. Related to this factor, while the references FDA received pertaining to the A&E firm were overall quite high, some of them indicated the A&E firm had a weakness in the area of estimating. Specifically, two of the four references indicated a weakness in the area of estimating. Accordingly, we believe FDA should have sought a second independent cost estimate, preferably from a construction management company, which estimates costs from a different perspective than an A&E firm.

- *Inflation:* The construction contract was not awarded until much later than anticipated, resulting in higher costs due to inflation. The A&E firm anticipated the construction contract would be awarded in the spring of 1996, but FDA did not actually award the contract until the end of September of 1997. According to FDA, the inflation was due to "completing the project in phases, which

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[2] A market factor is applied to estimates to adjust them for market conditions. In a very competitive or slow market, a discount is applied to the estimate because contractors are willing to submit lower bids in order to obtain the job. In a busy market, when contractors are already busy, they may add a premium to their bids.

pushed parts of the project back a year or more; and increased costs associated with 'General Conditions' spread over a longer period of time."

- *Effects of a building boom:* We were able to confirm through research that there is a building boom in the Little Rock area. Building projects in Little Rock currently include a new 20,000 seat multi-purpose arena, a new science and education building at the University of Arkansas at Little Rock, and a large expansion to the State House Convention Center.

- *Estimates are never exact:* According to cognizant GSA officials, project managers strive to achieve an estimate within 10 percent of the actual project costs.

OPPORTUNITIES TO IMPROVE FDA'S MANAGEMENT OF CONSTRUCTION PROJECTS

We identified several areas where FDA's management control of the ARL and future construction projects could be improved. The most significant areas requiring attention include the need for FDA to:

- *Centralize project management:* Early in the project, FDA did not establish clear lines of authority and responsibility for the fiscal management of the ARL project. Most importantly, there was no one individual responsible for ensuring that the ARL estimates were complete, accurate, and adequately supported; and that the budget request sent to Congress contained all costs necessary to ensure a successful project. Other key fiscal decisions, such as whether to hire a construction quality management contractor to offer a check on the initial cost estimates, also appeared not to be within the domain of any one specific individual. Cognizant FDA officials have advised us that they have now established control of the project within the Division of Facilities Planning, Engineering, and Safety.

- *Track estimates during budget formulation:* The FDA could not clearly document or explain to us certain figures used in its cost estimates. For example, FDA could not explain the fluctuation in the estimated cost of the construction management contract. The agency initially estimated the cost of this contract to be $1.4 million; later dropped its estimate to $0.8 million in October of 1996; and eventually awarded a contract for $1.37 million. Yet, FDA did not have support for any of these estimated figures. Cognizant FDA officials have informed us that the agency has now adopted a system for tracking project costs.

- *Estimate total project costs:* Although FDA could require the A&E firm to estimate total project costs, the agency only requested the A&E firm to prepare an ECCP.

- *Obtain a second estimate from a construction management company:* The FDA could have benefitted from obtaining a second cost estimate from a construction management viewpoint.

- *Adopt policies and procedures for planning construction projects:* The FDA does not have policies and procedures to guide certain key construction-related activities such as: selecting which organization within FDA will develop the project budget; calculating the construction contingency; determining whether a construction quality management firm should be hired; and, if a construction management firm is required, specifying when it should be brought into the project's time line. Cognizant FDA officials have informed us that they have adopted policies addressing when it is appropriate to hire a construction management firm and establishing control of construction projects within the Division of Facilities Planning, Engineering, and Safety.

RECOMMENDATIONS

To ensure that the ARL and future FDA construction projects are developed within reasonable budgets and with sufficient accountability, we recommend that FDA:

- Establish clear lines of responsibility for future construction projects by assigning responsibility for planning, budget development, and execution of the project to one high-level official within the Office of Management and Systems.

- Implement a system for tracking estimated project costs throughout the budget development stage. The budget tracking system should include management controls to ensure all costs entered into the system, or adjusted, have proper supporting documentation and approval. All costs of the project should be included in the project budget, unless another source of funding has been confirmed.

- Institute a policy to closely review budgets and estimates to ensure completeness and accuracy. Such a policy should ensure that necessary project costs outside of the construction contract are included when developing project budgets. The policy should also include a requirement to obtain a second opinion from a construction management firm for all contracts over a certain dollar threshold.

- Institute general policies regarding developing a construction project budget. The policies should address which organization within FDA should be used to

develop project estimates, how to calculate a construction contingency, when a construction quality management company is necessary, and at what point it should be hired.

FDA COMMENTS AND OIG RESPONSE

On August 10, 1999, we received FDA's written comments to the recommendations contained in a draft of this report, dated May 27, 1999. The FDA generally concurred with our four recommendations and stated that it had been implementing actions consistent with our recommendations. The FDA's comments are included in this report as Appendix A. We have asked FDA to advise us of any additional actions taken within the next 60 days. The FDA disagreed with some of the information presented in our report. These issues are addressed below:

Use of Term "Construction Costs"

In its comments, FDA stated that all references in the report made to "construction costs" should be changed to "project costs."

Based on earlier comments provided by FDA, we rephrased our report to use the phrase "project costs" as much as practicable to emphasize the fact that the project included more than just construction costs. However, we sometimes had to use the word "construction," for example, to explain that the goal of the project was to build a laboratory, and to emphasize the fact that our review and findings may not relate to other forms of acquisitions, such as equipment purchases.

Components of Estimate

The FDA disagreed with our finding that the estimate it obtained from the A&E firm only included construction costs and not total project costs.

While FDA now contends that the estimate it obtained from the A&E firm included project costs beyond the cost of construction, documentation obtained from the A&E firm shows that their estimate was only for the cost of the construction contract. The cover of the ECCP developed by the A&E firm, included in our report as Appendix B, clearly shows that only construction costs are estimated.

The FDA's comment is inconsistent with earlier written comments we received from the agency. In its attached comments to our report, FDA states: "The estimate obtained by FDA **correctly** (emphasis added), included the ECCP, construction quality management, demolition, and construction contingency costs." By contrast, in a prior written response to our discussion draft, which included a recommendation that FDA obtain estimates of total project costs, not just ECCP costs, FDA stated: "We believe

that it is entirely inappropriate to require that A/E firms estimate the total project costs. This activity is, in fact, an inherently governmental function and should not be the responsibility of the A/E contractor as it is outside an A/E's area of expertise." Since FDA has provided us with inconsistent information regarding who is responsible for estimating non-construction costs, we are relying on the documentary evidence provided by the A&E firm, which indicates their estimate included construction costs only. The contradictory statements made by FDA regarding this issue reinforce our recommendation that FDA establish clear lines of responsibility for construction projects by assigning responsibility for the projects to one high-level official within the Office of Management and Systems. This official should have authority to resolve such conflicts within the organization.

Project Leadership

In its comments, FDA states that the report does not acknowledge that one individual assumed full responsibility for the ARL project as of August of 1995.

While FDA's comments now state that there was one high-level official responsible for the management and coordination of the ARL project since August of 1995, prior evidence provided to us by FDA contradict this statement. In responding to an earlier draft, FDA stated: "A functional statement was developed in July 1997 in which the Director, Division of Facilities Planning, Engineering, and Safety (DFPES), OFACS was identified as the sole person responsible for the planning, budget development and execution of projects . . . . This role did not exist in the agency prior to the establishment of this organization."

Regardless of when this leadership position was established by FDA, we noted that the individual appointed to this position, while highly knowledgeable about construction projects, did not appear to possess full authority to manage and coordinate the ARL project.

A&E Knowledge of Arkansas Area

The FDA commented that it did not believe our statements regarding the A&E firm's knowledge of market conditions in Arkansas were accurate, but it did not provide documentation to support its claim. Our statements about the A&E's limited knowledge of market conditions were based on documentation we reviewed during our visit to the A&E firm, which showed that the firm had not previously done any work in Arkansas, and had performed limited work in the area of assessing market conditions.

Planned Date of Contract Award

While FDA comments state that the contract was to be awarded in July of 1997, FDA documents indicate that originally the contract was to be awarded in January of 1996. The A&E firm informed us that FDA had instructed them to prepare their estimate based on a planned award date of the spring of 1996. For purposes of our analysis, we used the spring of 1996 target because the A&E firm responsible for developing the estimate used this time frame.

Thomas D. Roslewicz

APPENDICES

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food & Drug Administration

Memorandum

Date AUG 10 1999

From: Deputy Commissioner for Management and Systems

Subject: Comments on "Review of the Food and Drug Administration's Cost Increase for the Arkansas Laboratory

To: Deputy Inspector General for Audit Services

Thank you for the opportunity to comment on the final draft report of your review of the cost history of our Arkansas Regional Laboratory (ARL) project. As we have stated in our earlier comments on the discussion draft, we generally agree with your recommendations. However, we believe that the report still gives less than adequate credit to the fact that the recommendations have already been implemented. As has been noted in our earlier comments and the ensuing meetings between our staffs, FDA has taken steps over the last three and one-half years in establishing and staffing our Division of Facilities Planning, Engineering and Safety to achieve the goals inherent in your recommendations. This and other related management changes are more fully described in our point-by-point comments.

Attached are our specific comments regarding your findings, followed by a brief discussion of our views on each of your recommendations.

Robert J. Byrd

Robert J. Byrd

Attachment

FDA Comments on Draft OIG Report: "Review of the Food and Drug Administration's Cost Increase for the Arkansas Regional Laboratory

Throughout the report the auditor incorrectly refers to construction cost increases going up $10.4 million. The report should specifically state that the ARL project costs increased $10.4 million. The construction costs went up $7 million, not $10.4 million. Elsewhere in the report the $3.4 million project cost difference is correctly characterized as due to other factors.

The report also incorrectly states under the Summary of Findings that the FDA obtained an estimate that only included the estimated cost of construction (ECCP). The estimate obtained by FDA correctly included the ECCP, construction quality management, demolition and construction contingency costs. This statement is also inconsistent with the auditor's findings on Page 6 of the report which acknowledges that we increased the construction contingency which was attributable to $1.3 million of the $3.4 million cost increase.

There are a number of references in the draft concerning weaknesses in assigning responsibility for planning and budget development of construction projects to an official in the Office of Management and Systems. The report fails to acknowledge that FDA identified these weaknesses early on and established the organization and staffed the position of Director, Facilities Long Range Planning Staff in August 1995. That organization's title was later changed to the Division of Facilities Planning and Engineering (DFPES) by issuance of Staff Manual Guide 1124.75 in July 1997. The Division is responsible for the planning of current and future construction projects as described in the Staff Manual Guide functional statements. DFPES made budget corrections that lead to the $3.4 million project cost increase by establishing the categories and amounts to make a comprehensive budget projection as would have been done if they had developed the budget initially. Staff Manual Guide 1124.75, a copy of which was provided early in the review process, designates the Director, DFPES as the one high-level official responsible for management and coordination of the project.

We take exception that the report states that the Architect/Engineer (A/E) contractor revised its estimate upward in October 1996. The report fails to mention that when the FDA's FY 1997 appropriation did not include funds for ARL we asked the A/E to investigate phasing the project and reviewing cost estimates, i.e. this is the action that triggered the upward budget revision. Coincident with this effort, the A/E advised FDA of price escalations on the project and a value engineering effort was undertaken to offset these increases. When FDA subsequently did receive a 1997 appropriation for ARL, the A/E was directed to redocument the design packages into phases that reflected the appropriation amount and the value engineering items. FDA also included options in the construction solicitation package to guard against increasing prices and to assure that the construction contract could be awarded within available funds.

The draft also contains statements that seem to question the A/E's knowledge of the market conditions in the Arkansas area. We do not believe that these statements are accurate, and they would seem to be inconsistent with the auditors finding in this regard. The report correctly states that market conditions were escalating throughout the development of the estimate, and were corrected, as the A/E became aware of them.

The draft includes inaccurate information related to our original planned contract award for this project. We never intended to make a contract award in the spring of 1996. The Agency would not have received any apportionment of funds until at least January 1997 from our FY 1997 appropriation. We planned our contract award for June 1997 knowing that the A/E would need to redesign the project into phases and revise the construction cost estimates accordingly. FDA asked the A/E to undertake this work in October 1996 in accordance with the FY 1997 appropriation. This change resulted in a project that needed to be constructed in phases which resulted in an increased cost estimate, increased construction duration and delayed the award until September 1997.

General Comments:

Background, first paragraph – This characterizes ARL as focusing on Foods work. Reword sentence to read as follows: The ARL, now under construction, is part of FDA's 1994 plan to replace the existing array of 18 field laboratories with 5 large regional laboratories and 4 full service laboratories. The ARL, to be co-located with FDA's National Center for Toxicological Research (NCTR) in Jefferson, Arkansas, is a full service lab that will be most heavily involved in foods and animal drug and feed work. This includes both micro and chemistry for foods, drug residue work for CVM programs. Delete....."this includes conducting chemical and microbiological examination for biological hazards in foods for the Southwest region and part of the Central region."

Second paragraph – The sentence should be reworded as follows: "In its budget request for FY 1998, (formulated in January, 1996), FDA estimated laboratory costs to be $27,550,000." and total project costs to be $37,400,000."

Page 3, fourth bullet – National Center for Toxocological Research: assisted ORA in the development of the Program of Requirements for the project in FY 1994 which included a construction cost estimate.

Recommendations

1. Establish clear lines of responsibility for future construction projects by assigning responsibility for planning, budget development, and execution of the project to one high level official within the Office of Management.

The position of Director, Division of Facilities Planning Engineering and Safety (DFPES) (formerly titled Director, Facilities Long Range Planning Staff), was established in August 1995. The Director, DFPES, OFACS was identified as the sole person

responsible for the planning, budget development and execution of projects. This position is located within the Office of Management and Systems. The functional statement, provided to the auditor, was included in a Staff Manual Guide and published on July 16, 1997. The Director, DFPES takes final action to ensure that these actions occur. This role did not exist in the Agency prior to the establishment of this organization. Because the Agency did not have many major construction projects, this was not a problem that existed at that time.

2. Implement a system for tracking project costs throughout the budget development stage.

We have implemented a system for tracking project costs. As described in our previous response, by establishing the Director, DFPES as the single point of responsibility, the Agency provides all necessary oversight and guidance necessary to successfully complete construction projects. This system will enable management to monitor the accuracy of the costs entered into the system and to ensure that they have proper supporting documentation and approval. We have established a standard approach to the inclusion of all costs in the project budget – i.e., telecom, security operations, and contingency for all categories. Historically, the end user has requested that the Agency provide for telecommunication and security costs, which led to this funding coming out of an operating budget as opposed to the construction budget. Other agencies also budget these costs separately. Due to budget constraints, FDA had previously provided for these costs in another account.

3. Institute a policy to closely review budgets and estimates to ensure completeness and accuracy.

We have implemented a policy regarding the use of construction managers. Our policy states that there are three independent considerations that shall be analyzed by the Project Officer when evaluating the method for management of construction contracts. The project size measured in dollars, the project complexity, and the government's in-house skills. This range of considerations is consistent with the Public Health Service's Facilities Manual (PHS Chapter 5-1 PHS Facilities Manual (Volume I), PHS Transmittal 90.1).

4. Institute general policies regarding developing construction project budget.

Refer to answer number 1, 2, and 3 above. We relied on standard operating procedures provided in the PHS Facilities Guide that provide guidance on the development of project estimates, on the calculation of construction contingency and when a construction quality management company is necessary. Since this project was established, PHS is no longer in existence and there is no supplemental Departmental guidance on the procedures that we are required to follow. Therefore, we will continue to rely on the PHS Facilities Guide as our policy to develop construction project budgets.

In conclusion, we want to emphasize that the FDA took appropriate action to address the observations and recommendations presented in this report and responsibly implemented policies and procedures that have been firmly in place for a significant period of time.

TKLP The Kling-Lindquist Partnership, Inc.

Architecture Engineering
Interior Design &
Consulting Services

UNITED STATES FOOD AND DRUG ADMINISTRATION

JEFFERSON LABORATORIES

Arkansas Regional Laboratory
and
National Center for Toxicological Research

Jefferson, Arkansas

ESTIMATE OF PROBABLE CONSTRUCTION COST FOR TOTAL PROJECT

- Site / Civil
- Mall
- ARL Building
- Building 50
- Building 62 Addition

January 11, 1996

2301 Chestnut Street
Philadelphia, Pennsylvania 19103
215 569 2900

FDA Contract Number: 223-95-9527
KL Project Number: 89-3190-00