DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Memorandum

Date AUG 27 1993

From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Financial Audit of the Food and Drug Administration's Revolving Fund for Certification and Other Services (A-15-93-00007)

To Philip R. Lee, M.D.
Assistant Secretary for Health

The attached audit report prepared by KPMG Peat Marwick (KPMG), independent public accountants, under contract with the Office of Inspector General indicates opportunity for improving financial management at the Food and Drug Administration (FDA). The Chief Financial Officers Act requires that the audit report be prepared in accordance with Government Auditing Standards and the Office of Management and Budget's Bulletin 93-06, Audit Requirements for Federal Financial Statements.

The KPMG auditors expressed an unqualified opinion on FDA's Revolving Fund for Certification and Other Services' (Fund) financial statements but found problems with internal controls and compliance with laws and regulations in the areas of input and processing controls, overhead allocation, and proprietary and budgetary account balancing. They also found that while some prior year problems were resolved, other problems found in the previous year's audit have not been fully resolved.

The FDA comments on KPMG's recommendations for resolving problems found this year and those continuing since last year's audit were incorporated in the final report. We would appreciate receiving written comments and a status report on progress in implementing the recommendations within 60 days from the date of this memorandum. If you wish to discuss this report please call me or have your staff contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301) 443-3583.

We would like to express our appreciation for the efforts made by FDA officials in producing the Fund's financial reports. These efforts represent a substantial commitment to improving the Fund's financial management.

Attachment

cc:
Kenneth S. Apfel, Chief Financial Officer
Department of Health and Human Services

Anthony L. Itteilag, Chief Financial Officer
Public Health Service

David A. Kessler, M.D.
Commissioner of Food and Drugs

Sharon Smith Holston, Chief Financial Officer
Food and Drug Administration

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

FINANCIAL AUDIT OF THE FOOD AND DRUG ADMINISTRATION'S REVOLVING FUND FOR CERTIFICATION AND OTHER SERVICES

AUGUST 1993 A-15-93-00007

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From Bryan B. Mitchell
Principal Deputy Inspector General

Subject Financial Audit of the Food and Drug Administration's Revolving Fund for Certification and Other Services (A-15-93-00007)

To Philip R. Lee, M.D.
Assistant Secretary for Health

The audit report prepared by KPMG Peat Marwick (KPMG), independent public accountants, under contract with the Office of Inspector General indicates significant opportunity for improving financial management at the Food and Drug Administration (FDA). The following KPMG report on reasonableness of amounts, internal controls, and compliance with laws and regulations for FDA's Revolving Fund for Certification and Other Services (Fund) for Fiscal Year (FY) 1992 financial statements are located at the pages indicated.

Reports	Pages
Opinion on financial statements	B-1 to B-2
Internal controls and compliance	C-1 to C-3
Summary of current year findings	C-4 to C-6
Problems identified last year that are not fully corrected	C-7 to C-11
Problems identified last year that were corrected	C-12 to C-14

The Chief Financial Officers (CFO) Act requires that the audit report be prepared in accordance with Government Auditing Standards and the Office of Management and Budget's Bulletin 93-06, Audit Requirements for Federal Financial Statements.

The KPMG auditors expressed an unqualified opinion on the Fund's financial statements but found problems in the following areas:

- Input and Processing Controls - Most of the year-end adjustments, which are supposed to be for the purpose of closing out the books for the year, were to correct errors made during the year due to incorrect posting, duplication of entries, and unposted prior year audit adjustments. Accounting errors, especially those not detected on a timely basis, can erode internal controls, result in erroneous financial reports, and increase the likelihood of noncompliance with laws and regulations.

- Overhead Allocation - The FDA did not adjust the estimates used in allocating expenses during the year to reflect actual data at year-end. As a result the Fund could be using erroneous data as a basis for determining charges to customers.

- Proprietary and Budgetary Account Balancing - An out-of-balance condition existed within the proprietary accounts and the budgetary accounts as the result of use of the Unobligated Allotments budgetary account as an equity account. One requirement of the United States Treasury Standard General Ledger accounting system is that budgetary and proprietary accounts be self-balancing.

The KPMG auditors also found that while some prior year problems were resolved, the following problems found in the previous year's audit have not been fully resolved.

- Controls Over Equipment Inventory and Costs - The FDA has not fully addressed internal control concerns of independence and segregation of duties pertaining to the conduct of physical inventories of equipment.

- Controls Over Transfers of Expenses - The FDA implemented procedures requiring review and approval of journal vouchers at a supervisory level lower than was recommended in instances where material amounts are transferred between appropriations.

- Compliance With Requirements for Setting Fees - The FDA's evaluation of the color fee is expected to be completed by the end of FY 1993.

- Controls Over Cash Collections - The FDA implemented segregation of duties improvements recommended in the prior year, but additional safeguards are needed to strengthen FDA's handling of checks.

- Compliance with the Federal Managers' Financial Integrity Act (FMFIA) - The FDA needs to assure that FMFIA reviews of all of its programs and activities take into account problems noted in the Fund's CFO Act audits, since the internal control and accounting system used for the Fund is also used for other FDA programs.

The FDA comments on KPMG's recommendations for resolving problems found this year and those continuing since last year's audit are incorporated in the final report. We would appreciate receiving written comments and a status report on progress in implementing the recommendations within 60 days from the date of this memorandum. If you wish to discuss this report please call me or have your staff contact Daniel W. Blades, Assistant Inspector General for Public Health Service Audits, at (301) 443-3583.

KPMG Peat Marwick

Certified Public Accountants

2001 M. Street, N.W.
Washington, DC 20036

Independent Auditors' Report

Principal Deputy Inspector General and
The Assistant Secretary for Health
U.S. Department of Health and Human Services:

We have audited the statement of financial position of the Food and Drug Administration's Revolving Fund for Certification and Other Services (Certification Fund) as of September 30, 1992, and the related statements of operations, cash flows, and budget and actual expenses for the year then ended. These financial statements are the responsibility of the management of the Certification Fund. Our responsibility is to express an opinion on these financial statements based on our audit. The financial statements of the Certification Fund for the year ended September 30, 1991, were audited by the Department of Health and Human Services' Office of Inspector General (DHHS-OIG). The DHHS-OIG report, dated June 30, 1992, contained an unqualified opinion on the statement of financial position and did not give an opinion on the statements of operations, cash flows, and budget and actual expenses.

We conducted our audit in accordance with generally accepted auditing standards; Government Auditing Standards, issued by the Comptroller General of the United States; and OMB Bulletin No. 93-06, "Audit Requirements for Federal Financial Statements." Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

As required by OMB Bulletin No. 93-02, "Form and Content of Agency Financial Statements," Note 1 to the financial statements describes the accounting policies used by the Certification Fund to prepare the financial statements. These policies comprise a comprehensive basis of accounting other than generally accepted accounting principles.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Food and Drug Administration's Revolving Fund for Certification and Other Services as of September 30, 1992, and the results of its operations and its cash flows for the year then ended, in conformity with the basis of accounting described in Note 1.

The financial information presented in Management's Discussion and Analysis is not a required part of the basic financial statements but is supplementary information required by OMB Bulletin No. 93-02. This information has not been subjected to the auditing procedures applied in the audit of the principal financial statements and, accordingly, we express no opinion on such information.

This report is intended for the information of the Certification Fund's management, the DHHS-OIG, and the Office of Management and Budget. However, this report is a matter of public record and its distribution is not limited.

KPMG Peat Marwick

June 11, 1993

KPMG Peat Marwick

Certified Public Accountants

2001 M. Street, N.W.
Washington, DC 20036

Independent Auditors' Report on Internal Controls and Compliance

Principal Deputy Inspector General and
The Assistant Secretary for Health
U.S. Department of Health and Human Services:

We have audited the financial statements of the Food and Drug Administration's Revolving Fund for Certification and Other Services (Certification Fund), as of and for the year ended September 30, 1992, and have issued our report thereon dated June 11, 1993.

We conducted our audit in accordance with generally accepted auditing standards; Government Auditing Standards, issued by the Comptroller General of the United States; and Office of Management and Budget (OMB) Bulletin No. 93-06, "Auditing Requirements of Federal Financial Statements." Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

In planning and performing our audit of the Certification Fund's financial statements for the year ended September 30, 1992, we considered its internal control structure. The purposes of this consideration were to: (i) determine our auditing procedures for the purpose of expressing our opinion on the financial statements; and (ii) determine whether the internal control structure meets the objectives identified in the following paragraph. Our consideration included obtaining an understanding of the significant internal control structure policies and procedures and assessing the level of control risk relevant to all significant cycles, classes of transactions, or account balances.

Management of the Certification Fund is responsible for establishing and maintaining an internal control structure. In fulfilling this responsibility, estimates and judgments by management are required to assess the expected benefits and related costs of internal control structure policies and procedures. The objectives of an internal control structure are to provide management with reasonable, but not absolute, assurance that transactions, including those related to obligations and costs, are executed in compliance with laws and regulations that the OMB, Certification Fund management, or the Office of Inspector General have identified as being significant for which compliance can be objectively measured and evaluated; funds, property, and other assets are safeguarded against loss resulting from unauthorized use or disposition; transactions are properly recorded and accounted for to permit the preparation of reliable financial reports in accordance with applicable accounting policies and to maintain accountability over assets; and data supporting the reported performance measures are properly recorded and accounted for to permit preparation of reliable and complete performance information. Because of inherent limitations in any internal control structure, errors or irregularities may nevertheless occur and not be detected. Also, projection of an evaluation of the structure to future periods is subject to

the risk that procedures may become inadequate because of changes in conditions or that the effectiveness of the design and operation of policies and procedures may deteriorate.

For the purpose of this report, we have classified the significant internal control structure policies and procedures in the following categories:

- Revenue and receipts
- Purchases and disbursements
- Payroll
- Financial reporting
- Performance measures

For all the internal control structure categories listed above, we obtained an understanding of the design of relevant policies and procedures, determined whether they have been placed in operation, assessed control risk, and performed tests of the control procedures. Our review of the controls for performance information was limited to obtaining an understanding of those controls designed to ensure the existence and completeness of the information.

Compliance with laws and regulations applicable to the Certification Fund is the responsibility of the Certification Fund's management. As part of obtaining reasonable assurance about whether the financial statements are free of material misstatements, we tested compliance with certain provisions of the following laws and regulations that may directly affect the financial statements and certain other laws and regulations designated by OMB, the Certification Fund, and the Office of Inspector General, including but not limited to the: Budget and Accounting Procedures Act of 1950; Prompt Payment Act; Chief Financial Officers Act of 1990; Debt Collection Act of 1982; Antideficiency Act; Federal Employees' Compensation Act; Civil Service Reform Act; Civil Service Retirement Act; and Fair Labor Standards Act. We also obtained an understanding of management's process for evaluating and reporting on internal control and accounting systems as required by the Federal Managers' Financial Integrity Act (FMFIA) and compared the FDA's most recent FMFIA reports with the evaluation we conducted of the Certification Fund's internal control structure. Our objective was not, however, to provide an opinion on overall compliance with the above provisions. Accordingly, we do not express such an opinion.

We noted certain matters involving the internal control structure and its operation that we consider to be reportable conditions under standards established by the American Institute of Certified Public Accountants and OMB in Bulletin No. 93-06. Reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of the internal control structure that, in our judgment, could adversely affect the entity's ability to ensure that the objectives of the internal control structure, as previously defined, are being achieved. These reportable conditions are described below in the section titled Summary of Current Year Findings. In addition, we have included in Exhibit I the uncorrected prior year's reportable conditions that we consider to be reportable conditions for the current year.

A material weakness is a reportable condition in which the design or operation of the specific internal control structure elements does not reduce to a relatively low level the risk that errors or irregularities in amounts that would be material in relation to the financial statements being audited, or to a performance measure or aggregation of related performance data, may occur and not be detected within a timely period by employees in the normal course of performing their assigned functions.

Our consideration of the internal control structure would not necessarily disclose all matters in the internal control structure that might be reportable conditions and, accordingly, would not necessarily disclose all reportable conditions that are also considered to be material weaknesses as defined above. However, we believe none of the reportable conditions previously referred to is a material weakness.

The results of our tests of compliance indicate that, with respect to the items tested, the Certification Fund complied, in all material respects, with the provisions referred to in the seventh paragraph of this report. With respect to the items not tested, nothing came to our attention that caused us to believe that the Certification Fund had not complied, in all material respects, with those provisions.

We also noted other matters involving the internal control structure and its operations that we reported to the Certification Fund's management in a separate letter.

This report is intended for the information of the Certification Fund's management, the Department of Health and Human Services' Office of Inspector General, and the Office of Management and Budget. However, this report is a matter of public record and its distribution is not limited.

KPMG Peat Marwick

June 11, 1993

SUMMARY OF CURRENT YEAR FINDINGS

We noted the following reportable conditions and nonmaterial instances of noncompliance in performing the current year audit.

REPORTABLE CONDITIONS

Input and Processing Controls

We noted that several of the year-end adjustments made by FDA were corrections resulting from the incorrect posting of approved journal vouchers or the duplication of entries. For example, depreciation expense had a negative (credit) balance on the September 30, 1992 pre-close general ledger as a result of incorrect posting. These items were not discovered until year end when the financial statements were being prepared.

These kinds of input and posting problems can be prevented if the individuals preparing the journal vouchers review the general ledger "offlines" (edit reports) prior to posting. These problems can also be detected if a monthly analytical review of general ledger balances for reasonableness is performed. The DHHS accounting manual incorporates the U.S. General Accounting Office's Policy and Procedures Manual for Guidance of Federal Agencies, Title 2, Appendix III, which requires that agencies' accounting processes and procedures include (1) input controls to detect erroneous and duplicate transactions and ensure control until corrected and (2) output controls to provide reasonable assurance that the output is correct and complete. (See Exhibit I, Controls Over Transfer of Expenses, for prior year comments related to journal voucher processing.)

Recommendation #1

We recommend that FDA institute a written procedure requiring the individuals who prepare and input the journal vouchers to review the "offlines" to ensure proper posting of the journal vouchers to the general ledger.

FDA Comment

The FDA officials concurred and indicated that the Office of Financial Management (OFM) will draft written procedures that document existing prevention and detection controls pertinent to journal voucher input.

Recommendation #2

We recommend that FDA institute a written procedure requiring the supervisor of Accounting Reports and Analysis, or a senior operating accountant, under the direction of this supervisior, to perform a monthly review of general ledger balances to identify any irregularities. This would include investigating significant variances between actual and budgeted amounts and current and prior month actuals.

FDA Comment

The FDA officials concurred with the intent of the recommendation and indicated that (1) a senior operating accountant would perform monthly reviews and analyses of the general ledger balances, and (2) the Chief, Accounting Reports and Analysis Branch, would perform a quarterly review and analysis. The officials added that workload requirements and resource limitations do not permit monthly reviews by the branch chief.

Overhead Allocation

FDA allocates to the Certification Fund a percentage of the agency's rent, rent-related expenses, telecommunications, postage, and health-related costs. At the beginning of the fiscal year Budget Execution estimates what the expenditures will be for the year. On a quarterly basis, the Certification Fund records an entry for a quarter of the Certification Fund's total allocation.

In our review of the overhead allocation of expenses, we noted that the estimate was not adjusted at year end to reflect actual data. The lack of an adjustment to actual resulted in the operating expense accounts for rental, communications and utilities, and printing and reproduction, to be inaccurate.

Recommendation #3

We recommend that FDA institute a formal policy requiring Accounting Reports and Analysis, in conjunction with Budget Execution, to adjust the overhead allocation to actual expenditures at year end .

FDA Comment

The FDA officials concurred and indicated a formal year-end overhead allocation policy will be drafted and procedures will be issued to implement the policy.

INSTANCE OF NONCOMPLIANCE

Proprietary and Budgetary Account Balancing

The Certification Fund's general ledger, including both proprietary and budgetary accounts, was in balance as of September 30, 1992. However, neither the proprietary accounts alone nor the budgetary accounts alone were in balance. This out-of-balance condition resulted from the use of the Unobligated Allotments budgetary account as an equity account (cumulative results of operations). (This condition did not, however, affect the accuracy of the financial statements.) One of the U.S. Treasury's Standard General Ledger (SGL) accounting system requirements is that budgetary and proprietary accounts be self-balancing.

Recommendation #4

We recommend that FDA discontinue using budgetary accounts as equity accounts and begin to use the cumulative results of operations equity account as provided for in HHS' Accounting Manual Section 5-20.

FDA Comment

The FDA officials concurred and indicated that OFM will implement procedures to use the proper general ledger equity account and discontinue using a budgetary account as an equity account.

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Exhibit II is a summary of the status of corrected prior year reportable conditions.

We also noted certain other matters involving the internal control structure and its operation and compliance with laws and regulations that we have reported to management of the Certification Fund in a separate letter.

This report is intended for the information of the Certification Fund's management, the Department of Health and Human Service's Office of Inspector General, and the Office of Management and Budget. This restriction is not intended to limit the distribution of the report, which is a matter of public record.

Reportable Conditions and Instances of Noncompliance Uncorrected or Partially Corrected Since Prior Year Report

As part of the procedures performed, we followed up on prior year findings to determine the extent to which the recommendations have been implemented by the management of the Certification Fund. We consider the following uncorrected items identified in the prior year's Auditors' Report on Internal Controls and Compliance as reportable conditions and instances of noncompliance.

Revolving Fund Fees

Controls over Equipment Inventory and Costs

1991 Finding: In its 1991 audit, the Department of Health and Human Services Office of Inspector General (DHHS-OIG) concluded that FDA's accounting records maintained by the Division of Financial Management (DFM)* and the subsidiary records maintained by the Personal Property Management Section (PPMS) did not support the amounts shown on the financial statements. This condition existed because PPMS generally did not get involved in physical inventory activities and had not taken action to adjust the subsidiary property records to reflect the February 1992 physical inventory results. The DFM, PPMS and the custodial officers did not sufficiently work together, as designed, to assure the existence of appropriate internal controls and the maintenance of accurate records of the Fund's financial management activities and stewardship of assets.

1991 Recommendation #2: The DHHS-OIG recommended that FDA require PPMS, together with the custodial officers, to conduct all future physical inventories of property, plant and equipment until such time as the accounting and property records are current and accurately maintained.

Current Status: Public Health Service (PHS)/FDA agreed with the intent of this recommendation. During our audit, however, FDA/PPMS reiterated its position that it has no plans to perform an inventory with the custodial officers. It further indicated that FDA conforms to current HHS inventory requirements and it is not practical or cost-effective to change its practices. Accordingly, the DHHS-OIG's 1991 recommendation remains open.

Due to the nature of the assets to which FDA has title (i.e. they are expensive and movable), we support the recommendation that PPMS and the custodial officer conduct annual physical inventories of property, plant and equipment, so that the inventory is taken, in part, by an independent party. The U.S. General Accounting Office's Standards for Internal Controls in the Federal Government requires that key duties and responsibilities in recording and reviewing transactions be separated among individuals. FDA officials have not addressed this independence/segregation of duties issue.

* The title has since been changed to the Office of Financial Management.

1991 Recommendation #5: DHHS-OIG recommended that FDA management determine whether the problems experienced with the Fund's accounting and control over property are occurring in other FDA activities.

Current Status: FDA is currently performing a detailed agency wide FMFIA Section 2 review of property management. Accordingly, the DHHS-OIG's 1991 recommendation, with which we concur, remains open.

Controls Over Transfers of Expenses

1991 Findings: The DHHS-OIG found that, with regard to the transfer of expenses between appropriations, FDA did not have a written policy requiring supervisory approval of journal vouchers (JVs) or the Director of DFM to review all journal vouchers over a certain threshold amount.

1991 Recommendations #6 & 7: The DHHS-OIG recommended that FDA establish written procedures requiring all JVs be reviewed and approved by a supervisor, and JVs over a specified amount be reviewed by the Director of DFM. The DHHS-OIG further recommended that the FDA establish what the threshold amount should be.

Current Status: PHS/FDA concurred with recommendation #6. A memo was written and distributed to all accounting personnel that requires all JVs to be reviewed and approved by one of two supervisors (or designees, in the supervisors' absence) in Accounting Reports and Analysis or by the Accounting Branch chief. Per review of fiscal year 1992 JVs, review and approval was properly evidenced by signature of one of the supervisors or their designees. PHS/FDA noted, however, that they did not believe it reasonable or necessary for the Director of DFM to be involved with the review and approval of JVs. We find PHS' corrective action to be acceptable, except as regards the transfer of expenses between appropriations.

1992 Recommendation #5

We support the DHHS-OIG's 1991 recommendation. Due to the potential sensitivity of interappropriation transfers, we believe that director-level approval of transfers over a certain threshold amount is needed. Accordingly, we recommend FDA implement a policy and procedures for the Director of OFM to review and approve JVs over a specified amount involving transfers between appropriations and that FDA establish the appropriate threshold.

FDA Comment

The FDA officials did not concur, stating that it is not necessary for the Director of OFM to review and approve vouchers, because the Director of the Accounting Division (who currently reviews and approves JVs) is FDA's chief certifying officer and can certify payments at any level.

Auditors' Comment

We do not find FDA's comment to be responsive to the recommendation as regards interappropriation transfers.

Compliance With Requirements for Setting Fees

1991 Finding: The DHHS-OIG found that certain equipment costs were not considered in the analysis on which the November 1991 insulin fee schedule revision was based. The DHHS-OIG noted that the then-pending revision to the color additive fee schedule would also have to take into consideration such equipment costs.

1991 Recommendation #8. The DHHS-OIG recommended that FDA reevaluate the adequacy of the 1991 insulin fee after the equipment inventory previously discussed is completed and include the revised equipment costs in the current evaluation of the color additive fee.

Current Status: During our audit, we noted that a fee study for insulin was not performed by the end of FY 1992 but was completed during FY 1993. The color fee study is in the process of being performed and should be completed by the end of FY 1993. Accordingly, the DHHS-OIG's 1991 recommendation, with which we concur, remains open.

Controls Over Cash Collections

1991 Finding: The DHHS-OIG found the segregation of duties over cash collections to be inadequate. For example, a single DFM employee received manufacturers' certification checks, deposited the checks and recorded the cash receipts, including the certification revenue entry. The DHHS-OIG noted that the FDA issued a new procedure during FY 1992 that addressed the segregation of duties related to cash receipts; however, the DHHS-OIG did not evaluate the new procedure.

1991 Recommendations #14 and #15: The DHHS-OIG recommended that FDA separate the functions of cash receipt, deposit, and accounting and establish procedures to reconcile mail room lists to deposit slips.

Current Status: During our audit, we found that DFM has instituted a policy that all mail initially goes to a person in Funds Control who prepares a listing of the checks. However, the person in Funds Control does not restrictively endorse the checks "For Deposit Only- FDA Account XXXX." The checks go without endorsement to Accounts Receivable where another listing is prepared, the deposit slip is prepared, and the checks are endorsed. Accounts Receivable also makes the deposit to the bank. An accountant in Accounting Reports and Analysis reconciles the two lists to each other and the validated deposit ticket.

1992 Recommendation #6

We recommend that the person in Funds Control restrictively endorse the checks, deposit the checks in the bank, and forward the list of checks, together with photocopies, to Accounts Receivable. A less effective control would be achieved if the person in Funds Control were to endorse each check, and then forward the checks to Accounts Receivable.

FDA Comment

The FDA officials concurred and agreed to implement restrictive endorsement procedures and to begin forwarding to Accounts Receivable a list of checks accompanied by check photocopies.

Compliance with FMFIA

1991 Finding: The DHHS-OIG raised a question about the validity of FDA's FMFIA activities. Because of the internal control weaknesses and accounting system nonconformances identified in the 1991 audit, the OIG felt that the Certification Fund's management could not provide assurance of its compliance with FMFIA requirements until the OIG's reported deficiencies were corrected.

1991 Recommendation #16: The DHHS-OIG recommended that FDA management implement all of the recommendations included in the 1991 audit report prior to the end of FY 1992.

Current Status: Some recommendations have been implemented (Exhibit II); others have not (Exhibit I). Accordingly, the DHHS-OIG's 1991 recommendation, with which we concur, remains open.

1991 Finding: The DHHS-OIG found that FDA's FMFIA reports did not include the system nonconformances identified by the DHHS-OIG as a result of the 1991 audit.

1991 Recommendation #17: The DHHS-OIG recommended that FDA management require FDA's Internal Control Officer (ICO) to determine the cause(s) for the failure of FDA's FMFIA reviews to identify the nonconformances with Title 2 that were identified in the 1991 audit, and report those causes to the PHS ICO and CFO by the end of FY 1992.

Current Status: FDA officials concurred with the intent of the recommendation. They informed PHS that the nonconformances were not identified because the purpose of FMFIA reviews is substantially different from the purpose of an audit of the Certification Fund's financial statements under the CFO Act. They also stated that the objective of FMFIA reviews is not to provide 100% assurance that all areas of nonconformance will be identified. However, because reportable conditions continued to be noted in the 1992 audit that were not identified in the 1992 FMFIA reports (see the Summary of Current Year Findings as well as all uncorrected prior year findings discussed in Exhibit I), this condition still exists.

1992 Recommendation #7

We recommend that, in light of the matters identified in the 1991 and 1992 audits, FDA's ICO consider the annual CFO Act internal control and compliance audit findings when planning and conducting subsequent years' FMFIA activities and incorporate the audit-identified internal control and accounting system areas of concern into ensuing OMB Circulars A-123 and A-127 reviews.

1991 Recommendation #18: The DHHS-OIG recommended that FDA management document the accounting system, including its ADP aspects, to meet the requirements of Title 2.

Current Status: PHS/FDA concurred with the objective of this recommendation but maintained that the accounting system was adequately documented. FDA stated that it would update the system documentation periodically as changes are made or software is replaced. It is our understanding, however, that no changes were made as a result of the OIG's 1991 recommendation. Accordingly, the DHHS-OIG's 1991 recommendation remains open.

1991 Recommendation #20: The DHHS-OIG recommended that FDA management ensure that the reviews required by Sections 2 and 4 of FMFIA evaluate the other FDA activities for the deficiencies identified in the 1991 audit report. These reviews were to be completed as part of the financial reporting for FY 1992 on compliance with FMFIA.

Current Status: PHS/FDA concurred with the intent of this recommendation, except that, due to the lateness of the prior year audit report, they did not feel there was sufficient time to consider all of the OIG's 1991 findings for inclusion in the 1992 FMFIA report. Accordingly, the DHHS-OIG's 1991 recommendation, with which we concur, remains open.

1992 Recommendation #8

We recommend that FDA ensure that future FMFIA Section 2 and Section 4 reviews of other FDA components' activities consider the results of the FY 1991 and FY 1992 CFO Act audits. Because these "other" FDA activities (outside FDA's Revolving Fund for Certification and Other Services) make use of the internal control and accounting processing systems used by the Fund, the other activities are likely affected by some or all of the findings noted in the Fund's CFO Act audit reports.

Reportable Conditions and Nonconformances Corrected Since the Prior Year Report

Management of the Certification Fund has corrected the following reportable conditions and nonmaterial instances of noncompliance identified in the prior year Auditor's Report on Internal Control and Compliance.

Revolving Fund Fees

Controls over Equipment Inventory and Costs

1991 Finding: In its 1991 audit, the DHHS-OIG found that the FDA's accounting records maintained by the Division of Financial Management (DFM) and the subsidiary records maintained by the Personal Property Management Section (PPMS) did not support the 1991 financial statement amounts.

1991 Recommendation #1: The DHHS-OIG recommended that FDA require PPMS to adjust the subsidiary property records to reflect the value of equipment on hand at the end of FY 1991.

Current Status: We determined that the subsidiary property records and the general ledger were adjusted to reflect the proper value of equipment on hand.

1991 Recommendation #3: The DHHS-OIG recommended that FDA require DFM and PPMS to reconcile monthly the subsidiary property records with the amount recorded for property in the general ledger and advise the FDA's CFO of the results.

Current Status: We determined that monthly reconciliations are now prepared between the subsidiary property records and the general ledger.

1991 Recommendation #4: The DHHS-OIG recommended that FDA require DFM to establish and follow procedures for preparing financial statements based on amounts recorded in the general ledger.

Current Status: We determined that Accounting Reports and Analysis now prepares a spreadsheet using the general ledger balances. Except for audit adjustments, which are recorded in the subsequent period, adjustments are recorded on the spreadsheet and posted to the general ledger in the current period.

Compliance With Requirements for Setting Fees

1991 Finding: The DHHS-OIG found that FDA had no written requirement for annual fee schedule reviews and adjustments.

1991 Recommendation #9: The DHHS-OIG recommended that FDA establish a written procedure to evaluate fee schedules on an annual basis and seek revisions, as needed, to fully recover all direct and indirect costs for processing certifications for which FDA is permitted by law to charge a fee.

Current Status: We found that a directive has been written and distributed to the appropriate accounting personnel requiring Accounting Reports and Analysis to prepare a monthly status of funds report, and for the Accounting Branch chief to perform a quarterly review of income statement and balance sheet amounts. In addition, the Color Division Director and the Branch Chief are to perform an annual review of the year-end financial reports. FDA management believes these reviews are sufficient to identify any deficiencies in fees.

Compliance with Prepayment Requirements for Certification Fees

1991 Finding: The DHHS-OIG found that FDA was not enforcing regulatory requirements for manufacturers to prepay fees for certifying color additives and insulin.

1991 Recommendation #10: The DHHS-OIG recommended that FDA establish formal procedures affixing responsibility to ensure both color and insulin laboratories do not begin tests on product samples unless the fee is prepaid. The FDA was to assign this responsibility to administrative officers in the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Drug Evaluation and Research (CDER).

Current Status: FDA management assigned the responsibility to designated individuals to ensure that there are sufficient funds prior to initial testing. Also, within the ORACLE data base system for color, there is an adjunct system which is accessed to ensure sufficient funds are on account. When color samples are received for testing, they are logged into the ORACLE. However, the ORACLE will not accept the sample if, after accessing the adjunct system, there are insufficient funds for the sample. All samples which are rejected by ORACLE for insufficient funds will remain in the receiving area. An FDA representative will also call the manufacturer and inform them that their sample is on hold until sufficient funds are received. Accounting Reports and Analysis has access to the adjunct system to record receipts from manufacturers.

Color Additive Petition Revenue

1991 Finding: The DHHS-OIG found that the FDA accounting system's procedures and computer software did not comply with Title 2 requirements in that receivables and payables related to color additive petition revenues were not recorded.

1991 Recommendation #11: The DHHS-OIG recommended that FDA evaluate its accounting system and procedures for the netting of receivables against liabilities and take appropriate action to correct the recording and reporting deficiency.

Current Status: In the FY 1991 financial statements, the netting was corrected and recognized at the gross amounts. In FY 1992, FDA decided to manually correct the results of any netting, however, there was none.

1991 Recommendation #12: The DHHS-OIG recommended that FDA establish manual procedures or correct its accounting system software to properly record and report expenses and liabilities for items received but not paid at the end of the reporting period.

Current Status: For FY 1992, FDA has recorded an accrual for items received and invoiced, but not paid, in the "AutoPay" system. We tested this accrual without exception.

1991 Recommendation #13: The DHHS-OIG recommended that FDA establish procedures to properly record petition revenue for that portion of the fee that is not refundable.

Current Status: Procedures have been developed to monitor the status of the petition and to record the nonrefundable processing fee revenue up front and the balance after the petition is accepted.

Compliance with FMFIA

1991 Recommendation #19: The DHHS-OIG recommended that FDA management demonstrate the connection between the FMFIA reviews conducted and the Fund management's statement that the Fund had been subjected to FMFIA review.

Current Status: In the 1992 detailed FMFIA review of the central accounting system, FDA specifically included Certification Fund transactions as evidence of the Fund being subjected to FMFIA review.

U.S. PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
FINANCIAL STATEMENTS
FISCAL YEAR 1992

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

INTRODUCTION

The Chief Financial Officers (CFO) Act of 1990 requires the Food and Drug Administration to prepare financial statements for all accounts that involve substantial commercial activity. The Revolving Fund for Certification Services falls under this requirement and will be discussed in the following section.

Background on Overall Agency

The Food and Drug Administration (FDA), established by the Food and Drug Act of 1906, is the oldest and principal consumer protection agency of the Federal Government. FDA, which is part of the Department of Health and Human Services (DHHS), is mandated to maintain and protect the public health. In carrying out its mandate, FDA regulates over $750 billion worth of products which account for some 25 cents of every dollar spent annually by American consumers.

FDA's responsibilities include ensuring 1) that food is safe and wholesome; 2) that human and animal drugs, biological products (vaccines and blood products), and medical devices are safe and effective; 3) that radiological products are safe and do not expose people to unnecessary radiation; 4) that cosmetics are safe and unadulterated; and 5) that all these products are honestly and informatively labeled.

FDA consists of the Office of the Commissioner, field organizations which include 25 district and local offices in 157 cities, and six centers. FDA's administrative headquarters are located in Rockville, Maryland. With the exception of the National Center for Toxicological Research which is located in Jefferson, Arkansas, the Centers are headquartered in the Washington metropolitan area. About 9,000 employees carry out FDA responsibilities. These employees include physicians, attorneys, investigators, inspectors, biologists, toxicologists, pharmacists, microbiologists, consumer affairs officers, information specialists, engineers, and clerical and support staff. The majority of FDA employees are employed in headquarters offices. Approximately 3,000 of FDA's employees constitute the Agency's field force and are responsible for surveillance and enforcement of all programs. FDA's total funding for Fiscal Year (FY) 92 was over $746 million.

Background on Audited Funds

As mentioned above, FDA operates funds involving substantial commercial activity. The Fund for Certification Services is the largest and most active of the funds, totaling $4.3 million, or about one-half of one percent of FDA's total funding. Insulin and color additive certifications take place in the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Drug Evaluation and Research (CDER).

While these statements have been prepared from FDA's books and records in accordance with the formats prescribed by OMB, they are different from the financial reports used to monitor and control budgetary resources that are prepared from the same books and records. In addition, these statements should be read with the realization that they are for a sovereign entity and that unfunded liabilities reported in these financial statements cannot be liquidated without the enactment of an appropriation and that the payment of all liablities other than for contracts can be abrogated by FDA.

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

EXECUTIVE SUMMARY

Color Certification Program

The FDA Color Additive Certification Program is a statutorily mandated program which certifies an estimated 10 million pounds of color annually for use in foods, drugs, cosmetics, and medical devices sold in the United States. For example, color additives are used to impart color to everyday products such as hot dogs, hair dyes, OTC drugs, and contact lenses. The number of companies that manufacture color additives has fluctuated only slightly over the past five years and averages twenty-five annually. As mandated by Federal Statute, this program is self-supporting by fees paid by the manufacturers.

Color certification fees, which are based on the size of the batch certified, have not increased since 1983. Despite this, the steady growth of the color additive market, with its corresponding increase in the amount of color additives, generated sufficient revenue through FY 89 to keep revenue ahead of expense and build up retained earnings. However, the number of pounds certified, which is a key indicator in forecasting workload/revenue, has leveled off and the costs associated with the Program continue to escalate. Specifically, 11.5 million pounds of color additives were certified in FY 92 compared to 9.2 million pounds in FY 89. The current fee structure is based upon the size of the batch certified. For example, the cost to the manufacturer is 22 cents per pound based on the weight of each batch with a minimum charge of $160.00.

A fee study of the Color Certification Program is currently underway. The study, which is similar in scope to the Insulin Program cost study discussed below, will evaluate all aspects of the program including overhead rates and inflation factors. Publication of a new fee structure is targeted for FY 1993.

Insulin Certification Program

The FDA Insulin Certification Program is a statutorily mandated program which serves an estimated 1 million insulin dependent diabetic patients in the United States. Currently, two manufacturers, Eli Lilly and NOVO NORDISK, hold the necessary New Drug Application approvals to market insulin preparations. The overriding concern in requiring the pre-market certification of insulin is the diabetic patient's extreme fragility. The patient's survival not only depends upon a continuing supply of insulin, but more importantly on the precision with which the potency is determined. Both over or under dosing can be fatal.

The Insulin Certification Program was established in 1941 by amendment to the FD&C Act of 1938. The fund was established on a user fee basis, i.e., the manufacturers are assessed a fee to provide funding for the program. No appropriated funds are provided. Samples of insulin are required to be submitted to FDA for certification at various stages of the manufacturing process including samples of the 1) master lot of insulin crystals, 2) modified insulin mixtures, and 3) final product. The samples must be accompanied by 1) a description of the equipment, methods, and processes used, 2) the tests and assays made, and 3) the laboratory facilities used.

The Insulin Certification Fund had been operating at a loss for several years. However, in FY 1991 a complete cost study was undertaken. The study resulted in a new fee structure which was published in the Federal Register on October 4, 1991 and became effective on November 4, 1991. Among other things, the new fees are based on "certifications issued" rather than tests completed, thus affording the Agency the flexibility to certify without replicating tests and losing revenue.

With the implementation of the new fees, the Agency reevaluated the need for replicate testing of insulin in all cases and began to certify based on selective testing and manufacturers test results. The Agency has the discretion to discontinue testing the insulin when the firms have demonstrated the ability to perform satisfactorily over time. This decision has altered the cost of the program during this fiscal year and led to reduced costs and higher than expected revenues. The Agency is currently assessing the number of FTEs that will be required to deal with new manufacturers and developing a new two tier fee schedule, and changes may be required in FY 93.

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

FEDERAL MANAGERS FINANCIAL INTEGRITY ACT SUMMARY FOR FDA

FDA continually strives to comply with the requirements of the FMFIA through the effective and efficient management of all program areas and the implementation of safeguards to prevent waste, fraud, and mismanagement of Agency resources. FDA has made substantial progress in implementing the FMFIA, both in identifying weaknesses and moving aggressively to correct them. For example, a master inventory of all major programs within the Agency has been created and every program will receive a detailed examination over the next 5 years. If problems are uncovered, this newly adopted process will allow for systematic correction, including the allocation of more resources where necessary.

In addition, substantial progress has been made in the quality and leadership of the generic drug supply through a combination of regulatory actions and strengthened administrative procedures. The regulatory actions include testing a large sample of generic drugs on the market, inspecting the facilities of generic drug manufacturers, removing violative products from the market, and supporting the prosecution of persons who have committed criminal acts. The administrative actions include the reorganization of the Office of Generic Drugs, implementation of tight security to control access to documents and visits by industry representatives to FDA staff, and establishment of a quality assurance function to ensure that the generic drug review process is maintaining appropriate standards.

Also, a 1991 survey of the Revolving Fund for Certification Services resulted in the development by FDA of a Certification Analytical Manual. This manual established a uniform set of policy and procedures concerning color certification and was made available to regulated industry in FY 92.

During FY 92, financial statements for Color and Insulin Certification were developed and published in accordance with Chapter 5-20 HHS Financial Statements. The audit of the fiscal year 1991 statements received an unqualified audit opinion from the Inspector General on the Statement of Financial Position.

Additional efforts concerning the FMFIA review for FY 92 included a survey questionnaire completed by financial managers in all the Centers concerning the timeliness, usefulness, accuracy, etc., of our system and related reports. The results indicated 96% user satisfaction with our current system.

Revised Imprest Fund procedures incorporating additional controls and actions were executed. Improvements in collection procedures, specifically, furthering separation of duties and initiating debt collection through the IRS Income Offset Program were incorporated. And to promote effective communication with the cost effectiveness and efficiency of accessing software and data files from a secured central point, the BANYAN local area network was installed.

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS

The Revolving Fund for Certification Services

FDA's Revolving Fund for Certification Services was established, pursuant to Public law 99-136, on October 11, 1963. The Revolving Fund appropriation is available without fiscal year limitation for salaries and expenses. User fees collected primarily from sources outside the government provide the funding. The fees charged to manufacturers to keep the Fund solvent are periodically revised in the Code of Federal Regulations (CFR) after the Agency re-assesses the cost to operate the programs.

The activities financed by this Fund include 1) the certification of synthetic colors (which are added to foods, drugs, and cosmetics...colored contact lenses, for example) and the retesting of previously approved colors for safety, and 2) the testing, assaying, and evaluation of insulin samples manufactured for sale in this country. Both of these programs have specific legislative authority and are user fee programs supported by industry for government pre-market review and approval of their products.

In addition to the two Certification Programs just mentioned, there is a small, revenue providing fee for new "Color Additive Petitions." (A petition is a proposal to use a color additive in or on a food, drug, or cosmetic.) This fee is charged for the Agency's analysis, and approval/disapproval, of these petitions. An average of five petitions, generating a revenue of less than $10,000, are processed annually.

Revenues, Expenditures, and Fund Balance

The revenues generated by this Fund vary from year to year based on industry trends and manufacturer's surplus inventory of approved colors and insulin products. It is important to note that the insulin and color activities are separate; there is no co-mingling of funds.

As Figure 1 below illustrates, the Fund sustained a loss in Fiscal Years 1990 and 1991, but rebounded in FY 92 due to the implementation of a new insulin fee schedule.

An overview of both programs financed by this Fund follows.

The Color Additive Certification Program

The Office of Cosmetics and Colors (OCC) in the Center for Food Safety and Applied Nutrition is the unit responsible for color certification activities. Twenty-six employees within this Office directly carry out the Color Certification Program including the actual testing of batches and developing of new methods of analysis. The size of the batches to be certified can vary widely depending upon the manufacturer and the specific color. The average size of a color additive batch is 2,900 pounds. A four ounce sample from every batch manufactured must be submitted to FDA for testing and certification prior to marketing. The number of companies that manufacture color additives has fluctuated only slightly over the past five years and averages twenty-five annually. The primary steps

Figure 1

THE REVOLVING FUND FOR CERTIFICATION SERVICES

COLOR AND INSULIN COMBINED

TYPE	1989	1990	1991	1992
REVENUES	2,798,000	2,922,000	3,264,000	4,241,000
EXPENSES	2,570,000	3,123,000	3,365,000	3,397,000
PROFIT/LOSS	228,000	(201,000)	(101,000)	844,000
UNOBLIGATED BALANCE	2,205,000	592,000	438,000	1,071,000

Unobligated balance includes charges for extraordinary items

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS (Cont'd)

involved in certifying a color additive are outlined below.

The color additive manufacturers submit a sample and a "Request for Certification", for each batch of color additive manufactured, to OCC. (As previously mentioned, each sample submitted must be four ounces.) The request is reviewed for completeness and accuracy, and the samples are analyzed to determine whether or not it meets certification specifications. A record is established in the computer database for each new sample. Using internal tables, a set of required analytical tests is established including accompanying specification limits necessary for the sample to be certified. After analysis, a certificate is generated by the certification computer system for those batches of color additive that meet certification specifications. The certificate provides a certification lot number which is required by the manufacturer before the batch can be sold. Those batches that do not meet certification specifications are issued a notice of rejection.

Once the laboratory certification process is complete, copies of the certificates or notices of rejection, showing the total fee for service, are forwarded to the Accounting Branch.

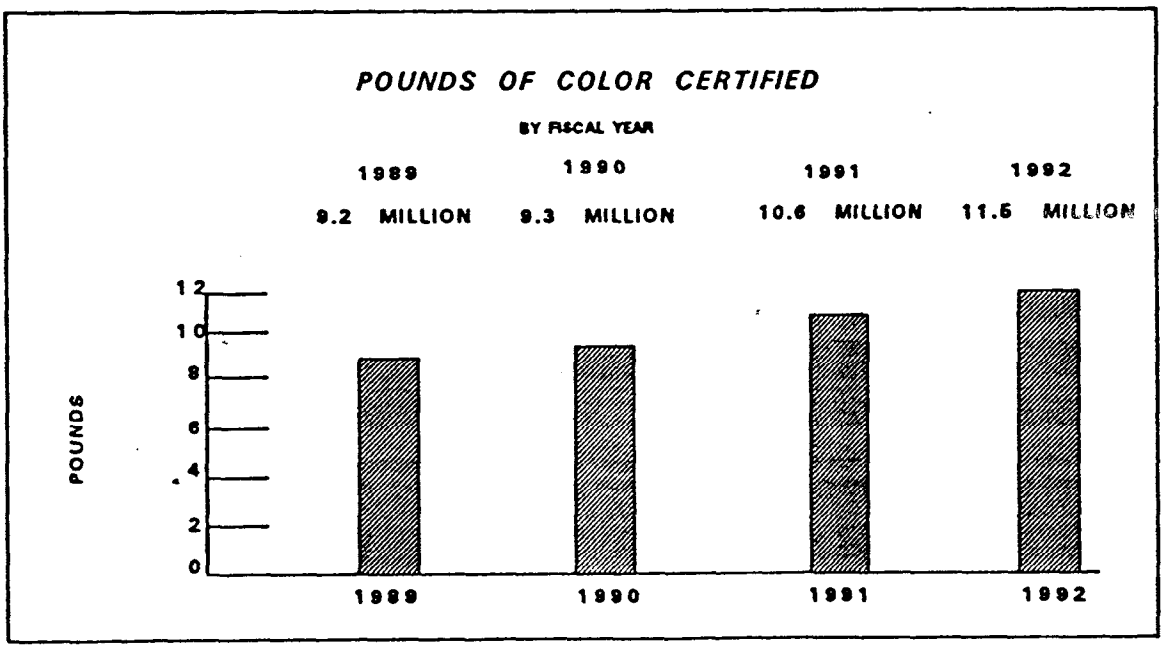
Program Performance

Figure 2 shows that the pounds of color certified has increased from 9.2 million in FY 89 to 11.5 million in FY 92. However, while the number of pounds certified over the past four fiscal years has increased, the number of batches certified has decreased from 4,526 batches in FY 89 to 3,946 batches in FY 92. This reduction is due to the manufacture of color additive batches of larger individual weight. The average batch size has increased approximately 43% from FY 89 to FY 92.

During the same time period the rejection rate for samples submitted has averaged 1.1%. It is important to note that the rejection rate does not include data on verbal and written warnings given to companies on anomalies found in samples during analysis. Both rejections and anomalies frequently occur in samples that have been previously tested by the submitting company prior to submitting for certification. Further the rejection rate does not, and cannot, demonstrate the impact or health hazard involved if one of the rejected batches entered the market place.

As Figure 3 indicates, the average number of days to certify a color has been reduced from 6.4 days per sample in FY 89 to 5.5 days per sample in FY 92. Timeliness is largely dependent on laboratory workload as it relates to the number of color additives batches submitted at a given time and the whether the information that the manufacturers are required to provide in the Request for Certification is complete.

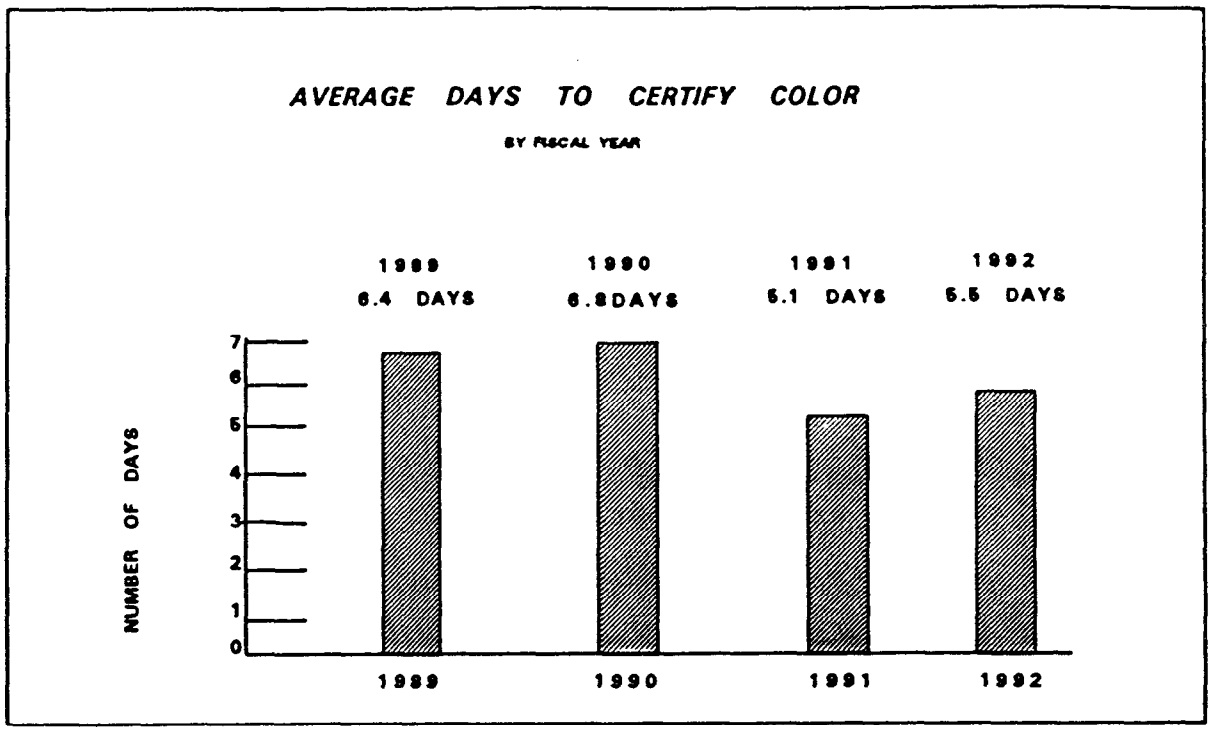
Figure 2



OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS (Cont'd)

Figure 3



Financial Performance

Color certification fees, which are based on the size of the batch certified, have not increased since 1983. Despite this, the steady growth of the color additive market, with its corresponding increase in the amount of color additives, generated sufficient revenue through FY 89 to keep revenue ahead of expense and build up retained earnings.

The number of pounds certified, which is a key indicator for revenues, has grown significantly in FY 91 and FY 92. The number of batches certified (and samples analyzed) has been relatively constant, helping to contain costs. Figure 4 shows that the Fund sustained a loss in Fiscal Years 1990 and 1991, but because of the above factors, had a profit in FY 92.

Figure 4

THE REVOLVING FUND FOR CERTIFICATION SERVICES

COLOR

TYPE	1989	1990	1991	1992
REVENUES	2,270,000	2,385,000	2,692,000	2,844,000
EXPENSES	1,841,000	2,468,000	2,732,000	2,730,000
PROFIT/LOSS	429,000	(83,000)	(40,000)	114,000
UNOBLIGATED BALANCE	1,938,000	529,000	407,000	310,000

Unobligated balance includes changes for extraordinary items

OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS (Cont'd)

A study of the Color Certification Program was initiated in late FY 91. The scope of the study will include all aspects of the program including overhead rates and inflation factors. The study is scheduled for completion in FY 93.

Figure 5 illustrates that the cost for color certification analysis has increased from 20 cents per pound in FY 89 to 22 cents per pound in FY 92.

The Insulin Certification Program

The Insulin Certification Program was established in 1941 by amendment to the FD&C Act of 1938. The Fund was established on a user fee basis, that is, the manufacturers are assessed a fee to provide funding for the program. No appropriated funds are provided. Samples of insulin are required to be submitted to FDA for certification at various stages of the manufacturing process including samples of the master lot of insulin crystals, samples of modified insulin mixtures, and samples of the final product. The samples must be accompanied by 1) a description of the equipment, methods, and processes used, 2) the tests and assays made, and 3) the laboratory facilities used. FDA, through the end of FY 91, replicated the manufacturer's tests to verify the results. After analysis of all information, including the results of tests and assays when required, the Agency will certify that the batch is safe and efficacious for use.

The FDA Insulin Certification Program is a statutorily mandated program which serves an estimated 1 million insulin dependent diabetic patients in the United States. Currently, two manufacturers, Eli Lilly and NOVO NORDISK, hold the necessary New Drug Application approvals to market insulin preparations. The overriding concern in requiring the pre-market certification of insulin is the diabetic patient's extreme fragility. The patient's survival not only depends upon a continuing supply of insulin, but more importantly on the precision with which the potency is determined. Both over or under dosing can be fatal.

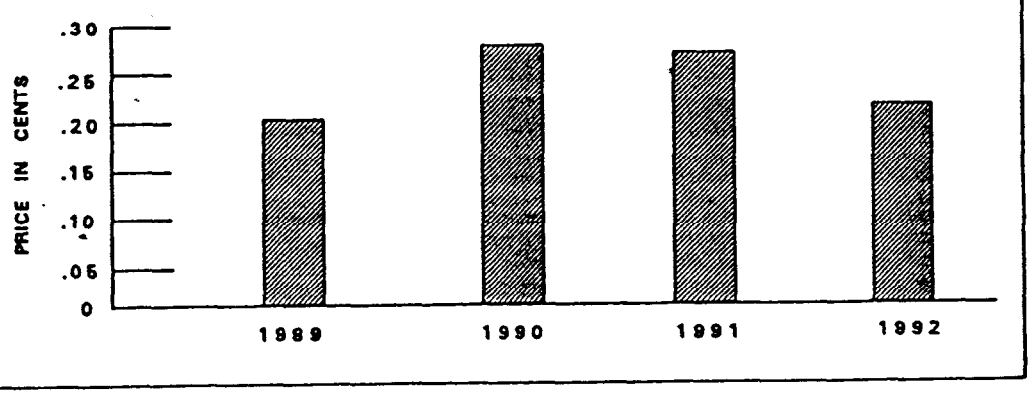
FDA's Center for Drug Evaluation and Research (CDER) is the component responsible for insulin certification activities. Specifically, the CDER Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II is responsible for the review and approval of insulin Investigational New Drug Applications and their supplements. The CDER Office of Research Resources is responsible for the management and maintenance of the FDA Insulin Laboratory and all insulin analytical, research and scientific/technical support activities. The CDER Product Surveillance Branch, Division of Drug Quality Evaluation, Office of Compliance is the working echelon to which authority to issue insulin certificates is delegated. An overview of the primary steps involved in insulin certification follows.

Figure 5

COLOR CERTIFICATIONS PRICE PER POUND ANALYSIS

BY FISCAL YEAR

	1989	1990	1991	1992
EXPENSES	$1,841,000	$2,468,000	$2,732,000	$2,730,000
# OF POUNDS	9,200,000	9,300,000	10,600,000	11,500,000
PRICE PER POUND	$0.20	$0.27	$0.26	$0.23



OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS (Cont'd)

The insulin manufacturers submit the paperwork and analytical data for a "Request for Certification" concurrently to the Product Surveillance Branch and the Insulin Laboratory. The Laboratory also receives physical product samples. The Product Surveillance Branch reviews the incoming request and consults with the Insulin Laboratory concerning which tests are to be performed.

After completion of testing and review of the data in the manufacturer's "Request for Certification", the Insulin Laboratory forwards their report and recommendation to the Product Surveillance Branch. The Product Surveillance Branch again reviews the data sets for compliance with the requisite standards of identity, strength, quality and purity, and then issues the appropriate document (either an Approval, Release, Certificate) to the certification requestor. An approval is issued for protamine sulfate a substance used in the production of the insulins, a release document is issued when the insulin product is not listed in the US, and a certificate is issued for USP listed insulins.

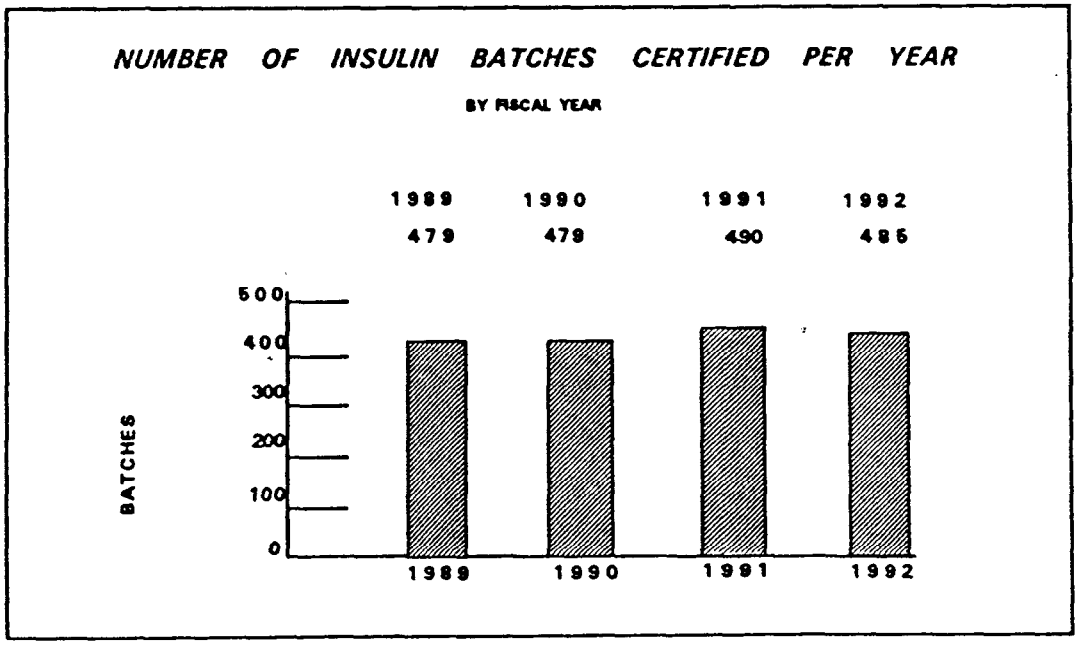
As a final note, in response to an OMB request, the Agency recently reevaluated the need for replicate testing of insulin in all cases. The Agency will have the discretion to discontinue testing the insulin when the firms have demonstrated the ability to perform satisfactorily over time. This decision will significantly alter the cost of the program. The Agency is currently assessing the number of FTE's that will be required to deal with new manufactures and developing a new two tier fee schedule.

Program Performance

Figure 6 illustrates that the number of insulin batches decreased slightly from 490 in FY 91 to 485 in FY 92. Since the testing performed by the FDA was usually done after the manufacturer's testing, no failures were expected. However, one batch of Protamine Sulfate did fail validation testing due to high moisture content. The FDA policy of permitting the manufacturers to withdraw batches under test prior to rejection was continued. Six of eight consumer complaint samples were found to be in compliance with specifications. One sample displayed extensive clumping indicative of zinc:insulin complexes. It was recommended that batch tracing be undertaken by the field office to ascertain that the problem was local in nature. A second sample which showed signs of consumer abuse and the introduction of a foreign substance was referred to the Cincinnati Forensic Center. A total of 93 post market surveillance samples were analyzed and found to be in compliance.

During FY 92, the average "dwell time" in the FDA system for master lots/trial dilutions was 51 calendar days and 14 calendar days for dosage form batches. The timeliness of certification is related to the number of products in the

Figure 6



OVERVIEW OF FDA FUNDS SUBJECT TO AUDIT

MANAGEMENT'S DISCUSSION AND ANALYSIS (Cont'd)

pipeline and the degree of completeness of data from the manufacturer. In other words, poor or incomplete data slows the process. Sometimes, this is caused by the fact that the manufacturers may submit their product for FDA evaluation and testing prior to the completion of their tests. Unfortunately, the Agency has never maintained statistics on how often the untimely submission of manufacturers data has caused delays in the certification process. Rather, the statistics FDA maintains reflect total "dwell" time.

Financial Performance

The Insulin Certification Fund has been operating at a loss for several years, but new fees enacted on November 4, 1991 generated a dramatic increase in revenues in FY 92, as Figure 7 below indicates. Although the number of batches certified has remained relatively constant, the cost to certify an insulin batch has decreased as Figure 8 illustrates. Among other things, the new fees are based on "certifications issued" rather than tests completed, thus affording the Agency the flexibility to certify without replicating tests and losing revenue. The Agency began to certify (in some cases) batches without the replication of testing on final dosage form insulin. This programmatic change resulted in reduced labor costs during the year. In FY 93, the cost to operate the fund will

Figure 7

THE REVOLVING FUND FOR CERTIFICATION SERVICES
INSULIN

TYPE	1989	1990	1991	1992
REVENUES	528,000	537,000	572,000	1,397,000
EXPENSES	729,000	655,000	633,000	667,000
PROFIT/LOSS	(201,000)	(117,000)	(61,000)	730,000
UNOBLIGATED BALANCE	287,000	63,000	31,000	761,000

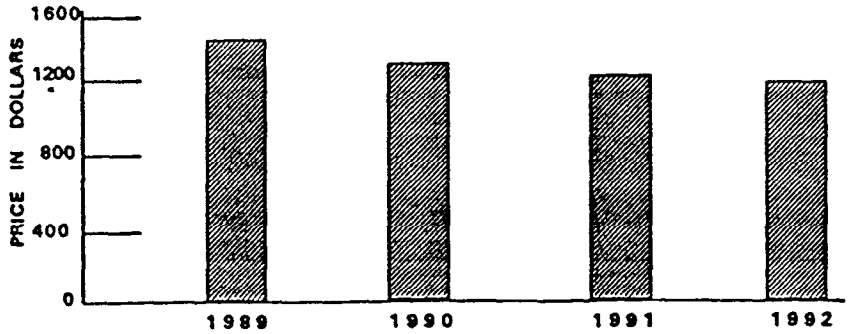
Unobligated balance includes changes for extraordinary items

Figure 8

INSULIN CERTIFICATIONS PRICE PER BATCH ANALYSIS

BY FISCAL YEAR

	1989	1990	1991	1992
EXPENSES	$729,000	$655,000	$633,000	$667,000
# OF BATCHES	479	479	490	485
PRICE PER BATCH	$ 1,521.92	$1,367.43	$1,291.84	$1,375.25



be reeavaluated considering the new testing strategies; fees may need to be adjusted. In addition to flexibility, an inflation factor was built into the fee structure to allow for periodic, automatic fee increases. In addition, finally now included is a factor for OS/PHS overhead and the unfunded liability of the Civil Service Retirement Fund.

The Agency had known for some time that a fee revision was needed not only because of inflation but also because of procedural changes that affected how insulin is manufactured and tested. At the time of our last fee review in 1982, virtually all insulin was extracted from beef or pork pancreas, processed, and refined into a dry form called master lots. However, the application of new scientific principles has resulted in major changes in the approach to the manufacture of insulin. For now and the foreseeable future, firms will be using a variety of different manufacturing processes. This has been the major impetus behind changing insulin certification testing procedures. For example, potency is currently being determined by a chemical analysis, High Performance Liquid Chromatography, that has been implemented since the last fee revision. This test has replaced the time-consuming and expensive 168-animal rabbit bioassay test originally employed for the purpose. The use of this assay method represents a major departure and improvement from the determination of insulin potency by strictly biological methods.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services
STATEMENT OF FINANCIAL POSITION

(Dollars in Thousands)

As of September 30

	1992	1991
ASSETS		
Financial Resources		
Fund Balances with Treasury (Note 2)	$ 1,889	$ 953
Cash (Note 3)	153	0
Accounts Receivable, Net, - Non-Federal	0	59
Total Financial Resources	2,042	1,012
Non-Financial Resources		
Advances and Prepayments - Non-Federal	0	2
Property, Plant & Equipment, Net (Note 4)	1,274	1,210
Total Non-Financial Resources	1,274	1,212
Total Assets	3,316	2,224
LIABILITIES		
Funded Liabilities		
Accounts Payable - Non-Federal	6	5
Accrued Payroll and Benefits	47	150
Deferred Revenue, Non-Federal	381	59
Other Funded Liabilities - Non-Fed	23	35
Total Funded Liabilities	457	249
Unfunded Liabilities		
Accrued Leave	99	89
Other Unfunded Liabilities	30	0
Total Unfunded Liabilities	129	89
Total Liabilities	586	338
NET POSITION		
Fund Balances: (Note 5)		
Revolving Fund Balance	2,859	1,975
Total Fund Balances	2,859	1,975
Less: Future Funding Requirements (Note 6)	129	89
Net Position	2,730	1,886
Total Liabilities and Net Position	$ 3,316	$ 2,224

The accompanying notes are an integral part of these statements.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

STATEMENT OF OPERATIONS & CHANGES IN NET POSITION

For the years ended September 30

(Dollars in Thousands)

	1992	1991
REVENUE AND FINANCING SOURCES		
Revenues from Sales of Goods & Services(Public)	$ 4,241	$ 3,256
Other Revenue and Financing Sources	0	8
Total Revenues and Financing Sources	4,241	3,264
EXPENSES		
Operating Expenses		
Personal Services and Benefits	2,018	1,903
Travel and Transportation	15	11
Rental, Communications and Utilities	585	684
Printing and Reproduction	1	2
Contractual Services	344	279
Supplies, Materials	172	185
Non-Capitalized Equipment	262	315
Total Expenses	3,397	3,379
Excess (Shortage) of Revenues and Financing Sources Over Total Expenses	844	(115)
Plus: Unfunded Expenses	40	14
Excess (Shortage) of Revenues and Financing Sources Over Funded Expenses	884	(101)
Net Position, Beginning Balance	1,886	2,001
Excess (Shortage) of Revenues and Financing Sources Over Total Expenses	844	(115)
Net Position, Ending Balance	$ 2,730	$ 1,886

The accompanying notes are an integral part of these statements.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services
STATEMENT OF CASH FLOWS

For the years ended September 30 (Dollars in Thousands)

	1992	1991
CASH PROVIDED (USED) BY OPERATING ACTIVITIES		
Cash Provided		
Sales of Goods & Services	$ 4,564	$ 3,377
Other Operating Cash Provided	61	4
Total Cash Provided	4,625	3,381
Cash Used		
Personnel Services and Benefits	2,082	1,854
Travel and Transportation	13	16
Rent, Communications and Utilities	585	684
Printing and Reproduction	1	1
Other Contractual Services	359	261
Supplies and Materials	176	180
Non-Capitalized Equipment	62	299
Other Operating Cash Used	0	2
Total Cash Used	3,278	3,297
Net Cash Provided by Operating Activities	1,347	84
CASH USED BY INVESTING ACTIVITIES		
Purchase of Property, Plant and Equipment	(258)	(287)
Net Cash Used by Investing Activities	(258)	(287)
Net Cash Provided (Used) by Operating & Investing Activities	1,089	(203)
Fund Balances with Treasury, Beginning of Year	953	1,156
Fund Balances with Treasury and Cash Balance, End of Year	$ 2,042	$ 953

The accompanying notes are an integral part of these statements.

Revolving Fund for Certification and Other Services
STATEMENT OF BUDGET AND ACTUAL EXPENSES
For the Year Ended September 30, 1992

(Dollars in Thousands)

Program Names	BUDGET			ACTUAL
		Obligations		
	Resources	Direct	Reimbursed	Expenses
Color	3,274	0	2,965	2,728
Insulin	1,428	0	666	669
	$ 4,702	$ 0	$ 3,631	$ 3,397

Budget Reconciliation:

Total Expenses		3,397
Add:	Capital Acquisitions	258
Less:	Depreciation & Amortization	193
	Unfunded Expenses	40
Accrued Expenditures		3,422
Less Reimbursements		4,241
Accrued Expenditures, Direct		$ (819)

The accompanying notes are an integral part of these statements.

Food & Drug Administration
Revolving Fund for Certification and Other Services
Footnotes to the Financial Statements

Note 1

Significant Accounting Policies

Entity and Basis of Combination

FDA is considered a separate reporting entity for financial reporting purposes to the U.S. Department of Treasury. FDA prepared the financial statements for the Revolving Fund for Certification and Other Services from its books and records in accordance with the guidance contained in OMB Bulletin 93-02 and the guidance of the Department of Health and Human Services.

The financial statements covered herein include the certification appropriation accounts only (75X4309). The certification appropriation is a commercial revolving fund completely supported by fees collected from the manufacturers of color additives and insulin products. No appropriated funding is provided, and each activity maintains its own internal General Ledger accounts and balances, with no intrafund balance transfers. There is also a small amount of revenue generated from a petition fee when manufacturers request the listing of a new color additive. The fees charged to manufacturers to keep the fund solvent are periodically revised in the Code of Federal Regulations (CFR), after the Agency re-assesses the cost to operate the programs.

Fund Balance with Treasury

All collections of fees from the manufacturers of certifiable products are deposited with Treasury and "advance accounts" are established in the FDA accounting system. All payroll and operating outlays for the fund are scheduled through Treasury to disburse the funds. General Ledger cash balances are reconciled with Treasury on a monthly basis.

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Footnotes to the Financial Statements

Equipment

All equipment valued at $5,000.00 or more and having a useful life of two years or more is depreciated on a straight-line basis. The new equipment acquisitions are funded from revenues generated by the user fees. Equipment transactions other than new acquisitions (trade-ins, donations, disposals, transfers, etc.), are maintained and recorded by the FDA Property Management System, and subsequently recorded in the certification general ledger via journal voucher. The useful life is assigned to each item by Agency property officials according to the Veterans Administration Federal Supply Catalog. The average useful life of equipment is between 8 and 12 years.

Deferred Revenue, Non-Federal

The FDA certification legislation requires manufacturers to establish deposit accounts in advance of FDA work. The balance of these advance deposits is reported in the financial statements as a liability. These deposits are recognized as revenue as soon as the manufacturer's petition passes testing and is accepted; however, if the manufacturer's petition is rejected, the advance balance is returned to the manufacturer.

Accounts Payable

Accounts payable represents the amount of monies or other resources that are likely to be paid by FDA as the result of a transaction or event that has already occurred. However, no accounts payable can be paid by FDA without an appropriation or other collection of revenue for services provided. Accounts payable for which an appropriation has not been enacted are classified as unfunded liabilities and there is no certainty that the appropriations will be enacted. Accounts payable arising from other than contracts, can be abrogated by the Government acting in its sovereign capacity.

Annual, Sick, and Other Types of Leave

Annual leave is accrued as it is earned, and the accrual is reduced as leave is taken. Monthly, the balance in the accrued annual

Food & Drug Administration
Revolving Fund for Certification and Other Services
Footnotes to the Financial Statements

leave account is adjusted to reflect current pay rates of cumulative annual leave earned but not taken. Sick and other types of leave are expensed as taken.

Pension Plan

The eligible employees assigned to the Certification fund are covered by the Civil Service Retirement System (CSRS) and the Federal Employees Retirement System (FERS). Matching employer contributions provided by the Certification Fund for all eligible employees were approximately $137,009 for Fiscal Year 1992 and approximately $268,000 for Fiscal Year 1991.

Although the certification fund contributes a portion of pension benefits for eligible employees and makes the necessary payroll withholding from them, the fund does not account for the assets of either of these retirement funds and does not have actuarial data with respect to accumulated plan benefits or the unfunded liability relative to its eligible employees. These amounts are reported by the U.S. Office of Personnel Management (OPM) and are not allocated to the individual employers. OPM also accounts for all health and life insurance programs for retired eligible employees.

Other Unfunded Liability

In Fiscal Year 1992, the Office of Management and Budget (OMB) mandated the FDA to include the annual cost of funding the "unfunded liability" for the Civil Service Retirement System (CSRS) in its fee calculation. The liability is reflected in the accompanying Statements of Financial Position for the Insulin account.

Cost Allocations

The Color and Insulin Programs of the Certification Fund receive administrative and management support from both the organization they are part of (CFSAN, CDER), and the Office of Management that supports the entire Agency. In order to arrive at the number of Full Time Equivalents (FTE) that are appropriate to allocate (offset) to the Certification Fund, total FTEs are divided by Headquarters and Center-level administrative positions to get a

Food & Drug Administration
Revolving Fund for Certification and Other Services
Footnotes to the Financial Statements

ratio. That ratio of support positions to program positions is then applied to the direct Color and Insulin positions.

Agency postage, telecommunications, and health unit costs are centrally funded. The cost applicable to the Certification Fund are prorated by calculating the "cost per FTE" agency-wide times total direct Certification positions. Rent for space for Color personnel is prorated on an FTE basis. Insulin personnel occupy an FDA owned facility, and amortization costs and support services are allocated on the percentage of Insulin positions to total positions in the building. Total costs allocated in Fiscal Year 92 were $1,000,963 and in Fiscal Year 1991 were $763,786.

Note 2. Fund Balance with Treasury

The fund balance with Treasury is made up of the following elements:

	FY 92		FY 91	
Treasury Account Symbol 75X4309			Treasury Account Symbol 75X4309	
Color	$	801,906	Color	$ 871,883
Insulin		1,087,766	Insulin	75,086
Color Petitions		0	Color Petitions	6,400
Fund Balance:	$	1,889,672	Fund Balance:	$ 953,369

Note 3. Cash

$153,000 was wire transferred to the Color Fund and deposited by the FDA at end of FY 92 into its commercial bank account. However the Treasury Department had not acknowledged the transfer to increase the fund balance for FDA's Revolving Fund by September 30, 1992.

Food & Drug Administration
Revolving Fund for Certification and Other Services
Footnotes to the Financial Statements

Note 4. Equipment, Net

Capitalized equipment on hand at the end of the last two fiscal years, less accumulated depreciation was as follows:

	FY 92	FY 91
Equipment	$2,215,807	$1,962,146
Accum. Dep.	(941,574)	(752,162)
Net	$1,274,233	$1,209,984

Note 5. Fund Balances

The revolving fund balance (net position) is made up of the following elements:

1. Unexpended Appropriations:	
a. Undelivered Orders	$ 513,474
2. Accumulated Results of Operations	941,992
3. Invested Capital	1,274,233
Total	$2,729,699

The revolving fund balance is less future funding requirements.

Food & Drug Administration
Revolving Fund for Certification and Other Services
Footnotes to the Financial Statements

Note 6. Future Funding Requirements

The future funding requirements are made up of the following elements:

	FY 92	FY 91
Non-Actuarial Liabilities		
1. Accrued Unfunded Leave	99,021	89,650
2. Unfunded Liability, CSRS	30,436	0
Total	$ 129,457	$ 89,650

Note 7. Related Party

During fiscal year 1992, the Revolving Fund for Certification and Other Services engaged in the following types of related party transactions with the Center for Food Safety and Applied Nutrition (CFSAN): Automated Data Processing costs, storeroom expenses and waste disposal costs. These transactions totalled $104,484 for fiscal year 1992 and $101,419 for fiscal year 1991.

Note 8. Reclassifications

Certain reclassifications were made to the September 30, 1991 financial statements to conform with the September 30, 1992 presentation.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

STATEMENT OF FINANCIAL POSITION

Supplemental Schedule
As of September 30, 1992

(Dollars in Thousands)

	Color	Insulin	Total
ASSETS			
Financial Resources			
Fund Balances with Treasury	802	1,087	1,889
Cash	153	0	153
Total Financial Resources	955	1,087	2,042
Non-Financial Resources			
Property, Plant & Equipment, Net	1,146	128	1,274
Total Non-Financial Resources	1,146	128	1,274
Total Assets	2,101	1,215	3,316
LIABILITIES			
Funded Liabilities			
Accounts Payable - Non-Federal	2	4	6
Accrued Payroll and Benefits	39	8	47
Deferred Revenue, Non-Federal	137	244	381
Other Funded Liabilities - Non-Fed	22	1	23
Total Funded Liabilities	200	257	457
Unfunded Liabilities			
Accrued Leave	71	28	99
Other Unfunded Liabilities	0	30	30
Total Unfunded Liabilities	71	58	129
Total Liabilities	271	315	586
NET POSITION			
Fund Balances:			
Revolving Fund Balance	1,901	958	2,859
Total Fund Balances	1,901	958	2,859
Less: Future Funding Requirements	71	58	129
Net Position	1,830	900	2,730
Total Liabilities and Net Position	2,101	1,215	3,316

The accompanying notes are an integral part of these statements.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

STATEMENT OF OPERATIONS & CHANGES IN NET POSITION

Supplemental Schedule
For the Year ended September 30, 1992

	(Dollars in Thousands)		
	Color	Insulin	Total
REVENUE AND FINANCING SOURCES			
Revenues from Sales of Goods & Services(Public)	2,844	1,397	4,241
Total Revenues and Financing Sources	2,844	1,397	4,241
EXPENSES			
Operating Expenses			
Personal Services and Benefits	1,595	423	2,018
Travel and Transportation	11	4	15
Rental, Communications and Utilities	473	112	585
Printing and Reproduction	1	0	1
Contractual Services	288	56	344
Supplies, Materials	136	36	172
Non-Capitalized Equipment	226	36	262
Total Expenses	2,730	667	3,397
Excess (Shortage) of Revenues and Financing Sources Over Total Expenses	114	730	844
Plus: Unfunded Expenses	9	31	40
Excess (Shortage) of Revenues and Financing Sources Over Funded Expenses	123	761	884
Net Position, Beginning Balance	1,714	172	1,886
Excess (Shortage) of Revenues and Financing Sources Over Total Expenses	114	730	844
Net Position, Ending Balance	1,828	902	2,730

The accompanying notes are an integral part of these statements.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

STATEMENT OF CASH FLOWS

Supplemental Schedule
For the Year ended September 30, 1992

(Dollars in Thousands)

	Color	Insulin	Total
CASH PROVIDED (USED) BY OPERATING ACTIVITIES			
Cash Provided			
Sales of Goods & Services	2,938	1,626	4,564
Other Operating Cash Provided	57	4	61
Total Cash Provided	2,995	1,630	4,625
Cash Used			
Personnel Services and Benefits	1,676	406	2,082
Travel and Transportation	13	0	13
Rent, Communications and Utilities	473	112	585
Printing and Reproduction	1	0	1
Other Contractual Services	302	57	359
Supplies and Materials	138	38	176
Non-Capitalized Equipment	58	4	62
Total Cash Used	2,661	617	3,278
Net Cash Provided by Operating Activities	334	1,013	1,347
CASH USED BY INVESTING ACTIVITIES			
Purchase of Property, Plant and Equipment	(258)	0	(258
Net Cash Used by Investing Activities	(258)	0	(258
Net Cash Provided (Used) by Operating, & Investing Activities	76	1,013	1,089
Fund Balances with Treasury, Beginning of Year	878	75	953
Fund Balance with Treasury and Cash Balance, End of Year	954	1,088	2,042

The accompanying notes are an integral part of these statements.

FOOD AND DRUG ADMINISTRATION

Revolving Fund for Certification and Other Services

STATEMENT OF BUDGET AND ACTUAL EXPENSES

Supplemental Schedule

For the Year ended September 30, 1992

(Dollars in Thousands)

Program Names	BUDGET			ACTUAL
		Obligations		
	Resources	Direct	Reimbursed	Expenses
Color	3,274	0	2,965	2,728
Insulin	1,428	0	666	669
Total Cert.	4,702	0	3,631	3,397

Budget Reconciliation:	Color	Insulin	Total
Total Expenses	2,728	669	3,397
Add: Capital Acquisitions	258	0	258
Less: Depreciation & Amortization	168	25	193
Unfunded Annual Leave	9	31	40
Accrued Expenditures	2,809	613	3,422
Less Reimsbursements	2,844	1,397	4,241
Accrued Expenditures, Direct	(35)	(784)	(819)

The accompanying notes are an integral part of these statements.